

Dated: December 11, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27655 Filed 12–15–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5344]

Pharmacyclics LLC.; Withdrawal of Approval of Indications for Mantle Cell Lymphoma and Marginal Zone Lymphoma for IMBRUVICA (ibrutinib) Capsules and Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the indications for mantle cell lymphoma (MCL) and marginal zone lymphoma (MZL) for IMBRUVICA (ibrutinib) Capsules and Tablets approved, respectively, under new drug applications (NDAs) 205552 and 210563. These NDAs are held by Pharmacyclics LLC, 1000 Gateway Blvd., South San Francisco, CA 94080 (Pharmacyclics). Pharmacyclics voluntarily requested that the Agency withdraw approval of these indications and waived its opportunity for a hearing.

DATES: Approval is withdrawn as of December 18, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On November 13, 2013, FDA approved NDA 205552 for IMBRUVICA (ibrutinib) Capsules for the treatment of adult patients with MCL who have received at least one prior therapy (the MCL indication). On January 18, 2017, FDA approved a prior approval supplement for NDA 205552 for IMBRUVICA (ibrutinib) Capsules for the treatment of adult patients with MZL who require systemic therapy and have received at least one prior anti-CD20-based therapy (the MZL indication). On February 16, 2018, FDA approved NDA 210563 for IMBRUVICA (ibrutinib) Tablets, a new dosage form of IMBRUVICA (ibrutinib), for the MCL and MZL indications. FDA

approved the MCL and MZL indications for both products under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. As a condition of accelerated approval of IMBRUVICA (ibrutinib) Capsules and Tablets for the MCL and MZL indications, the applicant was required to conduct postmarketing trials to verify the clinical benefit of ibrutinib for the MCL and MZL indications.

On February 8, 2023, FDA met with Pharmacyclics to inform the applicant of the plans to convene the Oncologic Drugs Advisory Committee regarding the accelerated approvals for the MCL and MZL indications because the required postmarketing trials did not verify the clinical benefit of ibrutinib for these indications. On March 21, 2023, FDA met with Pharmacyclics to discuss the applicant's request to voluntarily withdraw approval of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets. On April 6, 2023, Pharmacyclics submitted a letter requesting withdrawal of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets pursuant to § 314.150(d) (21 CFR 314.150(d)) and waiving its opportunity for a hearing.

Therefore, under § 314.150(d), approvals of the MCL and MZL indications for IMBRUVICA (ibrutinib) Capsules and Tablets are withdrawn as of December 18, 2023. Withdrawal of approval of these indications does not affect any other approved indication for IMBRUVICA (ibrutinib) Capsules and Tablets.

Dated: December 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Funding Opportunity for the Community Opioid Intervention Prevention Program

Announcement Type: New.

Funding Announcement Number: HHS–2024–IHS–COIPP–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.654.

Key Dates

Application Deadline Date: February 7, 2024.

Earliest Anticipated Start Date: April 1, 2024.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS), Office of Clinical and Preventive Services, Division of Behavioral Health (DBH) is accepting applications for grants for the Community Opioid Intervention Prevention Program (COIPP). This program is authorized under the Snyder Act, 25 U.S.C. 13, and the Transfer Act, 42 U.S.C. 2001(a). Funding for this program is provided in the Consolidated Appropriations Act, 2023, Public Law 117–328, 136 Stat. 4459, 4808 (2022). The Assistance Listings section of *SAM.gov* (<https://sam.gov/content/home>) describes this program under 93.654.

Background

The initial opioid prevention program, called the Community Opioid Intervention Pilot Project, was first established in Fiscal Year (FY) 2019, pursuant to Congressional instruction to better combat the opioid epidemic. The goal was to create a pilot program to address the opioid epidemic in Indian Country and award grants that supported the development, documentation, and sharing of locally designed and culturally appropriate prevention, treatment, recovery, and aftercare services for opioid use disorders in the American Indian and Alaska Native (AI/AN) communities. Evidence-based activities are available for reference at <https://www.ihs.gov/asap/coipp/>. A total of 35 grants were awarded to Tribal and Urban Indian communities in the pilot phase. Based on evaluation results from the pilot project, this funding opportunity will continue to provide grant support to Tribal and Urban Indian communities to continue efforts to combat the opioid epidemic and develop strategies that align with the Department of Health and Human Services Overdose Prevention Strategy.

The Centers for Disease Control and Prevention (CDC) reported that the AI/AN population had the highest drug overdose death rates in both 2020 and 2021, at rates of 42.5 and 56.6 deaths per 100,000 persons, respectively. The AI/AN population also experienced a 33 percent increase in drug overdose deaths from 2020 through 2021. Overdose deaths among AI/AN have continued to increase over the last 20 years. The CDC reported from 2019 to 2020, overdose death rates increased 39 percent for the non-Hispanic AI/AN population and drug overdose death rates were highest for AI/AN people compared to other racial and ethnic groups.

While the overall AI/AN population is at risk for overdoses, special populations to consider are youth, pregnant persons, young parents, and those experiencing housing insecurity. Over the last two decades, opioid-related overdose mortality among adolescent and young adults has increased dramatically. Low-income women and women of color are at higher risk for barriers to seek appropriate care for substance use disorders during pregnancy. AI/AN women with opioid use disorder (OUD) encounter barriers to accessing services for treatment. Maternal substance misuse can result in neonatal abstinence syndrome, a drug withdrawal process in newborns exposed in utero to drugs. Correct racial classification is an important factor in improving data quality for AI/AN populations and establishing accurate surveillance to help address the disproportionate burden of neonatal abstinence syndrome among AI/AN.

Housing insecurity takes on many forms, including homelessness, housing cost burden, overcrowding, poor quality housing, and living with persons who use substances. The rate of AI/AN that experience housing insecurity is 45 out of 10,000. Young AI/AN adults are three times more likely to experience homelessness than their non-Native peers and one third of AI/AN adults experienced homelessness.

Purpose

The purpose of this grant program is to address the opioid crisis in AI/AN communities by doing the following: first, developing and expanding community education and awareness of prevention, treatment, and recovery activities for opioid misuse and opioid use disorder; second, increasing knowledge and use of culturally appropriate interventions and to encourage an increased use of medication-assisted treatment/medications for opioid use disorder (MAT/MOUD); third, supporting Tribal and Urban Indian communities in their effort to provide prevention, treatment, and recovery services to address the impact of the opioid crisis; and fourth, increase harm reduction within their communities.

Recipients for this funding opportunity are required to address the following four objectives:

1. Increase public awareness and education about culturally appropriate and family-centered opioid and overdose prevention, treatment, and recovery practices and programs in AI/AN communities.

2. Create comprehensive support teams to strengthen and empower AI/AN families in addressing the opioid and overdose crisis in Tribal or Urban Indian communities.

3. Increase access to MAT/MOUD treatment for persons who experience opioid misuse, opioid use disorder, and opioid related overdoses.

4. Increase harm reduction activities in Tribal and Urban Indian communities.

In alignment with the agency goals to ensure that comprehensive, culturally appropriate personal and public health services are available and accessible to AI/AN people, the COIPP is designed to provide recipients with the ability to develop unique and innovative community interventions that will address the opioid crisis at a local level. The IHS supports Tribal and Urban Indian efforts that include addressing substance use prevention, treatment, and aftercare from a community-driven context. The IHS encourages applicants to develop and submit a plan that emphasizes cross-system collaboration, the inclusion of family, youth, community resources, and culturally appropriate approaches.

Recipients are also encouraged to incorporate foundational elements, priorities, and strategies from the National Tribal Behavioral Health Agenda (TBHA) as appropriate. The TBHA was developed by Substance Abuse and Mental Health Services Administration (SAMHSA) in collaboration with Tribes, the Indian Health Service, and the National Indian Health Board. A component of the TBHA is the AI/AN Cultural Wisdom Declaration (CWD), which elevates the importance of Tribal identities, culture, spiritual beliefs, and practices for improving well-being. This grant announcement supports the CWD and inclusion of ancestral cultural knowledge, wisdom, ceremony, and practices of AI/AN Tribes into the grant application. The TBHA can be found at <https://store.samhsa.gov/product/The-National-Tribal-Behavioral-HealthAgenda/PEP16-NTBH-AGENDA>.

Required Activities

The focus of this program is to support AI/ANs in their efforts to provide prevention, treatment, aftercare, and recovery services to address the impact of the opioid crisis in Native communities. All COIPP activities should be culturally-based, and family-oriented.

The IHS is seeking applications that include the following required activities:

1. Community Awareness and Education:

- a. Recipients shall promote family, youth and community engagement in the planning and implementation of opioid use prevention and harm reduction activities.

- b. Recipients shall design community awareness campaigns and education programs that inform and train community members on how to recognize the signs of opioid misuse and overdose. Educational tool(s) shall be culturally-appropriate and intended to engage families.

- c. Recipients will develop educational resources, such as factsheets using culturally relevant messaging; disseminate materials through community stakeholders and community partners, and identify culturally appropriate ways to implement educational programs in their local communities.

- d. Awareness Campaign should include instructions on the following, among others:

- How to access local opioid-specific services.

- How to safeguard controlled prescription medications from children and adolescents.

- How to dispose properly of unused controlled prescription medications.

2. Expand access to MAT/MOUD services that include Tribal values, culture and treatments:

- a. Promote family, youth and community engagement in the planning and implementation of opioid use treatment.

- b. Increase number of providers receiving training in MAT/MOUD services that include Tribal values, culture, and treatments.

- c. Increase access to continuing education on MAT/MOUD.

- d. Expand access to integrated MAT/MOUD services for Tribal communities, including TeleMAT.

- e. Increase the availability and utilization of buprenorphine to Tribal communities in both rural and urban settings including increased collaboration with local Emergency Departments to establish buprenorphine bridge programs.

3. Build a support system for strengthening Native families by implementing culturally-appropriate approaches.

- a. Promote family, youth and community engagement in the planning and implementation of opioid use recovery activities.

- b. Develop a family-focused and culturally-based assessment that captures biopsychosocial needs of AI/ANs.

c. Link assessment needs to support and recovery services.

d. Collaborate with relevant partners to build a support system for recovery.

4. Increase harm reduction activities.

a. Increase awareness and distribution of naloxone as an overdose intervention and teach skills in how to use it.

b. Increase awareness and distribution of medication lock boxes and teach skills in how to use.

c. Collaborate with relevant partners to implement harm reduction activities.

II. Award Information

Funding Instrument—Grant

Estimated Funds Available

The total annual funding identified is approximately \$9.5 million. Individual award amounts for the first budget year are anticipated to be between \$350,000 and \$500,000. The funding available for subsequent budget years issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards to applicants selected for funding under this announcement.

The actual amount available will not be determined until enactment of the FY 24 Fiscal Year federal budget. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner.

Anticipated Number of Awards

The IHS anticipates issuing up to 27 awards under this program announcement.

Period of Performance

The period of performance is for 5 years.

III. Eligibility Information

1. Eligibility

To be eligible for this funding opportunity 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). The term “Indian Tribe” means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or group, or regional or village corporation, as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 *et seq.*], which is recognized as eligible for the special programs and services provided by the

United States to Indians because of their status as Indians.

- A Tribal organization as defined by 25 U.S.C. 1603(26). The term “Tribal organization” has the meaning given the term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(l)): “Tribal organization” means the recognized governing body of any Indian Tribe; any legally established organization of Indians which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: provided that, in any case where a contract is let or grant made to an organization to perform services benefiting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant. Applicant shall submit letters of support and/or Tribal Resolutions from the Tribes to be served.

- An Urban Indian Organization (UIO), as defined by 25 U.S.C. 1603(29). The term “Urban Indian Organization” means 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 nonprofit status with the application, *e.g.*, 501(c)(3).

2. Additional Information on Eligibility

The IHS does not fund concurrent projects. If an applicant is successful under this announcement, any subsequent applications in response to other COIPP announcements from the same applicant will not be funded. Applications on behalf of individuals (including sole proprietorships) and foreign organizations are not eligible. Applications deemed ineligible will be disqualified from competitive review and funding under this funding opportunity.

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 nonprofit status, etc.

3. Cost Sharing or Matching

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

4. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The DGM will notify the applicant.

Additional Required Documentation Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any Tribe or Tribal organization selected for funding. An applicant that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date 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 application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Applicants organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization. Please include documentation explaining and substantiating this.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit a current copy of the 501(c)(3) Certificate with the application.

IV. Application and Submission Information

Grants.gov uses a Workspace model for accepting applications. The Workspace consists of several online forms and three forms in which to

upload documents—Project Narrative, Budget Narrative, and Other Documents. Give your files brief descriptive names. The filenames are key in finding specific documents during the merit review and in processing awards. Upload all requested and optional documents individually, rather than combining them into a single file. Creating a single file creates confusion when trying to find specific documents. Such confusion can contribute to delays in processing awards, and could lead to lower scores during the merit review.

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at <https://www.Grants.gov>.

Please direct questions regarding the application process to DGM@ihs.gov.

2. Content and Form Application Submission

Mandatory documents for all applications are listed below. An application is incomplete if any of the listed mandatory documents are missing. Incomplete applications will not be reviewed.

- Application forms:
 1. SF-424, Application for Federal Assistance.
 2. SF-424A, Budget Information—Non-Construction Programs.
 3. SF-424B, Assurances—Non-Construction Programs.
 4. Project Abstract Summary form.
 - Project Narrative (not to exceed 10 pages). See Section IV.2.A, Project Narrative for instructions.
 - Budget Narrative (not to exceed 4 pages). See Section IV.2.B, Budget Narrative for instructions.
 - One-page Timeframe Chart.
 - Biographical sketches for all Key Personnel.
 - Contractor/Consultant resumes or qualifications and scope of work.
 - Certification Regarding Lobbying (GG-Lobbying Form).
 - Organizational Chart (optional).
- The documents listed here may be required. Please read this list carefully.
- Tribal Resolution(s) as described in Section III, Eligibility.
 - Letters of Support from organization's Board of Directors.
 - Disclosure of Lobbying Activities (SF-LLL), if applicant conducts reportable lobbying.
 - Copy of current Negotiated Indirect Cost (IDC) rate agreement (required in order to receive IDC).
 - Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
 2. Face sheets from audit reports.
- Applicants can find these on the FAC website at <https://facdissem.census.gov/>.

Additional documents can be uploaded as Other Attachments in [Grants.gov](https://www.Grants.gov). These can include:

- Work plan, logic model, and/or timeline 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 Rate Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.*, data tables, key news articles, etc.).

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See <https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html>.

Requirements for Project and Budget Narratives

A. Project Narrative

This narrative should be a separate document that is no more than 10 pages and must: (1) have consecutively numbered pages; (2) use black font 12 points or larger (applicants may use 10 point font for tables); (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches). Do not combine this document with any others.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria), and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the overall page limit, the reviewers will be directed to ignore any content beyond the page limit. The 10-page limit for the project narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget narratives, and/or other items. Page limits for each section within the project narrative are guidelines, not hard limits.

There are four parts to the project narrative:

- Part 1—Statement of Need;
- Part 2—Program Plan—Objectives and Activities;
- Part 3—Organizational Capacity; and
- Part 4—Program Evaluation (Data Collection and Reporting).

See below for additional details about what must be included in the narrative.

Part 1: Statement of Need (Limit—1 Page)

Describe the extent of the problem related to opioid misuse, opioid use disorder, and opioid related overdoses in the applicant's community ("community" means the applicant's Tribe, village, Tribal organization, consortium of Tribes or Tribal organizations, or urban center). Provide the facts and evidence that support the need for the project and establish that the Tribe, Tribal organization, or UIO understand the problems and can reasonably address them. This section must also succinctly but completely answer the questions listed under the evaluation criteria in Section V.1.A. Statement of Need.

Part 2: Program Plan—Objectives and Activities (Limit—6 Pages)

Describe the scope of work the Tribe, Tribal organization, or UIO by clearly and concisely outlining the following required components:

1. Goals and Objectives. Reference all required objectives.
2. Project Activities. Link your project activities to your outlined goals and objectives.

This section must also succinctly but completely answer the questions listed under the evaluation criteria in Section V.1.B. Program Plan (Objectives and Activities).

Part 3: Organizational Capacity (Limit—2 Pages)

Describe the Tribe, Tribal organization, or UIO's organizational capacity to implement the proposed activities, in the following areas: Ability to provide direct care, treatment, and services, including MAT/MOUD; current or ongoing projects related to opioid prevention, treatment, recovery support, and aftercare; a detailed description of partnerships and networks with opioid misuse and harm reduction providers. Provide detail on significant program activities and achievements/accomplishments over the past 5 years associated with opioid prevention, treatment, recovery support, and aftercare activities. Provide success stories, data, or other examples of how other funded projects/programs made an

impact in your community to address opioid use. If applicable, provide justification for lack of progress of previous efforts. This section must also succinctly but completely answer the questions listed under the evaluation criteria in Section V.1.C. Organizational Capacity.

Part 4: Program Evaluation (Limit 1 Page)

Based on the required activities in Section V, describe how the Tribe, Tribal organization, or UIO plans to collect data for the proposed project and activities. Identify any type(s) of evaluation(s) that will be used and how you will collaborate with partners to complete any evaluation efforts or data collection. Progress reports will include compilation of quantitative data (e.g., number served; screenings completed, etc.) and qualitative or narrative (text) data. Reporting elements should be specific to activities/programs, processes and outcomes such as performance measures and other data relevant to evaluation outcomes including intended results (i.e., impact and outcomes). Logic Models are highly recommended to include in the application. The IHS will partner with Technical Assistance Providers to assist recipients develop data collection and evaluation plans and tools. Recipients will be required to collect and submit semi-annual and annual progress reports. Additional information regarding Data Collection refer to Section V.1.D. Program Evaluation (Data Collection & Reporting).

B. Budget Narrative (Limit—4 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF-424A (Budget Information for Non-Construction Programs) for the entire project, by year. The applicant can submit with the budget narrative a more detailed spreadsheet than is provided by the SF-424A (the spreadsheet will not be considered part of the budget narrative). The budget narrative should specifically describe how each item would support the achievement of proposed objectives. Be very careful about showing how each item in the "Other" category is justified. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will

notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at <https://www.Grants.gov>). If problems persist, contact Mr. Paul Gettys, Deputy Director, DGM, by email at DGM@ihs.gov. Please be sure to contact Mr. Gettys at least 10 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.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

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

5. Funding Restrictions

- The available funds are inclusive of direct and indirect costs.

- Only one grant may be awarded per applicant.

- Food is an allowable expense under this program. Recipient may not exceed \$10,000.00.

- While construction is not an allowable cost, alteration and renovation (A&R) is allowable. A&R must be consistent with the following criteria and documentation requirements:

- a. The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required.

- b. The A&R is essential to the purpose of the grant-supported project or program.

- c. The space involved will be occupied by the project or program.

- d. The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage.

- e. For minor A&R, if the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the period of performance.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the "Search Grants" link on the homepage. Follow the instructions for submitting an application under the

Package tab. No other method of application submission is acceptable.

If you cannot submit an application through *Grants.gov*, you must request a waiver prior to the application due date. You must submit your waiver request by email to DGM@ihs.gov. Your waiver request must include clear justification for the need to deviate from the required application submission process. The IHS will not accept any applications submitted through any means outside of *Grants.gov* without an approved waiver.

If the DGM approves your waiver request, you will receive a confirmation of approval email containing submission instructions. You must include a copy of the written approval with the application submitted to the DGM. Applications that do not include a copy of the waiver approval from the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the Assistance Listing 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, please contact *Grants.gov* Customer Support (see contact information at <https://www.Grants.gov>).

- 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 20 working days.

- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.

- Applicants must comply with any page limits described in this funding announcement.

- After submitting the application, you will receive an automatic

acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify you that the application has been received.

System for Award Management

Organizations that are not registered with the System for Award Management (SAM) must access the SAM online registration through the SAM home page at <https://sam.gov>. Organizations based in the United States (U.S.) 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. Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at <https://sam.gov>.

Unique Entity Identifier

Your *SAM.gov* registration now includes a Unique Entity Identifier (UEI), generated by *SAM.gov*, which replaces the DUNS number obtained from Dun and Bradstreet. *SAM.gov* registration no longer requires a DUNS number.

Check your organization's *SAM.gov* registration as soon as you decide to apply for this program. If your *SAM.gov* registration is expired, you will not be able to submit an application. It can take several weeks to renew it or resolve any issues with your registration, so do not wait.

Check your *Grants.gov* registration. Registration and role assignments in *Grants.gov* are self-serve functions. One user for your organization will have the authority to approve role assignments, and these must be approved for active users in order to ensure someone in your organization has the necessary access to submit an application.

The Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS recipients must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its UEI number to the prime recipient 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.

Additional information on implementing the Transparency Act, including the specific requirements for SAM, are available on the DGM Grants Management, Policy Topics web page at <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include the proposed activities for the entire period of performance. The project narrative 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 fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. 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–E. The number of points after each heading is the maximum number of points a review committee may assign to that section. Although scoring weights are not assigned to individual numbers, responses to each number are assessed in deriving the overall section score.

A. Statement of Need (20 Points)

(1) Describe the extent of the problem related to opioid misuse, opioid use disorder and opioid related overdoses in the applicant's community ("community" means the applicant's Tribe, village, Tribal organization, consortium of Tribes or Tribal organizations, or urban center). Provide 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.

(2) Include a description of social determinants of health that may contribute to the opioid misuse, opioid use disorder, and opioid related overdoses in the community. Include details on economic stability (such as housing and food insecurity); education (such as early childhood education and development, high school graduation, and language and literacy); social and community context (such as discrimination, incarceration, and social cohesion); health and health care (such as access to health care and health literacy); and neighborhood and built environment (such as access to foods that support healthy eating patterns, crime and violence, environmental conditions, and quality of housing).

(3) Provides background information on the Tribe, Tribal organization, or UIO.

(4) Based on the information and/or data currently available, document the prevalence of opioid misuse and overdose rates.

(5) Based on the information and/or data currently available, document the need to increase the capacity to implement, sustain, and improve effective opioid misuse and overdose prevention, treatment, aftercare, recovery, and harm reduction services in the proposed catchment area that is consistent with the purpose of this funding opportunity announcement.

(6) Describe the service gaps and other problems related to the need for funds targeting opioid misuse. Identify the source of the data.

(7) Describe potential Tribal and community partners and resources in the catchment area that can participate in the broad community awareness campaign.

(8) Affirm the goals of the project are consistent with priorities of the Tribal government or board of directors and that the governing body is in support of this application.

B. Program Plan—Objectives and Activities (35 Points)

(1) Identify the population of focus for your project. Describe the purpose of the proposed project, including goals and objectives and how they are linked. Describe how the achievement of goals will increase Tribe, Tribal organization, or UIO's capacity to support the goals and required activities identified in Section I of this announcement.

(2) Describe how the proposed project activities relate to the proposed project's goals and objectives. Describe how the project activities will increase the capacity of the community to prevent and treat opioid misuse, opioid use disorder, and overdose in the communities and implement harm reduction activities.

(3) Describe organizational capacity to implement the proposed activities, including increased public awareness and education on opioids and overdose; developing a comprehensive support team to strengthen and empower AI/AN families in addressing the opioid and overdose crisis in Tribal or Urban Indian communities; integrating the use of MAT/MOUD, and harm reduction into the community.

(4) Describe how community partners (prevention and recovery support providers, substance use disorder treatment programs, peer recovery specialists, social workers, behavioral health clinics, community health centers, youth serving organizations, family and youth homeless providers, child welfare agencies, primary care

providers, pharmacists, schools, clergy, and law enforcement, among others) will be involved in the planning and implementation of the project.

(5) Describe if/how the efforts of the proposed project will be coordinated with any other related Federal grants or programs funded through the IHS, SAMHSA, BIA, or other Federal agencies.

(6) Provide a timeline chart depicting a realistic timeline for the project period showing key activities, milestones, and responsible staff. These key activities should include the required activities identified in Section V of this announcement.

C. Organizational Capacity (15 Points)

Organizational capacity including increased public awareness and education on opioids; developing a comprehensive support team to strengthen and empower AI/AN families in addressing the opioid crisis in Tribal or Urban Indian communities; integrating the use of MAT/MOUD, and implementing harm reduction activities into the Tribal and Urban Indian community.

(1) Describe significant harm reduction activities, achievements, and/or accomplishments over the past five years for opioid misuse, opioid use disorder, and opioid related overdoses.

(2) Describe the applicant Tribe, Tribal organization, or UIO experience and capacity to provide culturally appropriate/competent opioid misuse and harm reduction services to the community and specific populations of focus.

(3) Describe the resources available for the proposed project (e.g., facilities, equipment, information technology systems, and financial management systems).

(4) Describe how project continuity will be maintained if/when there is a change in the operational environment (e.g., staff turnover, change in project leadership, change in elected officials) to ensure project stability over the life of the grant.

(5) Provide a complete list of staff positions anticipated for the project, including the Project Director, Project Coordinator, and other key personnel, showing the role of each and their level of effort and qualifications. Key staff have the following:

a. Relevant health or behavioral health experience.

b. Experience with award program management, including skills in program coordination, budgeting, reporting, and staff supervision.

(6) For key staff currently on board, include a biographical sketch for the

Project Director, Project Coordinator, or other key positions as attachments to the project proposal/application. Do not include any of the following in the biographical sketch:

- a. Personal Identifiable Information (i.e., SSN, home address, etc.);
- b. Resumes; or
- c. Curriculum Vitae.

D. Program Evaluation (Data Collection and Reporting) (20 Points)

Recipients will be required to collect and submit semi-annual and annual progress reports. Logic Models are highly recommended to provide guidance on collecting data for evaluation purposes (see Attachment A). Applicants are required to collect data within their communities on the prevalence and incidence rates for opioid misuse, opioid use disorders, opioid related overdoses, and other data metrics such as mortality and morbidity rates from opioid related events.

(1) Progress reports will include the compilation of quantitative data (e.g. number served; screenings completed, etc.) and qualitative or narrative (text) data.

(2) Reporting elements should include data from local community-based, and evidence-based programs which pertain to proposed activities, processes and outcomes such as performance measures and other data relevant to evaluation outcomes including intended results (i.e., impact and outcomes).

(3) Describe how the applicant will measure variables, what method will be used and how the data will be used for quality improvement and sustainability of program and meeting required reporting deadlines.

(4) Based on the required objectives, did the applicant describe any type(s) of evaluation(s) that will be used and how they will collaborate with partners such as Tribal Epidemiology Centers to complete any evaluation efforts or data collection?

(5) Did the applicant affirm their organization will participate in completing the annual progress report and did they describe their capability and experience with similar evaluations?

(6) Did applicant describe necessary data-sharing agreements established, or will be established in support of these activities?

E. Budget and Budget Justification (10 Points)

(1) The applicant is required to include a line item budget for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in

the project narrative for the entire period of performance. The budget expenditures should correlate with the scope of work described in the project narrative.

(2) The applicant must provide a narrative justification of the budget line items, as well as a description of existing resources and other support the applicant expects to receive for the proposed project. Other support is defined as funds or resources, whether Federal, non-federal or institutional, in direct support of activities through fellowships, gifts, prizes, in-kind contributions, or non-federal means. (This should correspond to Item #18 on the applicant's SF-424, Estimated Funding, and SF-424A Budget Information, Section C Non-federal resources.)

(3) Provide a narrative justification supporting the development or continued collaboration with other partners regarding the proposed activities to be implemented.

(4) Depending on the availability of funds, the IHS may host annual meetings to provide in-depth training and technical assistance to awardees. In order to help establish critical mass of community and staff members who are informed and committed to implement the project, awardees should plan to send a minimum of two people (including the Project Director/Project Coordinator) to one meeting of all awardees in each year of the grant. At these meetings, awardees will receive training related to grant objectives, discuss success and challenges in implementation of the program, present the results of their projects, and receive other technical assistance from IHS staff and/or contractors. Each meeting may be up to 3 days. The locations will be determined at a later date, but applicants should estimate costs for Denver, CO as a potential site that is accessible to most of "Indian Country" and attendance is strongly encouraged.

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in this funding announcement. The Review Committee (RC) will review applications that meet the eligibility criteria. The RC will review the applications for merit based on the evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, period of performance limit) will not be referred to the RC and will not be funded. The DGM will notify the applicant of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS DBH within 30 days of the conclusion of the review outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF-424) of the application.

A. Award Notices for Funded Applications

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 award, the terms and conditions of the award, the effective date of the award, the budget period, and period of performance. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved But Unfunded Applications

Approved applications not funded due to lack of available funds will be held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence, other than the official NoA executed 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 the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Awards:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at <https://www.govinfo.gov/content/pkg/CFR-2022-title45-vol1/pdf/CFR-2022-title45-vol1-part75.pdf>.

- If you receive an award, HHS may terminate it if any of the conditions in 2 CFR 200.340(a)(1)–(4) are met. Please review all HHS regulatory provisions for Termination at 2 CFR 200.340, at the time of this publication located at <https://www.govinfo.gov/content/pkg/CFR-2023-title2-vol1/pdf/CFR-2023-title2-vol1-sec200-340.pdf>. No other termination conditions apply.

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, “Cost Principles,” at 45 CFR part 75 subpart E, at the time of this publication located at <https://www.govinfo.gov/content/pkg/CFR-2022-title45-vol1/pdf/CFR-2022-title45-vol1-part75-subpartE.pdf>.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” at 45 CFR part 75 subpart F, at the time of this publication located at [https://www.govinfo.gov/content/pkg/CFR-2022-title45-vol1-part75-subpartF.pdf](https://www.govinfo.gov/content/pkg/CFR-2022-title45-vol1/pdf/CFR-2022-title45-vol1-part75-subpartF.pdf).

F. As of August 13, 2020, 2 CFR part 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR 200.216, at the time of this publication located at <https://www.govinfo.gov/content/pkg/CFR-2023-title2-vol1/pdf/CFR-2023-title2-vol1-sec200-216.pdf>. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of IDC in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an 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 award activities under the current award’s budget period. If the current rate agreement 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 agreement is provided to the DGM.

Please refer to 2 CFR 200.414(f) Indirect (F&A) costs, found at <https://www.govinfo.gov/content/pkg/CFR-2023-title2-vol1/pdf/CFR-2023-title2-vol1-sec200-414.pdf>.

Electing to charge a de minimis rate of 10 percent can be used by applicants that have received an approved negotiated indirect cost rate from HHS or another cognizant Federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS recipients are negotiated with the Division of Cost Allocation at <https://rates.psc.gov/> or the Department of the Interior (Interior Business Center) at <https://ibc.doi.gov/ICS/tribal>. For questions regarding the indirect cost policy, please write to DGM@ihs.gov.

3. Reporting Requirements

The recipient 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 award, 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 the imposition of special award provisions and/or 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 recipient organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must 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 use the form under the Recipient User section of <https://www.grantsolutions.gov/home/getting-started-request-a-user-account/>. Download the Recipient User Account Request Form, fill it out completely, and submit it as described on the web page and in the form.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). 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. Recipient must submit a final report within 120 days of the period of performance end date.

B. Financial Reports

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 120 days after the end of the period of performance.

Recipients are responsible and accountable for reporting accurate information on all required reports: the Progress Reports and the Federal Financial Report.

Failure to submit timely reports may result in adverse award actions blocking access to funds.

C. Data Collection and Reporting

All recipients will be required to collect and report data pertaining to activities, processes, and outcomes. Logic Models are highly recommended to provide guidance on collecting data for evaluation purposes (see Attachment A). The IHS DBH will provide guidance on data collection and reporting for evaluation purposes within 6 months of award. All reporting items will be submitted via the GrantSolutions. Technical assistance for web-based data entry will be timely and readily available to recipients by assigned IHS DBH staff. Recipients are responsible and accountable for accurate information being submitted by required due dates for Data Collection and Reporting.

D. 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 awards to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The 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 threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at <https://www.ihs.gov/dgm/policytopics/>.

E. Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance (FFA)

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in *SAM.gov*. You must also submit an Assurance of Compliance (HHS-690). To learn more, see <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html>. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS.

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 FAPIIS at <https://sam.gov/content/fapiis> before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The 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, 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 million 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 HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE 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.

All applicants and recipients must disclose in writing, in a timely manner, 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: Marsha Brookins, 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: DGM@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: <https://oig.hhs.gov/fraud/report-fraud/>. (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 part 180 and 2 CFR part 376).

VII. Agency Contacts

1. *Questions on the program matters may be directed to:* Cassandra Allen, Public Health Advisor, Indian Health Service, Division of Behavioral Health, 5600 Fishers Lane, Mail Stop: 0834NB, Rockville, MD 20857, Phone: (240) 485-7524, Email: Cassandra.Allen@ihs.gov.

2. *Questions on awards management and fiscal matters may be directed to:* Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Email: DGM@ihs.gov.

3. For technical assistance with *Grants.gov*, please contact the *Grants.gov* help desk at (800) 518-4726, or by email at *support@grants.gov*.

4. For technical assistance with GrantSolutions, please contact the GrantSolutions help desk at (866) 577-0771, or by email at *help@grantsolutions.gov*.

VIII. Other Information

The Public Health Service strongly encourages all grant, 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.

Roselyn Tso,
Director, Indian Health Service.

Attachment A: Community Opioid Intervention Prevention Program Logic Model (Example)

| Input | Activities | Outputs | Outcomes |
|--|--|--|---|
| <ul style="list-style-type: none"> ■ Implementing agency leadership and support. ■ Participants (families, community leaders, Tribal leaders, professional staff). ■ Community support and partnerships. ■ Program management, evaluation and continuous improvement. ■ Training. ■ Technical Assistance to grantees. ■ Annual convening of grantees. | <ol style="list-style-type: none"> 1. Community awareness/education: <ul style="list-style-type: none"> —Cultural integration. —Promote family and community engagement. 2. Build support system to strengthen AI/AN families: <ul style="list-style-type: none"> —Cultural integration. —Maternal & Child Health. —Promote family and community engagement. 3. Expand access to MAT/MOUD: <ul style="list-style-type: none"> —Cultural integration. —Buprenorphine/Suboxone. —Promote family and community engagement. 4. Implement harm reduction activities: <ul style="list-style-type: none"> —Naloxone. —Medication lock boxes. —Syringe Service Program. —Fentanyl Test Strips (FTS). | <ul style="list-style-type: none"> ● # of trainings offered. ● # of educational awareness campaigns across service population. ■ # of partnerships/collaboration (MOU, MOA, etc). ■ # of providers supporting activities. ■ # of facilities providing MAT/MOUD. ■ # of referrals to treatment. ■ # of systems involved (social services, child advocacy, etc). ■ # of providers trained in MAT/MOUD. ■ # of Buprenorphine/Suboxone administered. ■ # of active MAT/MOUD prescribers. ■ Promote family engagement in treatment. ■ # of Naloxone provided. ■ # of Naloxone administered. ■ # Medication lock boxes. ■ # Syringe exchange. ■ # of FTS administered. | <ul style="list-style-type: none"> ● Increasing community awareness. ● Develop a response team. ● Increase access to treatment. ● Increase access to harm reduction services. |

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BILLING CODE 4166-14 -P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 material, 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: National Institute on Aging Initial Review Group Career Development for Established Investigators and Conference Grants Study Section

Date: February 8-9, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite: 2W200, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajasri Roy, Ph.D., M.P.H., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg. Suite 2W200, Bethesda, MD 20892, 301-496-6477, *rajasri.roy@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 8, 2023.

Miguelina Perez,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-27685 Filed 12-15-23; 8:45 am]
BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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