material to patient or consumer audiences versus risk information that is material primarily to the prescriber or other health care providers? What data are available to answer this question?

5. What criteria should be used to determine which risk information that is material to patient or consumer audiences to include in the major statement for DTC prescription drug broadcast advertisements to best protect the public health? What data are available to answer this question?

6. What is the potential impact of including (or conversely, of not including), in the major statement for DTC prescription drug broadcast advertisements, additional language that states that there are other risks not included in the advertisement while simultaneously encouraging dialogue between patients and their health care providers? (For example, additional language could include, “This is not a full list of risks and side effects. Talk to your health care provider and read the patient labeling for more information.”) What data are available to answer this question?

7. What data are available on consumers’ comprehension of the difference between levels (i.e., severity) of risk? Would it be in the interest of public health to include a signal before the risk information that frames and categorizes the overall level of risk associated with the product? One approach may be to include an opening statement tailored to the risk profile of the drug. For example, drugs could be divided into three defined categories and include the corresponding opening statements:

   a. For drugs with severe, life-threatening risks: “[Drug] can cause severe, life-threatening reactions. These include . . . .”

   b. For drugs with serious but not life-threatening risks: “[Drug] can cause serious reactions. These include . . . .”

   c. For drugs with no severe or serious risks: “[Drug] can cause reactions. These include . . . .”

8. Should potential food and drug interactions be disclosed in DTC prescription drug broadcast advertisements, and if so, what criteria should be used to identify these interactions?

   FDA will consider all information and comments submitted.

III. References

The following references are on display in the Dockets Management Staff office (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov.


Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Charter Renewal of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is hereby giving notice that the charter for the National Vaccine Advisory Committee (NVAC) has been renewed.


SUPPLEMENTARY INFORMATION: NVAC is a non-disciplinary Federal advisory committee. The establishment of NVAC was mandated under Section 2102 and 2103 of the PHS Act; and (4) identifies annually for the Director of the NVP the most important areas of governmental and non-governmental cooperation that should be considered in implementing Sections 2101 and 2103 of the PHS Act.

On July 21, 2017, the Acting Assistant Secretary for Health approved renewal of the NVAC charter with minor amendments. The new charter was effected and filed with the appropriate Congressional committees and Library of Congress on July 30, 2017. Renewal of the NVAC charter gives authorization for the Committee to continue to operate until July 30, 2019. A copy of the NVAC charter is available on the Web site for the National Vaccine Program Office at http://www.hhs.gov/nvpo/nvac. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is http://www.facadatabase.gov/.


Melinda Wharton,
Acting Director, National Vaccine Program Office.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Behavioral Health; Office of Clinical and Preventive Services; Zero Suicide Initiative—Support


Key Dates

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), Office of Clinical and Preventive Service, Division of Behavioral Health (DBH), is accepting applications for cooperative agreements for Zero Suicide Initiative (ZSI)—to develop a comprehensive model of culturally informed suicide care within a system of care framework. This program was first established by the Consolidated Appropriations Act of 2017, Public Law 115–31, 131 Stat. 135 (2017). This program is authorized under the Snyder Act, 25 U.S.C. 13 and the Indian Health Care Improvement Act, Subchapter V–A (Behavioral Health Programs), 25 U.S.C. 1665 et seq.

Background

For at least the past fifteen years deaths by suicide have been steadily increasing. On April 22, 2016, the Centers for Disease Control and Prevention’s National Center for Health Statistics released a data report, Increase in Suicide in the United States, 1999–2014, which underscores this fact.

• From 1999 through 2014, the age-adjusted suicide rate in the United States increased 24%, from 10.5 to 13.0 per 100,000 population, with the pace of increase greater after 2006.
• Suicide rates increased from 1999 through 2014 for both males and females and for all ages 10–74.
• The percent increase in suicide rates for females was greatest for those aged 10–14, and for males, those aged 45–64.
• The most frequent suicide method in 2014 for males involved the use of firearms (55.4%), while poisoning was the most frequent method for females (34.1%).

There is a sizable disparity when comparing the rate for the general U.S. population to the rate for American Indians and Alaska Natives (AI/AN). During 2007–2009, the suicide rate for AI/ANs was 1.6 times greater than the U.S. all-races rate for 2008 (18.5 vs. 11.6 per 100,000 population).1

The ‘Zero Suicide’ initiative is a key concept of the National Strategy for Suicide Prevention (NSSP) and is a priority of the National Action Alliance for Suicide Prevention (Action Alliance). The ‘Zero Suicide’ model focuses on developing a system-wide approach to improving care for individuals at risk of suicide who are currently utilizing health and behavioral health systems. This award will support implementation of the ‘Zero Suicide’ model within federal, Tribal, and urban Indian health care facilities and systems that provide direct care services to AI/AN in order to raise awareness of suicide, establish integrated system of care, and improve outcomes for such individuals.


Purpose

The purpose of this cooperative agreement is to improve the system of care for those at risk for suicide by implementing a comprehensive, culturally informed, multi-setting approach to suicide prevention in Indian health systems. This award represents a continuation of IHS’s efforts to implement the Zero Suicide approach in Indian Country. Existing efforts have focused on training, technical assistance, and consultation for several ‘pilot’ AI/AN Zero Suicide communities. As a result of these efforts, both the unique opportunities and challenges of implementing Zero Suicide in Indian Country have been identified.

To best capitalize on opportunities and surmount such challenges, this award focuses on the core Seven Elements of the Zero Suicide model as developed by the Suicide Prevention Resource Center (SPRC):
• Lead—Create a leadership-driven, safety-oriented culture committed to dramatically reducing suicide among people under care. Include survivors of suicide attempts and suicide loss in leadership and planning roles;
• Train—Develop a competent, confident, and caring workforce;
• Identify—Systematically identify and assess suicide risk among people receiving care;
• Engage—Ensure every individual has a pathway to care that is both timely and adequate to meet his or her needs. Include collaborative safety planning and restriction of lethal means;
• Treat—Use effective, evidence-based treatments that directly target suicidal thoughts and behaviors;
• Transition—Provide continuous contact and support, especially after acute care; and
• Improve—Apply a data-driven, quality improvement approach to inform system changes that will lead to improved patient outcomes and better care for those at risk.

More specifically, each applicant will be required to address the following goals in their project narrative.

• Establishment of a leadership-driven commitment to transform the way suicide care is delivered within AI/AN health systems. Associated activities should describe the organizational steps to broaden the responsibility for suicide care to the entire system and emphasize the specific role of leadership to ensure that it is achieved.
• Assessment of training needs and creation of a training plan to develop and advance the skills of health care staff and providers at all levels. The aim of such trainings must target increased competence and confidence in the delivery of culturally informed, evidence-based suicide care.
• Implementation of policies and procedures for comprehensive clinical standards, including universal screening, assessment, treatment, discharge planning, follow-up, and means restriction for all patients under care and at risk for suicide (see https://www.jointcommission.org/sea_issue_56/).
• Development of strategy to collect, analyze, use, and disseminate data to enhance and better inform suicide care across the health system.
• Application of evidence-based practices to screen, assess, and treat individuals at risk for suicide that incorporates culturally informed practices and activities.
• Development of a Suicide Care Management Plan for every individual identified as at risk of suicide to include continuous monitoring of the individual’s progress through their electronic health record (EHR) or other data management system, and adjust treatment as necessary. The Suicide Care Management Plan must include the following:
  ○ Protocols for safety planning and reducing access to lethal means;
  ○ Rapid follow-up of adults who have attempted suicide or experienced a suicidal crisis after being discharged from a treatment facility e.g., local emergency departments, inpatient psychiatric facilities, including direct linkage with appropriate health care agencies to ensure coordinated care services are in place;
  ○ Protocols to ensure patient safety, especially among high-risk adults in health care systems who have attempted suicide, experienced a suicidal crisis, and/or have a serious mental illness. This must include outreach telephone contact within 24 to 48 hours after discharge and securing an appointment within 1 week of discharge.

Applicants are encouraged to visit http://zerosuicide.sprc.org to review the Zero Suicide strategies and tools required for this grant program.
Because relatively few resources currently exist that promote the use of culturally informed practices and activities for use with Evidence Based Practices (EBPs) in the treatment of suicide risk, applicants are also encouraged to explore, develop, and catalogue culturally informed practices and activities, and, utilize such activities and practices in conjunction with EBPs where appropriate. Applicants are expected to include how they plan to incorporate the use of culturally informed practices and activities in the Project Narrative. In addition to the Web site noted above, applicants may provide information on research studies to show that the services/practices applicants plan to implement are evidence-based. This information is usually published in research journals, including those that focus on minority populations. If this type of information is not available, applicants may provide information from other sources, such as unpublished studies or documents describing formal consensus among recognized experts.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2018 is approximately $2,000,000. Individual award amounts are anticipated to be approximately $400,000. The amount of funding available for non-competing and continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately five (5) awards will be issued under this program announcement.

Project Period

The project period is for three years and will run consecutively from November 1, 2017, to October 31, 2020.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated.

Substantial Involvement Description for Cooperative Agreement

IHS is interested in assessing the extent to which strategies employed by grantees are consistent with the Zero Suicide model, assessing the feasibility of implementing the Zero Suicide model in health care settings, and determining the outcomes associated with implementation. Enhanced evaluation questions may also be required of grantees to address these key evaluation goals.

The following is a partial list of the level of involvement by IHS and other expectations of the grantee/awardee:

A. IHS Programmatic Involvement

1. Approve proposed key positions/personnel.
2. Facilitate linkages to other IHS/federal government resources and help grantees access appropriate technical assistance.
3. Assure that the grantee’s projects are responsive to IHS’s mission, specifically the implementation of Zero Suicide Initiative.
4. Coordinate cross-site evaluation participation in grantee and staff required monitoring conference calls.
5. Promote collaboration with other IHS and federal health and behavioral health initiatives, including the Substance Abuse Mental Health Services Administration (SAMHSA), the National Action Alliance for Suicide Prevention (NAASP), the National Suicide Prevention Lifeline (NSPLL), and the Suicide Prevention Resource Center (SPRC).
6. Provide technical assistance on sustainability issues.

B. Grantee/Awardee Cooperative Agreement Award Activities

1. Seek IHS’s approval for key positions to be filled. Key positions include, but are not limited to, the Project Director and Evaluator.
2. Consult and accept guidance from IHS staff on performance of programmatic and data collection activities to achieve the goals of the cooperative agreement.
3. Maintain ongoing communication with IHS including the IHS National Evaluation Center (SPRC).
4. Maintain ongoing collaboration with the IHS National Evaluation contractor, the Suicide Prevention Resource Center, and the National Suicide Prevention Lifeline.
5. Maintain ongoing collaboration with the IHS National Evaluation contractor, the Suicide Prevention Resource Center, and the National Suicide Prevention Lifeline.

(6) Provide required documentation for monthly and annual reporting, and data surveillance around suicidal behavior in selected health and behavioral health care systems.

The following are examples of types of direct services that could be provided using the award (be sure to describe your use of grant funds for these activities in Project Narrative):

- Hire new staff or pay for salary;
- Universal Screening of all individuals receiving care to identify risk of suicidal thoughts and behaviors;
- Conducting comprehensive risk assessment of individuals identified at risk for suicide, and ensure reassessment as appropriate;
- Implementation of effective, evidence-based treatments that specifically treat suicidal ideation and behaviors;
- Training of clinical staff to provide direct treatment in suicide prevention and evaluate individual outcomes throughout the process;
- Training of the health care workforce in suicide prevention evidence-based, best-practice services relevant to their position, including the identification, assessment, management, and treatment, and evaluation of individuals throughout the overall process;
- Ensuring that the most appropriate, least restrictive treatment and support is provided, including brief intervention and follow-up from crisis, respite and residential care, and partial or full hospitalization; and
- Developing protocols for every individual identified as at risk of suicide to continuously monitor the individual’s progress through their electronic health record (EHR) or other data management system to include the following:
  - Protocols for safety planning and reducing access to lethal means;
  - Rapid follow-up of adults who have attempted suicide or experienced a suicidal crisis after being discharged from a treatment facility e.g., local emergency departments, inpatient psychiatric facilities, including direct linkage with appropriate health care agencies to ensure coordinated care services are in place; and
  - Protocols to ensure client safety, especially among high-risk adults in health care systems who have attempted suicide, experienced a suicidal crisis, and/or have a serious mental illness. This must include outreach telephone
of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the Estimated Funds Available section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Tribal Resolution

An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include Tribal 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.

An official signed Tribal resolution must be received by the DGM prior to a Notice of Award (NoA) being issued to any applicant selected for funding. However, if an official signed Tribal resolution cannot be submitted with the electronic application submission prior to the official application deadline date, a draft Tribal resolution must be submitted by the deadline in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a NoA will not be issued to that applicant and they will not receive any IHS funds until such time as they have submitted a signed resolution to the Grants Management Specialist listed in this Funding Announcement.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS DGM by obtaining documentation confirming delivery (i.e. FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at http://www.ihs.gov or http://www.ihs.gov/dgm/funding/. Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

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

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
- Budget Justification and Narrative (must be single-spaced and not exceed 5 pages).
- Project Narrative (must be single-spaced and not exceed 20 pages).
- Background information on the organization.
- Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Tribal Resolution(s).
- Letters of Support from organization’s Board of Directors.
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the Discrimination policy.

Requirements for Proposal

A. Project Narrative: This narrative should be a separate Word document that is no longer than 20 pages and must: be single-spaced; type written; have consecutively numbered pages; use black type not smaller than 12 points; and be printed on one side only of standard size 8½” x 11” paper.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored.

These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant’s activities and accomplishments prior to this possible cooperative agreement award. If the narrative exceeds the page limit, only the first 20 pages will be reviewed. The 20-page limit for the narrative does not include the work plan, timeline, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, and/or other appendix items.

Applicants must include the following required application components:

- Cover letter.
- Table of contents.
- Abstract (must be single-spaced and should not exceed one page).
- Project Narrative (must be single-spaced and not exceed 20 pages total).

- Includes: Population of Focus and Statement of Need; Organizational Structure and Capacity; Implementation Approach; and Local Data Collection and Performance Measurement.

B. Budget/Budget Narrative (Not to exceed 4 pages): This must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described above.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. Grants.gov will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to support@grants.gov or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Gettys (Paul.Gettys@ihs.gov), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

4. Intergovernmental Review

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

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the http://www.Grants.gov Web site to submit an application electronically and select the “Search Grants” link on the homepage. Follow the instructions for submitting an application under the Package tab. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant needs to submit a paper application instead of submitting electronically through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Robert.Tarwater@ihs.gov. The waiver must: (1) Be documented in writing (emails are acceptable), before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding. Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or http://www.Grants.gov registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in http://www.Grants.gov by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: support@grants.gov or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting Grants.gov, obtain a tracking number as proof of receipt. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.
- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
• After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the DBH will notify the applicant that the application has been received.
• Email applications will not be accepted under this announcement.
Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)
All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, you may access the SAM online registration through the SAM home page at https://www.sam.gov. For expedited service, call (866) 705–5711.
All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended (“Transparency Act”), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.
System for Award Management (SAM)
Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at https://www.sam.gov. U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active. Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at https://www.sam.gov. Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: http://www.ihs.gov/dgm/policytopics/.
V. Application Review Information
The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 20-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. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 70 points is required for funding. Points are assigned as follows:
1. Criteria
A. Population Focus/Statement of Need (20 points)
The criteria in this section being evaluated includes the scope and scale of suicide behavior within the community served and systems challenges to providing comprehensive (see 7 Elements), culturally informed suicide care to those at risk for suicide. The following aspects will be assessed:
• A clear description of the proposed catchment area and demographic information on the population(s) to receive services through the targeted systems or agencies, e.g., race, ethnicity, Federally recognized Tribe, language, age, socioeconomic status, sex, and other relevant factors, such as literacy.
• Presentation of the prevalence of suicidal behavior (i.e., ideation, attempts, and deaths) within the population(s) of focus, including any current limitations of data collection in the health system. In addition, discuss how the proposed project will address disparities in access, service use, and outcomes for the population(s) of focus.
• Documentation of the need for an enhanced infrastructure (system/process improvements) to increase the capacity to implement, sustain, and improve comprehensive, integrated, culturally informed, evidence-based suicide care within the identified health care system that is consistent with the purpose of the program as stated in this announcement. This may also include a clear description of any service gaps, staff/provider training deficits, service delivery fragmentations, and other barriers that could impact comprehensive suicide care for patients seen in the health system.
Documentation of need may come from a variety of qualitative and quantitative sources. Examples of data sources for the quantitative data that could be used are local epidemiologic data (Tribal Epidemiology Centers, IHS Area offices), state data (e.g., from state needs assessments), and/or national data (e.g., SAMHSA’s National Survey on Drug Use and Health or from National Center for Health Statistics/Centers for Disease Control reports, and census data). Additionally, you may also submit data obtained as a result participating in any previous Zero Suicide model training or technical assistance activity (e.g., Zero Suicide Academy, Community of Learning, Workforce Survey, Organization Self Study, etc.). This list is not exhaustive; applicants may submit other valid data, as appropriate for the applicant’s program.
B. Organizational Infrastructure/Capacity (25 points)
This section focuses on how the organization may capitalize on existing resources, such as human capital, quality initiatives, collaborative agreements, and surveillance capabilities, as a means of overcoming barriers to a comprehensive, culturally informed, system of suicide care. The following aspects will be assessed:
• Thorough description of experience (successes and/or challenges) with the Zero Suicide model (e.g., attended a Zero Suicide Academy, etc.) or similar collaborative efforts (e.g., patient centered medical home, behavioral integration, trauma-informed systems, and improving patient care, etc.).
• Discussion of the applicant Tribe or Tribal organization experience with and capacity (or detailed plan) to provide culturally informed practices and activities for specific populations of focus.
• Identification of how all departments/units/divisions will be involved in administering this project. May also include how applicant organization currently (or plans to) collaborate with other organizations and agencies to provide care, including critical transition of care.
• Description of the resources available for the proposed project (e.g., facilities, equipment, information technology systems, and financial management...
systems, data sharing agreement, MOUs, etc.),
• Listing of all staff positions for the project, such as Project Director, project coordinator, and other key personnel, showing the role of each and their level of effort and qualifications. Demonstrate successful project implementation for the level of effort budgeted for Project Director, Project Coordinator, and other key staff.
• Include position descriptions as attachments to the application for the Project Director, project coordinator, and all key personnel. Position descriptions should not exceed one page each.

Note: Attachments will not count against the 20 page maximum.

For individuals that are currently on staff, include a biographical sketch (not to include personally identifiable information) for Project Director, project coordinator, and other key positions. Describe the experience of identified staff in suicide care, behavioral health & primary care integration, quality and process improvement, and related work within the community/communities. Include each biographical sketch as attachments to the project proposal/application. Biographical sketches should not exceed one page per staff member. Reviewers will not consider information past page one.

Note: Attachments will not count against the 20 page maximum.

Do not include any of the following:
• Personally Identifiable Information;
• Resumes; or
• Curriculum Vitae.

C. Implementation Approach/Plan (30 points)

The criteria being evaluated is the quality of your strategic approach and logical steps to implement a Zero Suicide Initiative within your health system. The following aspects will be assessed:
• A viable plan to address each of the 7 Elements in a systematic, measurable, and interconnected manner. Evidence of plan to the identification, use, and measurement of the use of culturally informed practices and activities. Please Include a Project Timeline as part of this section.
• A clear description of strategies to engage the highest levels of leadership and a broad cross section of the hospital system in order to develop organizational commitment, participation and sustainability (Letters of Commitment should be included as attachments). If the program is to be managed by a consortium or Tribal organization, identify how the project office relates to the member community/communities.
• A contingency plan that addresses short-term maintenance and long-term sustainability. How will continuity be maintained if/when there is a change in the operational environment (e.g., health care system leadership, staff turnover, change in project leadership, change in elected officials, etc.) to ensure project stability over the life of the grant. Additionally, describe long-term plan for sustainability of the ZSI model beyond the life of Cooperative Agreement project period.
• Describe: (a) how achievement of goals will increase the health system’s capacity to provide timely, integrated, culturally informed, evidenced-based system of suicide care; (b) how project activities will increase the capacity of the health system to collaborate with community-based organizations to plan and improve the overall delivery of suicide care; and (c) what overall impact that the successful implementation of this ZSI model will have on the specific AI/AN community served.
• Include input of survivors of suicide attempts and suicide loss in assessing, planning and implementing your project.

D. Data Collection, Performance Assessment & Evaluation (20 points)

In this area applicants need to clearly demonstrate the ability to collect and report on required data elements associated with Zero Suicide and this particular project; and engage in all aspects of local and national evaluation. The following aspects will be assessed:
• Ability to collect and report on the required performance measures specified in the Data Collection and Performance Management section.
• A clear, specific plan for data collection, management, analysis, and reporting. Indication of the staff person(s) responsible for tracking the measureable objectives that are identified above.
• Description of your plan for conducting the local performance assessment as specified above and evidence of your ability to conduct the assessment.
• Description of the quality improvement process that will be used to track progress towards your performance measures and objectives, and how these data will be used to inform the ongoing implementation of the project and beyond.

E. Categorical Budget and Budget Justification (5 points)

Applicants must provide a budget and narrative justification for proposed project budget. The following aspects will be assessed:
• Evidence of reasonable, allowable costs necessary to achieve the objective outlined in the project narrative.
• Description of how the budget aligns with the overall scope of work.
• Please use Budget/Budget Narrative Template Worksheet to support your responses in this section.

The Biographical Sketch, Timeline Chart, Local Data Collection Plan Worksheet, and Budget/Budget Narrative templates can be downloaded at the ZSI Web site.

Multi-Year Project Requirements

Projects requiring a second and third year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project.

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

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS Program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (i.e., budget narratives, audit documentation, key
contact form] needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (https://www.grantsolutions.gov). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval, 70, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF–424) of the application. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved but Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be “Approved,” but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2018 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

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

2. Administrative Requirements

Cooperative Agreements are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.
B. Administrative Regulations for Grants:
   • Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.
C. Grants Policy:
   • HHS Grants Policy Statement, Revised 01/07.
D. Cost Principles:
   • Uniform Administrative Requirements for HHS Awards, “Cost Principles,” located at 45 CFR part 75, subpart E.
E. Audit Requirements:
   • Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” located at 45 CFR part 75, subpart F.

3. Indirect Costs

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

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) https://rates.psc.gov and the Department of Interior (Interior Business Center) https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under “Agency Contacts” or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a “Grant Note” in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information. The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Reports

Federal Financial Report (FFR or SF–425). Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at https://pms.psc.gov. It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization. Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170. The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with
information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after, and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at http://www.hhs.gov/dgm/policytopics/.

D. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person’s race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html and http://www.hhs.gov/civil-rights/index.html. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/civil-rights/for-individuals/disability/index.html. Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1–800–368–1019 or TDD 1–800–537–7697.

Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at: https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS. Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following Web site: http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf, and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant’s integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113. Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857. (Include “Mandatory Grant Disclosures” in subject line). Office: (301) 443–5204, Fax: (301) 594–0899, Email: Robert.Tarwater@ihs.gov;

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201, URL: http://oig.hhs.gov/fraud/report-fraud/index.asp, [Include “Mandatory Grant Disclosures” in subject line], Fax: (202) 205–0604 (Include “Mandatory Grant Disclosures” in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371. Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Sean Bennett, LCSW, BCD, Public Health Advisor, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 08N34, Rockville, MD 20857, Telephone: (301)
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the meetings.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biomedical Library and Informatics Review Committee.

Date: November 2–3, 2017.

Time: November 2, 2017, 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Time: November 3, 2017, 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Contact Person: Joseph Rudolph, Ph.D., Acting Scientific Review Officer, NLM, Chief and Scientific Review Officer, CSR, Center for Scientific Review, NIH, 6701 Rockledge Drive, Room 5216, Bethesda, MD 20817, 301–408–9098, josephru@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Discussion


As delegated, section 70110(a) authorizes the Coast Guard to impose conditions of entry on vessels arriving in U.S. waters from ports that the Coast Guard has not found to maintain effective anti-terrorism measures.

On May 3, 2016 the Coast Guard found that ports in the Federated States of Micronesia failed to maintain effective anti-terrorism measures and that the Federated States of Micronesia’s designated authority oversight, access control, security monitoring, security training programs, and security plans drills and exercises are all deficient.

On July 7, 2016, as required by 46 U.S.C. 70109, the Federated States of Micronesia was notified of this determination and given recommendations for improving antiterrorism measures and 90 days to respond. To date, we cannot confirm that the Federated States of Micronesia has corrected the identified deficiencies.

Accordingly, beginning September 5, 2017, the conditions of entry shown in Table 1 will apply to any vessel that visited a port in the Federated States of Micronesia in its last five port calls.

TABLE 1—CONDITIONS OF ENTRY FOR VESSELS VISITING PORTS IN THE FEDERATED STATES OF MICRONESIA

<table>
<thead>
<tr>
<th>No.</th>
<th>Conditions of Entry for Vessels Visiting Ports in the Federated States of Micronesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Implement measures per the vessel’s security plan equivalent to Security Level 2 while in a port in the Federated States of Micronesia. As defined in the ISPS Code and incorporated herein, “Security Level 2” refers to the “level for which appropriate additional protective security measures shall be maintained for a period of time as a result of heightened risk of a security incident.”</td>
</tr>
<tr>
<td>2</td>
<td>Ensure that each access point to the vessel is guarded and that the guards have total visibility of the exterior (both landside and waterside) of the vessel while the vessel is in ports in the Federated States of Micronesia.</td>
</tr>
</tbody>
</table>