

spanning at least seven different countries, were associated with more than 300 fatalities—mostly in children under the age of 5.² At this time, FDA has no indication that any contaminated products connected to these recent international incidents have entered the U.S. drug supply chain.

This guidance is intended to replace the 2007 guidance and to alert the industry that in addition to glycerin, there are other components at a high risk of contamination with DEG and EG, including, but not limited to, propylene glycol, maltitol solution, hydrogenated starch hydrolysate, and sorbitol solution (hereinafter, “high-risk components”). This guidance provides recommendations, including analytical testing, to help pharmaceutical manufacturers, repackers, other suppliers of high-risk components, and compounders, prevent the use of glycerin and other high-risk components that are contaminated with DEG or EG.

The guidance represents the current thinking of FDA on “Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and Other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

action-to-protect-children-from-contaminated-medicines. The WHO has issued global medical alerts addressing these incidents in The Gambia (October 5, 2022), Indonesia (November 6, 2022), Uzbekistan (January 11, 2023), and the Marshall Islands and Micronesia (Apr 25, 2023). See *Medical Product Alert N°6/2022: Substandard (contaminated) paediatric medicines*, World Health Organization, October 5, 2022, available at [https://www.who.int/news/item/05-10-2022-medical-product-alert-n-6-2022-substandard-\(contaminated\)-paediatric-medicines](https://www.who.int/news/item/05-10-2022-medical-product-alert-n-6-2022-substandard-(contaminated)-paediatric-medicines); *Medical Product Alert N°7/2022: Substandard (contaminated) paediatric liquid dosage medicines*, World Health Organization, November 2, 2022, available at [https://www.who.int/news/item/02-11-2022-medical-product-alert-n-7-2022-substandard-\(contaminated\)-paediatric-liquid-dosage-medicines](https://www.who.int/news/item/02-11-2022-medical-product-alert-n-7-2022-substandard-(contaminated)-paediatric-liquid-dosage-medicines); *Medical Product Alert N°1/2023: Substandard (contaminated) liquid dosage medicines*, World Health Organization, January 11, 2023, available at [https://www.who.int/news/item/11-01-2023-medical-product-alert-n-1-2023-substandard-\(contaminated\)-liquid-dosage-medicines](https://www.who.int/news/item/11-01-2023-medical-product-alert-n-1-2023-substandard-(contaminated)-liquid-dosage-medicines); and *Medical Product Alert N°4/2023: Substandard (contaminated) syrup medicines*, World Health Organization, Apr 25, 2023, available at [https://www.who.int/news/item/25-04-2023-medical-product-alert-n-4-2023-substandard-\(contaminated\)-syrup-medicines](https://www.who.int/news/item/25-04-2023-medical-product-alert-n-4-2023-substandard-(contaminated)-syrup-medicines).

² See *WHO urges action to protect children from contaminated medicines*, World Health Organization, January 23, 2023, available at <https://www.who.int/news/item/23-01-2023-who-urges-action-to-protect-children-from-contaminated-medicines>.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collection of information is subject to review by OMB under the PRA. The collection of information for CGMP requirements has been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: May 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09973 Filed 5–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Delegation of Authority

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of the United States Department of Health and Human Services delegated his authorities to the Assistant Secretary for Mental Health and Substance Use within the Substance Abuse and Mental Health Services Administration (SAMHSA) on May 4, 2023. This action is necessary to complete rulemaking being undertaken in conjunction with the Drug Enforcement Administration.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Secretary of the United States Department of Health and Human Services (HHS) has delegated to the Assistant Secretary for Mental Health and Substance Use within the Substance Abuse and Mental Health Services Administration (SAMHSA) the authorities vested in the Secretary of HHS under Title 21, Chapter 13, Subchapter I, Part A, Section 802(54)(G) of the United States Code (21 U.S.C. 802(54)(G)) on May 4, 2023.

21 U.S.C. 802(54)(G) authorizes the Secretary of HHS and the Attorney

General to issue regulations (including in 42 CFR chapter I, if appropriate) that define the term “practice of telemedicine” for purposes of Title 21, Chapter 13, Subchapter I, as the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of title 42, which practice is being conducted under any circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

These authorities may not be redelegated and shall be exercised under the Department’s policy on regulations and the existing delegation of authority to approve and issue regulations. In addition, I hereby ratify and affirm any actions taken by the Assistant Secretary for Mental Health and Substance Use, or other SAMHSA officials, which involved the exercise of the authorities delegated prior to the effective date of the delegation on May 4, 2023.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023–10041 Filed 5–9–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

National Indian Health Outreach and Education

Announcement Type: New.
Funding Announcement Number: HHS–2023–IHS–NIHOE–0001.
Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.933.

Key Dates

Application Deadline Date: July 10, 2023.

Earliest Anticipated Start Date: July 24, 2023.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a cooperative agreement for the National Indian Health Outreach and Education (NIHOE) program. This program is authorized under the Snyder Act, 25

U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); the Indian Health Care Improvement Act at 25 U.S.C. 1621b; and Section 330C of the Public Health Service Act, 42 U.S.C. 254c-3. The Assistance Listings section of *SAM.gov* (<https://sam.gov/content/home>) describes this program under 93.933.

Background

The IHS is committed to providing quality health care, consistent with its statutory authorities and its government-to-government relationship with each Indian Tribe. The IHS mission is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. To further mission success, the IHS seeks support on a national scale. The IHS serves as the principal Federal health care provider and health advocate for approximately 2.6 million American Indians and Alaska Natives from 574 federally recognized Tribes in 37 states, through a network of over 605 hospitals, clinics and health stations on or near Indian reservations and predominantly in rural locations. Tribes administer over half of the annual IHS discretionary appropriation. The IHS also enters into agreements with 41 Urban Indian Organizations (UIOs). These 41 UIOs are 501(c)(3) nonprofit organizations that provide culturally appropriate and quality health care and referral services for Urban Indians in 22 states. The IHS seeks to collaborate with local communities, not-for-profit organizations, universities and schools, foundations, businesses, and Federal agencies. This effort will foster outreach and education addressing health policy and health program issues; broadcast educational information to all American Indian and Alaska Native (AI/AN) people; provide policy/legislative updates, advocacy, and technical assistance.

Purpose

The purpose of this IHS cooperative agreement is to further the IHS mission and goals related to providing quality health care to the AI/AN community through outreach and education efforts with a focus on improving Indian health care, promoting awareness, visibility, advocacy, training, technical assistance, and education efforts. This program includes the following nine components, as described in this announcement: “Line Item 128 Health Education and Outreach funds;” “Health Care Policy Analysis and Review;” “Substance Abuse and Suicide Prevention (SASP) program;” “Domestic Violence Prevention (DVP) program;”—

a national awareness, visibility, advocacy, outreach and education award; the “Special Diabetes Program for Indians” (SDPI); “Tribal Budget Formulation Activities;” the “Affordable Care Act (ACA);” and the “Indian Health Care Improvement Act (IHCA).”

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for fiscal year (FY) 2023 is approximately \$851,311. The award amount for the first budget year is anticipated to be between \$246,311 and \$851,311. The following estimates are anticipated: \$246,311 is estimated for Line Item 128 Health Education and Outreach (this amount could vary based on Tribal shares assumptions); \$125,000 for the Health Care Policy Analysis and Review; \$150,000 for activities related to the SASP program; \$50,000 for activities related to the DVP program; \$75,000 associated with providing legislative education, outreach, and communication on the SDPI; \$100,000 for Tribal Budget Formulation activities; and \$105,000 for outreach and education activities on the ACA and the IHCA. The funding available for competing and subsequent continuation awards 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.

Anticipated Number of Awards

The IHS anticipates issuing one award under this program announcement.

Period of Performance

The period of performance is for 3 years.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. However, the funding agency, IHS, is anticipated to have substantial programmatic involvement in the project during the entire period of performance. Below is a detailed description of the level of involvement required for the IHS.

Substantial Agency Involvement Description for Cooperative Agreement

A. The IHS assigned program official will work in partnership with the recipient in all decisions involving

strategy, hiring of personnel, deployment of resources, release of public information materials, quality assurance, coordination of activities, any training, reports, budget, and evaluation. Collaboration includes data analysis, interpretation of findings, and reporting.

B. The IHS assigned program official will monitor the overall progress of the recipient’s execution of the requirements of the award noted below, as well as their adherence to the terms and conditions of the cooperative agreement. This includes providing guidance for required reports, development of tools and other products, interpreting program findings, and assisting with evaluation and overcoming any slippages encountered.

C. The IHS assigned program official will also coordinate the following:

- Routinely scheduled conference calls.
- Appropriate dissemination of required reports to each participating IHS program.

D. The IHS will jointly, with the recipient, plan and set an agenda for events that:

- Shares the outcomes of the outreach and health education training provided.
- Fosters collaboration amongst the participating IHS program offices.
- Increases visibility for the partnership between the recipient and the IHS.

E. The IHS may provide guidance in preparing articles for publication and/or presentations of program successes, lessons learned and new findings.

F. Agency staff will review articles concerning HHS for accuracy and may, if requested by the recipient, provide relevant articles.

G. The IHS will communicate, via routine conference calls and meetings, individual or collective (all participating programs) site visits to the recipient.

H. The IHS will provide technical assistance to the recipient as requested.

I. Agency staff may, at the request of the recipient’s board, participate on study groups, attend board meetings, and recommend topics for analysis and discussion.

III. Eligibility Information

1. Eligibility

To be eligible for this funding opportunity, an applicant must be a 501(c)(3) organization that has demonstrated expertise as follows:

- Representing Tribal governments and providing a variety of services to Tribes, area health boards, Tribal organizations, and Federal agencies, and

playing a major role in focusing attention on Indian health care needs, resulting in improved health outcomes for Tribes.

- Promoting and supporting health education for AI/AN people and coordinating efforts to inform AI/AN leaders of Federal decisions that affect Tribal government interests including the improvement of Indian health care.
- Administering national health policy and health programs.
- Maintaining a national AI/AN constituency and clearly supporting critical services and activities within the IHS mission of improving the quality of health care for AI/AN people.
- Supporting improved health care in Indian Country.

The Division of Grants Management (DGM) will notify any applicants deemed ineligible.

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 NIHOE announcements from the same applicant will not be funded. Applications on behalf of individuals (including sole proprietorships) and foreign organizations are not eligible and 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

Proof of Nonprofit Status

Organizations claiming nonprofit 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 applicants include:

- 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 for each of the components listed in Section I Purpose). See Section IV.2.A Project Narrative for instructions.
 - Budget Narrative (not to exceed 5 pages). See Section IV.2.B Budget Narrative for instructions.
 - One-page Timeframe or Work Plan Chart.
 - Letters of Support from organization's Board of Directors.
 - 501(c)(3) Certificate.
 - Biographical sketches for all Key Personnel.
 - Contractor/Consultant resumes or qualifications and scope of work.
 - Disclosure of Lobbying Activities (SF-LLL), if applicant conducts reportable lobbying.
 - 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:

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: <https://harvester.census.gov/facdissem/Main.aspx>.

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 per component 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 this 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 three parts to the project narrative: Part 1—Program Information; Part 2—Program Planning and Evaluation; and Part 3—Program Report. See below for additional details about what must be included in the narrative. The page limits below are for each narrative and budget submitted.

Part 1: Program Information (Limit—Two Pages)

Section 1: Capabilities and Qualifications

Describe how the applicant has the expertise to provide outreach and education efforts on a continuing basis

regarding the pertinent changes and updates in health care for each of the nine components listed herein.

Part 2: Program Planning and Evaluation (Limit—Six Pages)

Section 1: Program Plans

Describe fully and clearly how the applicant plans to address the NIHOE requirements, including how the applicant plans to demonstrate improved health education and outreach services to all federally recognized Tribes for each of the components described herein. Include proposed timelines as appropriate and applicable.

Section 2: Program Evaluation

Describe fully and clearly how the outreach and education efforts will impact changes in knowledge and awareness in Tribal communities. Identify anticipated or expected benefits for the Tribal constituency.

Describe fully and clearly how each project objective will be evaluated, including a sample list of data variables to be collected (*i.e.*, health education and outreach services, response from community surveys, rating of program or project's ability to use technology, program or project's ability to cover costs of peripherals and software to manage grant). Identify anticipated or expected benefits for the Tribal community or target population.

Part 3: Program Report (Limit—Two Pages)

Section 1: Describe your organization's significant program activities and accomplishments over the past 5 years associated with the goals of this announcement.

Section 2: Describe major activities over the last 24 months.

Please identify and summarize recent major health related project activities of the work done regarding each of the four components during the project period.

B. Budget Narrative (Limit—Six 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 first year of the project. 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

- Pre-award costs are allowable up to 90 days before the start date of the award provided the costs are otherwise allowable if awarded. Pre-award costs are incurred at the risk of the applicant.

- The available funds are inclusive of direct and indirect costs.
- Only one cooperative agreement may be awarded per applicant.
- The purchase of food (*i.e.*, as supplies, for meetings or events, etc.) is not an allowable cost with this award funding and should not be included in the budget.

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, the applicant 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 only the first year of activities. 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

A. Introduction and Need for Assistance (15 Points)

(1) Describe the organization's current health, education, and technical assistance operations as related to the broad spectrum of health needs of the AI/AN community. Include what programs and services are currently provided (*i.e.*, federally-funded, state-funded, etc.), any memorandums of agreement with other national, area, or local Indian health board organizations. This could also include HHS agencies that rely on the applicant as the primary gateway organization to AI/AN communities that are capable of providing the dissemination of health information. Include information regarding technologies currently used (*i.e.*, hardware, software, services, websites, etc.), and identify the source(s) of technical support for those technologies (*i.e.*, in-house staff, contractors, vendors, etc.). Include information regarding how long the applicant has been operating and its length of association/partnerships with area health boards, etc. (historical collaboration).

(2) Describe the organization's current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, memorandums of agreement with other national Indian organizations that deem the applicant as the primary source of health policy information for AI/AN communities, and memorandums of agreement with other area Indian health boards, etc.

(3) Describe the population to be served by the proposed projects.

(4) Identify all previous IHS cooperative agreement awards received, dates of funding and summaries of the projects' accomplishments. State how previous cooperative agreement funds facilitated education, training, and technical assistance nationwide for AI/AN people and relate the progression of health care information delivery and development relative to the current proposed projects. (Copies of reports will not be accepted.)

(5) Describe collaborative and supportive efforts with national, area, and local Indian health boards.

(6) Explain the need/reason for your proposed projects by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed projects. Explain how these gaps/weaknesses have been assessed.

(7) If the proposed projects include information technology (*i.e.*, hardware, software, etc.), provide further information regarding measures taken or to be taken that ensure the proposed projects will not create other gaps in services or infrastructure (*i.e.*, negatively or adversely affect IHS interface capability, Government Performance Results Act reporting requirements, contract reporting requirements, information technology compatibility, etc.), if applicable.

(8) Describe the effect of the proposed projects on current programs (*i.e.*, federally-funded, state-funded, etc.) and, if applicable, on current equipment (*i.e.*, hardware, software, services, etc.). Include the effect of the proposed projects on planned/anticipated programs and/or equipment.

(9) Describe how the projects relate to the purpose of the cooperative agreement by addressing the following: Identify how the proposed projects will address outreach and education regarding each of the components listed.

B. Project Objective(s), Work Plan and Approach (40 Points)

(1) Identify the proposed objective(s) for each of the nine components, as applicable. Objectives should be:

- Measurable and (if applicable) quantifiable.
- Results oriented.
- Time-limited.

Example: Issue quarterly newsletters, provide alerts, and quantify number of contacts with Tribes.

Goals must be clear and concise. Objectives must be measurable, feasible, and attainable for each of the selected projects.

(2) Address how the proposed projects will result in change or improvement in program operations or processes for each proposed project objective for all of the projects. Also address what tangible products, if any, are expected from the projects, (*i.e.*, policy analysis, outreach events, summits, etc.).

(3) Address the extent to which the proposed projects will provide, improve, or expand services that address the need(s) of the target population. Include a current strategic plan and business plan that includes the

expanded services. Include the plan(s) with the application submission.

(4) Submit a work plan that includes the following information.

- Provide the action steps on a timeline for accomplishing each of the projects' proposed objective(s).
- Identify who will perform the action steps.
- Identify who will supervise the action steps.
- Identify what tangible products will be produced during and at the end of the proposed projects' objective(s).
- Identify who will accept and/or approve work products during the duration of the proposed projects and at the end of the proposed projects.
- Include any training that will take place during the proposed projects and who will be attending the training.
- Include evaluation activities planned in the work plans.

(5) If consultants or contractors will be used during the proposed project, please include the following information in their scope of work (or note if consultants/contractors will not be used).

- Educational requirements.
- Desired qualifications and work experience.
- Expected work products to be delivered on a timeline.

If a potential consultant/contractor has already been identified, please include a resume.

(6) Describe what updates will be required for the continued success of the proposed projects. Include when these updates are anticipated and where funds will come from to conduct the update and/or maintenance.

C. Program Evaluation (20 Points)

Each proposed objective requires an evaluation component to assess its progression and ensure its completion. Include the evaluation activities in the work plan.

Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work plan and activities of the project.

(1) For outcome evaluation, describe:

- What will the criteria be for determining success of each objective?
- What data will be collected to determine whether the objective was met?
- At what intervals will data be collected?
- Who will collect the data, and what are their qualifications?
- How will the data be analyzed?
- How will the results be used?

(2) For process evaluation, describe:

• How will each project be monitored and assessed for potential problems and needed quality improvements?

• Who will be responsible for monitoring and managing each project's improvements based on results of ongoing process improvements, and what are their qualifications?

• How will ongoing monitoring be used to improve the projects?

• Describe any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.

• How will the organization document what is learned throughout each of the projects' periods?

(3) Describe any evaluation efforts planned after the period of performance has ended.

(4) Describe the ultimate benefit to the AI/AN population that the applicant organization serves that will be derived from these projects.

D. Organizational Capabilities, Key Personnel and Qualifications (15 Points)

This section outlines the broader capacity of the organization to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for successful completion of the projects outlined in the work plan.

(1) Describe the organizational structure of the organization beyond health care activities, if applicable.

(2) Describe the ability of the organization to manage the proposed projects. Include information regarding similarly sized projects in scope and financial assistance, as well as other cooperative agreements/grants and projects successfully completed.

(3) Describe what equipment (*i.e.*, fax machine, phone, computer, etc.) and facility space (*i.e.*, office space) will be available for use during the proposed projects. Include information about any equipment not currently available that will be purchased through the cooperative agreement/grant.

(4) List key personnel who will work on the projects. Include title used in the work plans. Include position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience requirements related to the proposed projects. Resumes must indicate that the proposed staff member is qualified to carry out the proposed projects' activities. If a position is to be filled, indicate that information on the proposed position description.

(5) If personnel are to be only partially funded by this cooperative agreement,

indicate the percentage of time to be allocated to the projects and identify the resources used to fund the remainder of the individual's salary.

E. Categorical Budget and Budget Justification (10 Points)

This section should provide a clear estimate of the projects' program costs and justification for expenses for the entire period of performance. The budgets and budget narratives should be consistent with the tasks identified in the work plans.

(1) Provide a categorical budget for each of the 12-month budget periods requested for each of the nine components.

(2) If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement.

(3) Explain in the budget narrative why each line item is necessary/relevant to the proposed project. Include sufficient cost and other details to facilitate the determination of cost allowability (*i.e.*, equipment specifications, etc.).

Additional documents can be uploaded as Other Attachments in *Grants.gov*.

These include:

- 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 Rate 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 for eligibility and completeness as outlined in this funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Review Committee (RC) based on 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 Office of Direct Service and Contracting Tribes within 30 days of the conclusion of the RC 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 Notice of Award (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, and 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 Grants:

- 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-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75.pdf>.

- Please review all HHS regulatory provisions for Termination at 45 CFR

75.372, at the time of this publication located at <https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-sec75-372.pdf>.

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgrps107.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-2021-title45-vol1/pdf/CFR-2021-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-2021-title45-vol1/pdf/CFR-2021-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 part 200.216. 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.

Per 2 CFR 200.414(f) Indirect (F&A) costs,

any non-Federal entity (NFE) [i.e., applicant] that does not have a current negotiated rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 200.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged

or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.

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. A final report must be submitted within 120 days of expiration of the period of performance.

B. Financial Reports

Federal Financial Reports are due 90 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. 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/>.

D. Non-Discrimination Legal Requirements for Awardees of Federal Financial Assistance (FFA)

The recipient must administer the project in compliance with Federal civil rights laws, where applicable, that

prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient must comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.

- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html>.

- HHS funded health and education programs must be administered in an environment free of sexual harassment. See <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/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.

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 FAPIIS at <https://www.fapiis.gov/fapiis/#/home> 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 the 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 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 programmatic issues may be directed to: Mr. Kenneth Coriz, Policy Analyst, ODSCT, Mail Stop, 8E17, 5600 Fishers Lane, Rockville, Maryland 20857, Phone: (301) 443-1104, Email: Kenneth.Coriz@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](https://www.grants.gov), please contact the [Grants.gov](https://www.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.

P. Benjamin Smith,

Deputy Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Information Collection: Indian Self-Determination and Education Assistance Act Contracts

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to comment on the information collection titled, “Indian Self-Determination and Education Assistance Act Contracts,” Office of Management and Budget (OMB) Control Number 0917-0037. The IHS is requesting OMB to approve an extension for this collection, which expires on August 31, 2023.

DATES: *Comment Due Date:* July 10, 2023. Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

ADDRESSES: Send your written comments or requests to obtain more information to Ms. Terri Schmidt, Director, IHS Office of Direct Services and Contracting Tribes, by email to Terri.Schmidt@ihs.gov.

SUPPLEMENTARY INFORMATION: This notice announces our intent to seek an extension of the collection already approved by OMB, and to solicit comments on specific aspects of the information collection. The purpose of this notice is to allow 60 days for public comment to be submitted to the IHS. A copy of the supporting statement is available at www.regulations.gov (see Docket ID IHS-2023-0001).

Information Collection Title: Indian Self-Determination and Education Assistance Act Contracts, 25 CFR part 900, 0917-0037.

Type of Information Collection Request: Extension of currently approved collection. *Form Numbers:* 0917-0037.

Need and Use of Information Collection: In 1975, Congress enacted the Indian Self-Determination and Education Assistance Act (ISDEAA) to authorize Tribes and Tribal organizations (T/TO) to assume control of certain Federal programs, e.g., health care programs that certain Federal agencies would otherwise provide to American Indians and Alaska Natives.

The T/TO that intend to establish a new or expanded Title I self-

determination contract with the IHS are required to provide proposal information identified at 25 CFR 900.8, which describes what a contract proposal must contain. This information is used by the IHS to determine applicant eligibility, evaluate applicant capabilities, protect the service population, and safeguard Federal funds and resources.

Subpart C contains provisions relating to the initial contract proposal contents (i.e., 25 CFR 900.8). The proposal contents consist of required items that must be included in a proposal for a new or expanded program. These items include basic information about the T/TO and program to be contracted, such as: name and address; authorizing resolution; date of submission of proposal; description of geographical service area; estimated number of people to be served; brief statement of program functions, services or activities to be performed; description of the proposed program; financial, procurement, and property management standards; description of reports to be provided; staff qualifications, if any; budget information; and waiver information; as requested. The information is collected at the time the T/TO makes an initial application to contract a program.

Subpart F contains the minimum standards for the management systems used by the T/TO when carrying out a self-determination contract. Sections 900.40-44, 48-49, 53, 55, and 60 discuss the information and record keeping requirements of the T/TO regarding the financial, procurement, and property management standards.

Subpart G provides for the negotiation of all reporting and data requirements between the T/TO and the Secretary (e.g., 25 CFR 900.65). The information collected is directly related to the operation of the program and is negotiated on a contract by contract basis. The IHS uses the information to monitor contract operations and determine if satisfactory services are being provided. The information is collected and reported during the operation of the contract based on the terms negotiated in each contract.

Subpart I establishes procedures regarding the donation of excess and surplus Federal property to T/TO, and the acquisition of property with funds provided under a self-determination contract. This subpart addresses the procedures to be followed when the T/TO wish to acquire excess IHS property, and excess or surplus government property from other agencies (e.g., 25 CFR 900.97). This subpart also addresses the process for T/TO to