

temporarily schedule 5F-ADB, its isomers, esters, ethers, salts and salts of isomers, esters, and ethers into Schedule I pursuant to the temporary scheduling provisions of the CSA.

Etizolam belongs to a class of substances known as benzodiazepines. Benzodiazepines produce central nervous system depression and are commonly used to treat insomnia, anxiety, and seizure disorders. Etizolam is currently prescribed in some countries to treat generalized anxiety disorder with depressive symptoms, but is not approved for medical use or controlled in the United States under the CSA. WHO reported that non-fatal intoxications that include cases of driving under the influence of drugs have been linked to etizolam. The ECDD at its 37th (2015 meeting reviewed etizolam and recommended that a critical review of etizolam is warranted.

Pregabalin is an anticonvulsant-type drug used to treat pain generated from the nervous system. It is available as an oral capsule and oral solution and approved for medical use in the United States for the management of neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia, and adjunctive therapy for partial onset seizures, fibromyalgia, and neuropathic pain associated with spinal cord injury. Although the mechanism of action of pregabalin is unknown, studies in animals suggest that binding to the nervous system tissues may be involved in its pain-relieving and anti-seizure effects. Pregabalin binds with high affinity to the alpha 2-delta receptor site (a subunit of voltage-gated calcium channels) in the central nervous system. The binding of pregabalin at this site is thought to be responsible for its therapeutic effect on neuropathic pain. Reports indicate that patients are self-administering higher than recommended doses to achieve euphoria, especially patients who have a history of substance abuse, particularly opioids, and psychiatric illness. While effects of excessively high doses are generally non-lethal, gabapentinoids such as pregabalin are increasingly being identified in post-mortem toxicology analyses. Pregabalin is a Schedule V controlled substance in the United States under the CSA.

Tramadol is an opioid analgesic that produces its primary opioid-like action through an active metabolite referred to as the M1 metabolite (O-desmethyltramadol). Tramadol was first approved for marketing in the United States in 1995 and is available as immediate-release, extended-release, and combination products for the

treatment of moderate to moderately severe pain. On July 2, 2014, the DEA published a final rule in the **Federal Register** controlling tramadol as a Schedule IV substance of the CSA effective from August 18, 2014. Tramadol was pre-reviewed by the ECDD at its 28th (1992) and 32nd (2000) meetings, and critically reviewed at the 33rd (2002) meeting and not recommended for international control but placed on surveillance. Tramadol was pre-reviewed again by the ECDD at its 34th (2006) meeting; however, the ECDD concluded that there was not sufficient evidence to justify a critical review. At the 36th (2014) meeting, the ECDD considered updated information on tramadol, but again concluded that there was insufficient evidence to warrant a critical review.

Cannabidiol (CBD) is one of the active cannabinoids identified in cannabis. CBD has been shown to be beneficial in experimental models of several neurological disorders, including those of seizure and epilepsy. In the United States, CBD-containing products are in human clinical testing in three therapeutic areas, but no such products are approved by FDA for marketing for medical purposes in the United States. CBD is a Schedule I controlled substance under the CSA. At the 37th (2015) meeting of the ECDD, the committee requested that the Secretariat prepare relevant documentation to conduct pre-reviews for several substances, including CBD.

Ketamine is classified as a rapid-acting general anesthetic agent used for short diagnostic and surgical procedures that do not require skeletal muscle relaxation. It is marketed in the United States as a solution for injection. Ketamine is controlled in Schedule III of the CSA in the United States. It is not controlled internationally under the Convention on Psychotropic Substances or the Single Convention on Narcotic Drugs. The ECDD reviewed ketamine at its 34th (2006), 35th (2012), and 36th (2014) meetings. On March 13, 2015, the Commission on Narcotic Drugs (CND) decided by consensus to postpone the consideration of a proposal concerning the recommendation to place ketamine in Schedule IV of the Psychotropic Convention. The CND requested additional information from the WHO. The ECDD reviewed updated information at its 37th (2015) meeting and found no reason to recommend a new pre-review or critical review of ketamine that could potentially change its standing 2014 recommendation that ketamine should not be placed under international control.

#### IV. Opportunity To Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the 17 named drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation of these drug substances. HHS will forward a scientific and medical evaluation of these drug substances to WHO, through the Secretary of State, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in early 2018. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by section 201(d)(2)(B) of the CSA.

#### V. Electronic Access

Persons with access to the Internet may obtain the document at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: August 9, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

**Division of Behavioral Health; Office of Clinical and Preventive Services; Behavioral Health Integration Initiative (BH2I)**

*Announcement Type: New.*

*Funding Announcement Number:*  
HHS-2017-IHS-BH2I-0001.  
*Catalog of Federal Domestic*  
*Assistance Number:* 93.933.

#### **Key Dates**

*Application Deadline Date:*  
September 16, 2017.  
*Review Date:* September 18, 2017.  
*Earliest Anticipated Start Date:*  
September 30, 2017.  
*Signed Tribal Resolutions Due Date:*  
September 16, 2017.  
*Proof of Non-Profit Status Due Date:*  
September 16, 2017.

#### **I. Funding Opportunity Description**

##### *Statutory Authority*

The Indian Health Service (IHS) Office of Clinical and Preventative Services, Division of Behavioral Health, is accepting applications for its Behavioral Health Integration Initiative (Short Title: BH2I) to plan, develop, implement, and evaluate behavioral health integration with primary care, community based settings, and/or integrating primary care, nutrition, diabetes care, and chronic disease management with behavioral health. This program is authorized under: The Snyder Act, 25 U.S.C. 13, and 25 U.S.C. 1665j. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

##### *Background*

IHS supports changing the paradigm of mental health and substance use disorder services from being episodic, fragmented, specialty, and/or disease focused to incorporating it into the patient-centered home model. Research has shown that more than 70 percent of primary care visits stem from behavioral health issues. Depression is the most common type of mental illness, currently affecting more than a quarter of the U.S. adult population. With major depression currently the second leading cause of disability, it is clear that primary care settings have become an important access point for addressing both physical and behavioral health care needs. In addition, American Indian and Alaska Native (AI/AN) communities experience alarming rates of suicide, alcohol and drug-related deaths, domestic and sexual violence, and homicide. Describing the burden of trauma within any population is difficult, however indicators in terms of socially destructive behaviors are often used to illustrate this public health issue that creates impact through lifespan accumulation and chronic stress. Studies now indicate that resulting trauma from such events can

even be passed from one generation to the next, resulting in intergenerational and historical trauma. While mental health needs can often go untreated and even unnoticed, the lasting effects of childhood trauma into adulthood is often evident in physical manifestations leading to negative health consequences. These extreme disparities highlight an urgent need for improving access to mental health services in primary care for children and families through the integration of behavioral health services, including trauma-informed care, within primary care settings. In addition, recognizing that behavioral and physical health problems are interwoven, delivery of behavioral health services in primary care settings reduces stigma and discrimination, and the majority of people with behavioral health disorders treated within an integrated primary care setting have improved outcomes.

##### *Purpose*

The purpose of the Behavioral Health Integration Initiative (BH2I) grant opportunity is to improve the physical and mental health status of people with behavioral health issues by developing an integrative, coordinated system of care between behavioral health and primary care providers. This effort supports the IHS mission to raise the physical, mental, social and spiritual health of AI/ANs to the highest level. Increasing capacity among IHS, Tribal, and Urban Indian Organization (I/T/U) health facilities to implement an integrative approach in the delivery of behavioral health services, including trauma-informed care, nutrition, exercise, social, spiritual, cultural, and primary care services will improve morbidity and mortality outcomes among the AI/AN population. In addition, this effort will support activities that address improving the quality of life for individuals suffering from mental illness, substance use disorders, and adverse childhood experiences. Other outcomes related to this effort include improved behavioral health services that will increase access to integrated health and social well-being services and the early identification and intervention of mental health, substance use, and serious physical health issues, including chronic disease. This work will also identify and assess various models addressing unique integrative needs and the challenges, barriers and successes in AI/AN health systems. Finally, an improvement in the overall health of patients participating in integrative programs is expected.

For this grant, the full spectrum of behavioral health services are strongly encouraged and are defined as: Screening for mental and substance use disorders, including serious mental illness; alcohol, substance, and opioid use disorders; suicidality and trauma (e.g., interpersonal violence, physical abuse, adverse childhood experiences) assessment, including risk assessment and diagnosis; patient-centered treatment planning, evidence based outpatient mental and substance use disorder treatment services (including pharmacological and psychosocial services); crisis services; peer support services; and care coordination.

##### *Models of Care*

IHS understands unique challenges and circumstances exist across Tribal communities and sites. In fact, integrative models of care vary according to needs and capabilities but all strive to enhance clinical processes and workflow across multi-disciplinary teams. This grant will support sites that have identified gaps in services and established efforts that moved toward linking those critical connections, including those with new and innovative ways of conducting business between differing management of operations between Federal and Tribal health services.

#### **II. Award Information**

*Type of Award:* Grant.

##### *Estimated Funds Available*

The total amount of funding identified for the current fiscal year (FY) 2017 is approximately \$6,000,000. Individual award amounts are anticipated to be \$500,000. The amount of funding available for competing awards issued under this announcement are 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 12 awards will be issued under this notice of funding opportunity announcement.

##### *Project Period*

The project period will be for three years and will run consecutively from September 30, 2017, to September 29, 2020.

### III. Eligibility Information

#### I.

##### 1. Eligibility

To be eligible for this New Funding Opportunity under this announcement, an applicant must be one of the following as defined by 25 U.S.C. 1603:

- A Federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14);
- A Tribal organization as defined by 25 U.S.C. 1603(26);
- An Urban Indian organization as defined by 25 U.S.C. 1603(29); a nonprofit corporate body situated in an urban center, governed by an Urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in 25 U.S.C. 1653(a). Applicants must provide proof of non-profit status with the application, *e.g.*, 501(c)(3).

**Note:** Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

##### 2. Cost Sharing or Matching

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

##### 3. Other Requirements

If application budgets exceeds the award 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 Notice of Award 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.Grants.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.
  - SF-424B, Assurances—Non-Construction Programs.
  - Project Narrative (must be single-spaced and not exceed 12 pages).
  - Statement of need, program planning and implementation approach,

staff and organizational capacity, performance assessment and data, and evaluation plan.

- Budget, Budget Justification and Narrative (must be single-spaced and not exceed four pages).
- Tribal Resolution(s).
- Letter(s) of Support:
  - For all applicants: Local organizational partners;
  - For all applicants: Community partners;
  - For Tribal organizations and UIOs: From the board of directors (or relevant equivalent);
  - 501(c)(3) Certificate (if applicable).
  - Biographical sketches for all Key Personnel (*e.g.*, project coordinator etc.).
  - 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
- Face sheets from audit reports. These can be found on the FAC Web site: <https://harvester.census.gov/facdissem/Main.aspx>.

#### Public Policy Requirements

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

#### Requirements for Project and Budget Narratives

##### A. Project Narrative (12 pages)

The project narrative (Parts A through E listed below) should be in a separate Word document that should not exceed 12 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 address all items listed under the evaluation criteria section (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 grant award. If the narrative exceeds the page limit, only the first 12 pages will be reviewed. The 12-page limit for the narrative does not include the table of contents, abstract, standard forms, Tribal resolutions, budget, budget justification narrative, and/or other appendix items.

There are five (5) parts to the project narrative:

- Part A—Statement of Need;
- Part B—Program Planning and Implementation Approach;
- Part C—Staff and Organization Capacity;
- Part D—Performance Assessment and Data; and
- Part E—Evaluation Plan.

Below are additional details about what must be included in the project narrative.

#### Part A: Statement of Need (2 pages)

The statement of need describes the current situation in the applicant's Tribal community ("community" means the applicant's Tribe, village, Tribal organization, or consortium of Tribes or Tribal organizations). The statement of need provides the facts and evidence that support the need for the project and establishes that the Tribe, Tribal organization, or UIO understands the problems and can reasonably address them. The statement of need must not exceed two single-spaced pages.

- Describe the community and priority population for your program including the patients or participants that you expect to serve and the reasons integrated behavioral health and primary care services are needed.
- Describe current behavioral health and/or primary care services in place along with challenges and gaps to provide integrated behavioral health/primary care services to individuals.
- Explain how the BH2I can improve or enhance the current systems in place.

#### Part B: Program Planning and Implementation Approach (5 pages)

- State the purpose, goals and objectives of your proposed project.
- Describe evidence-based programs, services or practices proposed for implementation, or will continue implementation through support of this grant opportunity.
- Describe your current level of behavioral health integration (using the SAMHSA–HRSA Center for Integrated Health Solutions six-level framework ([http://www.integration.samhsa.gov/integrated-care-models/A\\_Standard\\_Framework\\_for\\_Levels\\_of\\_Integrated\\_Healthcare.pdf](http://www.integration.samhsa.gov/integrated-care-models/A_Standard_Framework_for_Levels_of_Integrated_Healthcare.pdf)) and forecast how you

will progress to higher levels of health integration.

- Describe your plan to formally integrate behavioral health through:
  - Improving workflow in the assessment of behavioral health in primary care such as screenings, referral, and policy development.
  - Health information technology changes or improvements that facilitate behavioral health integration
  - Improving physical environment barriers in the delivery of integrated health care
  - Cross training staff, including psycho-education training for staff within primary care settings and basic medical education for behavioral health staff.
  - Establishing formal and informal channels of communication that facilitates behavioral health integration.
  - Describe how you will identify those individuals during the screening process who may indicate opioid and/or alcohol use disorders and how you will refer them to Medication-Assisted Treatment (MAT)-qualified specialty treatment providers.

#### Part C: Staff and Organization Capacity (2 pages)

This section should describe applicant agency organization and structure and the capabilities possessed to complete proposed activities. This grant opportunity will focus on applicants and the applicant's ability to implement a formalized integration plan focused on the enhancing the clinical processes for patient care among the IHS service areas.

- Identify qualified professionals who will implement proposed grant activities, administer the grant, including progress and financial reports or provide salary costs for the addition of full-time equivalent (FTE) licensed behavioral health provider(s).
- Describe the organization's current system of providing at least one service of primary care and/or behavioral health, including screening, assessment, and care management. The primary applicant must directly deliver, operate, and/or manage at least one portion of direct primary care or behavioral health treatment services.
- Describe the organization's plan to hire full-time equivalent (FTE) licensed behavioral health provider(s).

#### Part D: Performance Assessment and Data (2 pages)

This section of the application should describe efforts to collect and report project data that will support and demonstrate BH2I activities. BH2I grantees will be required to collect and

report data pertaining to activities, processes and outcomes. Data collection activities should capture and document actions conducted throughout awarded years including those that will contribute relevant project impact.

- Describe specific data collection efforts that will be required as part of the EBP, or proposed evidence-based projects.
- Describe data collection process and workflow that will assist in completing progress and evaluation requirements.
- Explain proposed efforts to utilize health technology including accessibility, collection and monitoring of relevant data for proposed BH2I project.

#### Part E: Evaluation Plan (1 page)

The evaluation section should describe applicant's plan to evaluate program activities. The evaluation plan should describe expected results and any identified metrics to support program effectiveness. Evaluation plans should incorporate questions related to outcomes and process including documentation of lessons learned.

- Describe proposed evaluation methods including performance measures and other data relevant to evaluation outcomes including intended results (*i.e.*, impact and outcomes), including any partners who will conduct evaluation if separate from the primary applicant.
- Describe efforts to monitor improvements through the evaluation of increased coordination of care, co-located care, and integrated care with reference to the SAMHSA–HRSA Center for Integrated Health Solutions framework at [http://www.integration.samhsa.gov/integrated-care-models/CIHS\\_Framework\\_Final\\_charts.pdf](http://www.integration.samhsa.gov/integrated-care-models/CIHS_Framework_Final_charts.pdf).

#### B. Budget Narrative (4 pages)

This narrative 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 in the project narrative. The budget and budget narrative should not exceed 4 pages.

#### 3. Submission Dates and Times

Applications must be submitted electronically through [Grants.gov](http://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](mailto: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](mailto: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 "Find Grant Opportunities" 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](mailto:GrantsPolicy@ihs.gov) with a copy to [Robert.Tarwater@ihs.gov](mailto: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](mailto: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 contact. 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 it through <http://fedgov.dnb.com/webform>, or to expedite the process, 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 12 page project narrative should include only the first budget 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 65 points is required for funding. Points are assigned as follows:

### 1. Evaluation Criteria

Applications will be reviewed and scored according to the quality of responses to the required application components in Sections A–F outlined below. In developing the required sections of this application, use the instructions provided for each section, which have been tailored to this program. The application must use the six sections (Sections A–F) in developing the application. The applicant must place the required information in the correct section *or it will not be considered for review*. The application will be scored according to how well the applicant addresses the requirements for each section listed below. The number of points after each section heading is the maximum number of points the review committee may assign to that section. Although scoring weights are not assigned to individual bullets, each bullet is assessed deriving the overall section score.

#### A. Statement of Need (25 points)

- The degree to which the applicant’s description of the service area/target population demonstrates the need for new/increased integrated primary health care/behavioral health services.
- How well the applicant describes the unique characteristics of the service area and population that impact access to or utilization of behavioral health care.
- How well the applicant describes existing behavioral health care

providers in the service area, including identified gaps in behavioral health care services that the applicant can address via BH2I funds.

#### B. Program Planning and Implementation Approach (25 points)

- The degree to which the applicant’s purpose, goals and objectives of proposed project will address the mental and physical health needs through integrated an approach between primary health care/behavioral health services.
  - How well the applicant describes the evidence-based practices, practice-based evidence, promising practices and intervention efforts, including culturally appropriate services and interventions, to produce meaning and relevant results including additional detail to support evidence of effectiveness will support proposed project.
  - How well the applicant describes their current level of behavioral health integration (using the SAMHSA–HRSA Center for Integrated Health Solutions framework at [http://www.integration.samhsa.gov/integrated-care-models/CIHS\\_Framework\\_Final\\_charts.pdf](http://www.integration.samhsa.gov/integrated-care-models/CIHS_Framework_Final_charts.pdf)) and forecasts how they will progress to higher levels of health integration.
  - How well the applicant describe their plan to formally integrate behavioral health through:
    - Improving workflow in the assessment of behavioral health in primary care such as screenings, referral, and policy development.
    - Health information technology changes or improvements that facilitate behavioral health integration.
    - Improving physical environment barriers in the delivery of integrated health care.
    - Cross training staff, including psycho-education training for staff within primary care settings and basic medical education for behavioral health staff.
    - Establishing formal and informal channels of communication that facilitates behavioral health integration.
    - How well the applicant describes how they will identify those individuals during the screening process who may indicate opioid and/or alcohol use disorders and how they will refer them to Medication-Assisted Treatment (MAT)-qualified specialty treatment providers.
- #### C. Staff and Organizational Capacity (20 points)
- The degree to which the applicant describes the organization’s current system of providing at least one service of primary care and/or behavioral

health, including screening, assessment, and care management. Does the applicant directly deliver, operate, and/or manage at least one portion of direct primary care or behavioral health treatment services?

- How well does the applicant identify qualified professionals who will implement proposed grant activities, administer the grant, including completion and submission of progress and financial reports, and how project continuity will be maintained if/when there is a change in the operational environment (*e.g.*, staff turnover, change in project leadership) to ensure project stability over the life of the grant.
- The degree to which the applicant describes the organization’s plan to hire full-time equivalent (FTE) licensed behavioral health provider(s).
- For individuals that are identified and currently on staff, include a biographical sketch for the project director, project coordinator, and other key positions as *attachments* to the project proposal/application. Each biographical sketch should not exceed one page. [Note: Attachments will not count against the 12 page maximum]. Do not include any of the following:
  - Personally Identifiable Information;
  - Resumes; or
  - Curriculum Vitae.

#### D. Performance Assessment & Data (10 points)

- How well does the applicant describe plans for data collection, management, analysis and reporting for integration activities.
- The degree to which the applicant lists expected data collection efforts that will be required as part of the EBP, or proposed evidence-based projects.
- How well does the applicant explain proposed efforts to utilize health information technology including accessibility, collection and monitoring of relevant data for proposed BH2I project.
- The degree to which the applicant discusses evaluation methods (including expertise and tools) that will be used to assess impacts and outcomes.

#### E. Evaluation Plan (10 points)

- How well did the applicant propose methods including quantitative and qualitative tools and resources, including techniques that will be utilized to measure outcomes, and partners who will conduct evaluation if separate from the primary applicant.
- The degree to which the applicant describes performance measures and other data relevant to evaluation

outcomes including intended results (*i.e.*, impact and outcomes).

- The degree to which the applicant discusses how expected results will be measured (define indicators or measures that will be used to monitor and measure progress).

- The degree to which the applicant describes a plan to monitor improvements through the evaluation of increased coordinated care, co-located care, and integrated care using the SAMHSA–HRSA Center for Integrated Health Solutions six-level framework ([http://www.integration.samhsa.gov/integrated-care-models/A\\_Standard\\_Framework\\_for\\_Levels\\_of\\_Integrated\\_Healthcare.pdf](http://www.integration.samhsa.gov/integrated-care-models/A_Standard_Framework_for_Levels_of_Integrated_Healthcare.pdf).)

#### F. Categorical Budget and Budget Justification (10 points)

This narrative 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 in the project narrative. The budget and budget narrative should not exceed 4 pages.

#### 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 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, 65 points, 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 2017 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

Grants 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 to be submitted annually, within 30 days after the budget period ends. Progress reports will include a set of standard questions that will be provided to each grantee. Additional information for reporting and associated requirements will be in the "Programmatic Terms and Conditions" in the official Notice of Award, if funded.

A final program progress report must be submitted within 90 days of expiration of the budget/project period at the end of the grant funding cycle.

##### 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, Notice of Funding Opportunities 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.ihs.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 law. 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/civil-rights/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 <http://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.

##### E. 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 (FAPIS) 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 FAPIS 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 FAPIS 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.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to 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](mailto: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](mailto: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: Miranda Carman, Public Health Advisor, Mental Health Lead, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop 08N34A, Rockville, MD 20857, Phone: (301) 443-2038, Fax: (301) 594-6213, Email: [Miranda.Carman@ihs.gov](mailto:Miranda.Carman@ihs.gov).

2. Questions on grants management and fiscal matters may be directed to: Willis Grant, Senior Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-5204, Fax: (301) 594-0899, Email: [Willis.Grant@ihs.gov](mailto:Willis.Grant@ihs.gov).

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 594-0899, Email: [Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov).

#### VIII. Other Information

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

Dated: August 8, 2017.

**Michael D. Weahkee,**

*Assistant Surgeon General, U.S. Public Health Service, Acting Director, Indian Health Service.*

[FR Doc. 2017-17103 Filed 8-11-17; 8:45 am]

**BILLING CODE 4165-16-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Preventing Alcohol-Related Deaths (PARD) Through Social Detoxification

*Announcement Type:* New.  
*Funding Announcement Number:* HHS-2017-IHS-PARD-0001.  
*Catalog of Federal Domestic Assistance Number:* 93.933.

#### Key Dates

*Application Deadline Date:* September 16, 2017.

*Review Date:* September 18, 2017.

*Earliest Anticipated Start Date:* September 30, 2017.

*Signed Tribal Resolutions Due Date:* September 16, 2017.

*Proof of Non-Profit Status Due Date:* September 16, 2017.

#### I. Funding Opportunity Description

##### Statutory Authority

The Indian Health Service (IHS) Office of Clinical and Preventive Health Services' Division of Behavioral Health is accepting applications for cooperative agreements for Preventing Alcohol-Related Deaths (PARD) through Social Detoxification. This program is authorized under: Snyder Act, 25 U.S.C. 13; Consolidated Appropriations Act of 2017, Public Law 115-31, 131 Stat. 135 (2017); and 25 U.S.C. 1665a. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

##### Background

Alcohol-related deaths are 520 percent greater among the American Indian and Alaska Native (AI/AN) population than the general United States population (IHS Trends in Indian Health, 2014). Providing social detoxification services is often a first step toward recovery for individuals with an alcohol use disorder to minimize physical harm, including death. Detoxification alone is not sufficient treatment for alcohol use disorder but is part of the continuum of care that fosters an individual's entry into treatment and rehabilitation. Alcohol use disorders are brain disorders and not evidence of moral weakness. All individuals with alcohol use disorders should be treated with respect and dignity at all times, in a nonjudgmental and supportive manner. Services should be completed in partnership with the individual and his or her social support network with due consideration for individual background, culture, preferences,