

which helps ensure that suppliers produce food that meets U.S. safety standards.

Occasionally, FDA will need to communicate with consumers and other stakeholders about immediate health issues which could affect public health and safety. This collection of information allows the use of fast-track methods of communication such as quick turnaround surveys, focus groups, and in-depth interviews collected from consumers and other stakeholders to communicate FDA issues of immediate and important public health

significance. We plan on using these methods of communication to collect vital public health and safety information.

For example, these methods of communication might be used when there is a foodborne illness outbreak, food recall, or other situation requiring expedited FDA food, dietary supplement, cosmetics, or animal food or feed communications. So that FDA may better protect the public health, the Agency needs quick turnaround information provided by this collection of information to help ensure its

messaging has reached the target audience, has been effective, and, if needed, to update its communications during these events.

Respondents to this collection of information include a wide range of consumers and other FDA stakeholders such as producers and manufacturers of FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Participation will be voluntary.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-depth Interviews, Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
In-depth Interviews, Cognitive Interviews	9	1	9	1	9
In-depth Interviews Screener	900	1	900	0.083 (5 minutes)	75
In-depth Interviews	180	1	180	1	180
Survey Cognitive Interviews Screener	45	1	45	0.083 (5 minutes)	4
Survey Cognitive Interviews	9	1	9	1	9
Pretest survey screener	750	1	750	0.083 (5 minutes)	62
Pretest survey	150	1	150	0.25 (15 minutes)	38
Self-Administered Surveys—Study Screener	75,000	1	75,000	0.083 (5 minutes)	6,225
Self-Administered Surveys	15,000	1	15,000	0.25 (15 minutes)	3,750
Focus Group/Small Group, Cognitive Groups Screener.	180	1	180	0.083 (5 minutes)	15
Focus Group/Small Group, Cognitive Groups	60	1	60	1.5 (90 minutes)	90
Focus Group/Small Group Participant Screening	720	1	720	0.083 (5 minutes)	60
Focus Group/Small Group Discussion	240	1	240	1.5 (90 minutes)	360
Total					10,881

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-08189 Filed 4-15-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Ending the HIV/HCV Epidemics in Indian Country: A Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Announcement Type: New.

Funding Announcement Number: HHS-2022-IHS-ETHIC-0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.933.

Key Dates

Application Deadline Date: June 17, 2022.

Earliest Anticipated Start Date: August 1, 2022.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for a cooperative agreement for the Ending the Human Immunodeficiency Virus (HIV) and Hepatitis C Virus (HCV) Epidemics in Indian Country (ETHIC) program. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1621q, 1660e. This program is described in the Assistance Listings located at <https://sam.gov/content/home> (formerly known as the CFDA) under 93.933.

Background

In February 2019, the White House announced a new initiative, Ending the HIV Epidemic in the U.S. (EHE). This 10-year initiative beginning with fiscal

year (FY) 2020, seeks to achieve the critical goal of reducing new HIV infections in the United States (U.S.) to less than 3,000 per year by 2030. The first phase of the initiative focuses on 48 counties, Washington, DC, San Juan, Puerto Rico, and seven states with a substantial rural HIV burden. By focusing on these geographic focus areas (see <https://files.hiv.gov/s3fs-public/Ending-the-HIV-Epidemic-Counties-and-Territories.pdf>) in the first phase of the initiative, the U.S. Department of Health and Human Services (HHS) plans to reduce new HIV infections by 75 percent within five years. To reduce new HIV infections in the U.S. by 75 percent by 2025 and 90 percent by 2030, EHE focuses on four key strategies that together can end the HIV epidemic in the U.S.: Diagnose, Treat, Prevent, and Respond. In this cooperative agreement, the IHS directs applicants to implement activities specific to strategies one, two, and three: Diagnose, Treat, and Prevent.

EHE is a collaboration of HHS agencies, primarily the Health Resources and Services Administration, the Centers for Disease Control and

Prevention (CDC), the National Institutes of Health, the IHS, and the Substance Abuse and Mental Health Services Administration. HHS recently released two national strategic plans, and the IHS expects applicants to adopt these plans as they design and carry out activities toward HIV and HCV elimination: (1) The HIV National Strategic Plan: A Roadmap to End the Epidemic in the United States (2022–2025);¹ and (2) The Viral Hepatitis National Strategic Plan for the U.S.: A Roadmap to Elimination 2021–2025.²

The HIV National Strategic Plan (2021–2025) is a 5-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic. The IHS promotes robust advances and innovations in HIV health care using the HIV National Strategic Plan to end the epidemic as its framework. Therefore, to the extent possible, activities funded by the IHS focus on addressing these four goals:

- (1) Reduce new HIV infections;
- (2) Increase access to care and improve health outcomes for people with HIV;
- (3) Reduce HIV-related health disparities and health inequities;
- (4) Achieve a more coordinated national response.

To achieve these shared goals, recipients should align their organization's efforts to ensure that people with HIV are linked to and retained in high-quality HIV care and have timely access to HIV treatment and the supports needed (e.g., mental health and substance use disorders services) to achieve HIV viral suppression.

The Viral Hepatitis National Strategic Plan for the U.S.: A Roadmap to Elimination 2021–2025, released on January 7, 2021, is a new phase in the fight against viral hepatitis in the U.S. Building on three prior National Viral Hepatitis Action Plans over the last 10 years, the Viral Hepatitis National Strategic Plan is the first to aim to eliminate viral hepatitis as a public health threat in the U.S.

The Viral Hepatitis Plan sets forth a clear vision for how the U.S. will be a place where new viral hepatitis

infections are prevented, every person knows their status, and every person with viral hepatitis has high-quality health care and treatment and lives free from stigma and discrimination. Both the HIV and viral hepatitis national strategic plans include AI/AN people in their priority populations.

In addition, for resources specific to AI/AN communities, the Northwest Portland Area Indian Health Board, with funding from the IHS and the Minority HIV/AIDS Fund, designed a document to help AI/AN health advocates, decision makers, and medical providers address the HCV epidemic in their communities through programmatic and policy changes. IHS encourages applicants to review the Hepatitis C Elimination Strategy for AI/AN Communities³ document's objectives which describes the rationale and program design, and provides a tool kit for implementing an HCV micro-elimination program in an AI/AN community—Tribal or IHS clinic, hospital, or health system.

A 2019 CDC analysis⁴ shows that the vast majority (about 80 percent) of new HIV infections in the U.S. in 2016 came from the nearly 40 percent of people who either did not know they had HIV or who received a diagnosis but were not receiving HIV care and treatment. This highlights the need to increase the proportion of people with HIV or HCV who are aware of their status and help them get into care and treatment.

Diagnosing AI/AN people with HIV or HCV, linking those with HIV or HCV to primary care, and achieving viral suppression are necessary public health steps toward ending the HIV and HCV epidemics in Indian Country. The HIV/HCV care continuum has five main “steps” or stages that include (1) diagnosis, (2) linkage to care, (3) retention in care, (4) adherence to therapy (ART), and (5) viral suppression (HIV)/viral clearance (HCV). The care continuum depicts a series of stages in which people with HIV or HCV engage in care from initial diagnosis through their successful treatment with medication. It also demonstrates the proportion of individuals living with HIV or HCV who are engaged at each

stage. The care continuum allows recipients and planning groups to measure progress and direct resources most effectively. For this funding opportunity, the IHS requires applicants to address, implement, and measure the HIV and HCV continuum of care. For example, applicants should be prepared to collect data on the number of new diagnosis of HIV, numbers of positive cases linked to care, how many of those linked to care are retained in care and adhering to therapy, and the number of those achieving an undetectable viral load.

Federal health care facilities in an administrative area of the IHS conducted a review to identify and address gaps in HCV treatment. Facilities generally treated HCV with a strong pharmacy component using a collaborative practice agreement and HCV telehealth services to external specialists. These data indicate that: (1) Rural clinics can be successful providing HCV diagnosis and treatment; (2) pharmacists can play a key role in HCV clinical services; (3) the outcomes of each step in the treatment process at the facility level can vary widely due to local factors; and (4) the barriers to HCV care that persist are nonclinical.⁵ In a study published in *The Journal of the American Medical Association*,⁶ the Cherokee Nation Health Services HCV elimination program demonstrated that implementation of a community-based HCV elimination program was associated with an improved cascade of care. In this cohort study, first-time HCV screening coverage increased from 20.9 percent to 38.2 percent from 3 years before to 22 months into implementation.⁷ This information may serve other organizations planning to implement similar programs in large rural areas.

⁵ A Regional Analysis of Hepatitis C Virus Collaborative Care With Pharmacists in Indian Health Service Facilities <https://journals.sagepub.com/doi/full/10.1177/2150132718807520>.

⁶ Evaluation of the Cherokee Nation Hepatitis C Virus Elimination Program in the First 22 Months of Implementation, Mera, Williams, Essex; et al <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2774323>.

⁷ Evaluation of the Cherokee Nation Hepatitis C Virus Elimination Program in the First 22 Months of Implementation, Mera, Williams, Essex; et al <https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2774323>.

¹ <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf> Accessed 3/11/2022

² <https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf> Accessed 3/11/2022.

³ <https://www.npaihb.org/wp-content/uploads/2020/08/HCV-Elimination-Strategy-for-AIAN-Communities.pdf> Accessed 3/11/2022.

⁴ <http://www.cdc.gov/nchhstp/newsroom/2019/hiv-vital-signs.html>.

For nearly four decades, the national investments in HIV have shown remarkable results in preventing new infections, improving health outcomes, and reducing deaths in hundreds of thousands of Americans. Despite this, progress has plateaued, and additional effort is needed to ensure that all affected groups benefit equally. Some groups, like AI/AN people, African American and Latino gay and bisexual men, transgender individuals, or people living in the South, have a higher burden of HIV and experience health disparities at each stage of the HIV care continuum. Southern states today account for an estimated 44 percent of all people living with an HIV diagnosis in the U.S.,⁸ despite having only about one-third (37 percent) of the overall U.S. population.⁹ Diagnosis rates for people in the South are higher than for Americans overall. Eight of the ten states and all ten metropolitan statistical areas with the highest rates of new HIV diagnoses are in the South. In addition to the severe burden in the South, nationally there is a high incidence of HIV among transgender individuals, high-risk heterosexuals, and persons who inject drugs.¹⁰

The U.S. has an unprecedented opportunity to end the HIV and HCV epidemics in America. We have access to the most powerful HIV and HCV prevention and treatment tools in history and new technology that allows us to pinpoint where infections are spreading most rapidly. By effectively equipping all vulnerable AI/AN communities with these tools, we can end the HIV and HCV epidemics in Indian Country. This ETHIC funding opportunity acts boldly on this unprecedented opportunity by providing the hardest-hit AI/AN communities with resources to implement the additional expertise, technology, and resources required to address the HIV and HCV epidemics in their communities.

HHS recently developed a set of critical health priorities for the nation known as “Leading Health

Indicators”¹¹ (or LHIs) that are a call to action in critical public health areas. The IHS will use the LHIs to assess the health of the AI/AN population over the next decade, to facilitate collaboration among diverse groups, and to motivate individuals and communities to take action to improve their health. The following LHIs also will be used by the IHS and public health professionals to track progress in local AI/AN communities as they work toward meeting these key national health goals:

- (1) Diagnose 95 percent of persons living with HIV or HCV who are aware of their status by 2025, working from a baseline of 85.8 percent in 2016.
- (2) Treat 95 percent of persons via linkage to appropriate care within one month of diagnosis by 2025, working from a baseline of 78.3 percent in 2017.
- (3) Treat 95 percent of persons diagnosed with HIV or HCV via sufficient viral suppression/viral clearance by 2025, working from a baseline of 61.5 percent in 2016.
- (4) Prevent new HIV infections by achieving 25 percent pre-exposure prophylaxis (PrEP) coverage among those for whom PrEP was indicated by 2025.

There are notable concerns in new HIV diagnoses in AI/AN populations: (1) New HIV diagnoses among AI/AN populations increased by 18 percent from 2015 to 2019; (2) rates of new HIV diagnoses among AI/AN adolescents increased by 53 percent; and (3) both male and female AI/AN individuals had the highest percent of estimated diagnoses of HIV infection attributed to injection drug use.¹² Mortality data also found that AI/AN individuals have significantly higher death rates from HIV/AIDS than whites, which could be attributable to later diagnosis, lack of linkage to care, difficulty accessing care, challenges to treatment adherence, or other factors or combination of factors.

HCV is a common co-morbidity for bloodborne HIV infections. In 2009, approximately 21 percent of HIV-infected adults who were tested for past or present HCV infection tested positive, although co-infection prevalence varies substantially according to HIV-infected risk group (e.g., men who have sex with men (MSM), high-risk heterosexuals, and persons who inject drugs).^{13 14 15} As

HCV is a bloodborne virus, primarily transmitted through direct contact with the blood of an infected person, coinfection with HIV and HCV is common among HIV-infected injection-drug users.^{16 17 18} Although transmission via injection drug use remains the most common mode of HCV acquisition in the U.S., sexual transmission is an important mode of acquisition among certain groups, including HIV-infected MSM with certain risk factors.¹⁹ Data have shown that HCV disproportionately affects AI/AN people, with HCV-related mortality more than double the national rate.²⁰ In a recent IHS survey, almost 50 percent of the AI/AN individuals diagnosed with HCV were born after 1965 and were younger than the targeted birth cohort for HCV screening campaigns (1945–1965, ‘Baby Boomers’). Untreated HCV can lead to a myriad of extrahepatic manifestations and cirrhosis with complications such as portal hypertension, end stage liver disease, and hepatocellular carcinoma (HCC). Early diagnosis and treatment of HCV infection prevents the development of extrahepatic manifestations and progressive liver disease including cirrhosis. Recently developed treatments for HCV are more accessible and highly effective at greatly reducing HCV- and HCC-related

infected Adults Receiving Medical Care in the U.S. Infectious Disease Society of America (IDSA). Philadelphia, PA, 2014.

¹⁴ Yehia BR, Herati RS, Fleishman JA, Gallant JE, Agwu AL, Berry SA, et al. Hepatitis C virus testing in adults living with HIV: A need for improved screening efforts. *PLoS ONE* 2014;9(7):e102766. <https://pubmed.ncbi.nlm.nih.gov/25032989/>.

¹⁵ Spradling PR, Richardson JT, Buchacz K. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996–2007. *J Acquir Immune Defic Syndr* 2010;53:388–396.

¹⁶ Yehia BR, Herati RS, Fleishman JA, Gallant JE, Agwu AL, Berry SA, et al. Hepatitis C virus testing in adults living with HIV: A need for improved screening efforts. *PLoS ONE* 2014;9(7):e102766. <https://pubmed.ncbi.nlm.nih.gov/25032989/>.

¹⁷ Spradling PR, Richardson JT, Buchacz K. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996–2007. *J Acquir Immune Defic Syndr* 2010;53:388–396.

¹⁸ Centers for Disease Control and Prevention. Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2019; vol.32. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2021. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2017.

¹⁹ Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: Recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at <https://www.ncbi.nlm.nih.gov/pubmed/19357635>. July 6, 2018.

²⁰ <https://aspe.hhs.gov/system/files/pdf/260026/HepC.pdf>.

⁸ Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2019; vol.32. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2021.

⁹ U.S. Census Bureau. Annual Estimates of the Resident Population: 2010–2020. Available at <https://www.census.gov/programs-surveys/popest/technical-documentation/research/evaluation-estimates/2020-evaluation-estimates/2010s-totals-national.html>.

¹⁰ Department of Health and Human Services, Centers for Disease Control and Prevention. HIV in the U.S. and dependent areas <https://www.cdc.gov/hiv/statistics/overview/ataglance.html>. Updated January 29, 2019. Accessed February 5, 2019.

¹¹ <https://health.gov/healthypeople/objectives-and-data/leading-health-indicators> Accessed 3/11/2020.

¹² Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2019; vol.32. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2021.

¹³ Garg S, Brooks J, Luo Q, Skarbinski J. Prevalence of and Factors Associated with Hepatitis C Virus (HCV) Testing and Infection Among HIV-

mortality. Treatment for HCV can be highly successful at the primary care level with appropriate planning and support.

Data also show that sexually transmitted infection (STI) rates remain elevated in Indian Country. Recurrent STIs can increase the likelihood of HIV transmission. Gonorrhea and syphilis often present as co-morbid conditions with HIV diagnosis, particularly among MSM. The latest Indian Health Surveillance Report: Sexually Transmitted Diseases 2015²¹ showed that AI/AN people have 3.8 times the incidence rate of whites for chlamydia and 4.4 times the rate of whites for gonorrhea. AI/AN people have the second highest rates for both chlamydia and gonorrhea compared to other races/ethnicities. Gonorrhea rates have continued to increase drastically since 2011. Regional differences in STI incidence in Indian Country are also observed. AI/AN youth and AI/AN women, particularly women of reproductive age, have a disparate and increased STI burden. In addition, recent outbreaks of syphilis have been observed among AI/AN communities. Some of these outbreaks are connected to the use of injection drugs and methamphetamines, all known risk factors for HIV transmission.

Finally, treatment for substance use disorders can be difficult to access in IHS catchment areas, as the appropriated budget includes fewer dollars per patient compared to other Federal direct-care networks. Untreated substance use disorders can exacerbate risk-taking behavior and reduce adherence to treatment. IHS recommends collaboration whenever possible between behavioral health services and HIV/HCV/STI prevention and care.

Confronting these intersecting epidemics requires collaboration across sectors and disciplines and the use of existing public health and clinical infrastructures. Lasting changes to these trends for HIV and related co-morbidities among AI/AN communities will also require innovative new approaches, incorporating existing and new data sources, all driven by community input. IHS recommends applicants research evidence-based approaches or identify culturally appropriate interventions as best-practices for collaborative efforts.

²¹ 2015 Indian Health Surveillance Report Sexually Transmitted Infections https://www.cdc.gov/std/stats/ihs/18IHS-DEDP102-REPORT_STD_M_508.pdf.

Purpose

The purpose of this program is to support communities in reducing new human HIV infections and relevant co-morbidities, specifically STI and HCV infections, improve HIV-, STI-, and HCV-related health outcomes, and reduce HIV-, STI-, and HCV-related health disparities among AI/AN people. In two separate but related parts, this initiative aims to implement effective and innovative strategies, interventions, approaches, and services to reduce new HIV and HCV infections among AI/AN communities in the U.S. This initiative's overarching goals are to: (1) Reduce new HIV infections in the U.S. to less than 3,000 per year by 2030; and (2) achieve a 90 percent reduction in new HCV infections and a 65 percent reduction in mortality, compared to a 2015 baseline.²²

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for FY 2022 is approximately \$2,480,000. Individual award amounts are anticipated to be between \$160,000 and \$200,000. The funding available for competing and subsequent 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 that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 14 awards will be issued under this program announcement.

Period of Performance

The period of performance is for 3 years.

Cooperative Agreement

Cooperative agreements awarded by the HHS are administered under the same policies as grants. 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 of the IHS.

²² <https://www.hhs.gov/hepatitis/viral-hepatitis-national-strategic-plan/national-viral-hepatitis-action-plan-overview/index.html>.

Substantial Agency Involvement Description for Cooperative Agreement

A. The IHS Office of Clinical and Preventive Services (OCPS), Division of Clinical and Community Services (DCCS) will provide ongoing consultation and technical assistance to plan, implement, and evaluate each component as described under Recipient Activities (see Section V.1.B, Application Review Information, Evaluation Criteria, Project Objective(s), Work Plan, and Approach).

B. The IHS will conduct site visits to recipient sites and/or coordinate recipient visits to IHS facilities to assess work plans and ensure data security, confirm compliance with applicable laws and regulations, assess program activities, and to resolve problems, as needed mutually.

C. DCCS will provide a forum for outreach and education to advance this program's goals through existing and new partnerships. The IHS will facilitate the formation of an IHS National HIV/HCV/STI Prevention workgroup, from clinical, public health, advocacy, and education sectors working in HIV/HCV/STI control. The purpose of the workgroup is to align IHS efforts with the HIV, Viral Hepatitis, and STI National Strategies.

D. DCCS will coordinate the various internal IHS and external HHS required reporting activities and provide recipients with program-related technical assistance as appropriate to provide leadership, advocacy, and support.

III. Eligibility Information

1. Eligibility

To be eligible for this funding opportunity, an applicant must be one of the following as defined under 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(1)): "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 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).

The program office will notify any applicants deemed ineligible.

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.

2. Cost Sharing or Matching

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

3. 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 Division of Grants Management (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 Tribal or Tribal organization applicant 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.

Tribes organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

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

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 Mr. Paul Gettys at (301) 443-2114 or (301) 443-5204.

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.
- Application forms:
 1. SF-424, Application for Federal Assistance.
 2. SF-424A, Budget Information—Non-Construction Programs.
 3. SF-424B, Assurances—Non-Construction Programs.
 - Project Narrative (not to exceed 10 pages). See Section IV.2.A, Project Narrative for instructions.
 1. Background information on the organization.
 2. Proposed scope of work, objectives, and activities that provide a description

of what the applicant plans to accomplish.

- Budget Justification and Narrative (not to exceed five pages). See Section IV.2.B, Budget Narrative for instructions.
- Tribal Resolution(s), if applicable.
- Letters of Support from organization's Board of Directors, if applicable.
- 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).
- Work plan with timeline for proposed activities.
- Logic model.
- Map of area identifying project location(s).
- Copy of current Negotiated Indirect Cost (IDC) rate agreement (required in order to receive IDC).
- Organizational Chart.
- 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/>.

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 (tables may be done in 10 point font); (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches). 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 page limit, the application will be considered not responsive and will not be reviewed. The 10-page limit for the narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget justifications, narratives, and/or other items.

There are three parts to the narrative: Part 1—Program Information; Part 2—Program Planning and Evaluation; and Part 3—Previous HIV/HCV Prevention, Care, or Treatment Work. 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—3 Pages)

Section 1: Community Infrastructure

Describe the applicant's current health program activities, how long it has been operating, and what programs or services the organization is currently providing. Describe how the applicant has determined it has the administrative infrastructure to support the activities proposed.

Part 2: Program Planning and Evaluation (Limit—3 Pages)

Section 1: Program Plans

Describe fully and clearly the applicant's plans to conduct activities that lead to increased HIV and Hepatitis C diagnoses, enhanced prevention, and to recruit and retain people in HIV and Hepatitis C treatment.

Section 2: Program Evaluation

Describe fully and clearly the improvements that will be made by the applicant to meet the public health needs of the community in the context of the funding requirements.

Part 3: Previous HIV/HCV Prevention, Care, or Treatment Work (Limit—4 Pages)

Section 1

Describe your organization's significant program activities and accomplishments over the past five years associated with HIV/HCV prevention, care, and/or treatment to enhance quality health care services.

B. Budget Narrative (Limit—5 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). The budget narrative can include a more detailed spreadsheet than is provided by the SF-

424A. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the "Other" category is justified. For subsequent budget years (see Multi-Year Project Requirements in Section V.1, Application Review Information, Evaluation Criteria), the narrative should highlight the changes from the first year or clearly indicate that there are no substantive budget changes during the period of performance. 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 (Paul.Gettys@ihs.gov), Deputy Director, DGM, by telephone at (301) 443-2114 or (301) 443-5204. 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.

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 the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Paul Gettys, Deputy Director, DGM. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Paul.Gettys@ihs.gov. The waiver request must: (1) Be documented in writing (emails are acceptable) before submitting an application by some other method; and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to the DGM. Applications that are submitted without a copy of the signed waiver from the Deputy Director of 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 (CFDA) number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, 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 the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) Applicants and recipient organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B that uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

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 DUNS 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.

System for Award Management (SAM)

Organizations that are not registered with SAM must have a DUNS number first, then access the SAM online registration through the SAM home page at <https://sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). 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>.

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

V. Application Review Information

Possible points assigned to each section are noted in parentheses. 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 (10 Points)

Must include the applicant’s background information, a description of HIV and/or HCV service, capacity, and history of support for such activities. Applicants need to include current public health activities, what program services are currently being provided, and interactions with other public health authorities in the region (state, local, or Tribal).

Please describe how the applicant will make improvements in capacity to address the IHS, Tribal, and urban (I/T/U), local-level, and/or Area-level HIV/HCV/STI burden. In order to significantly reduce transmission of HIV/HCV/STI, I/T/U need baseline and annual measurements of HIV/HCV/STI diagnoses, linkage to care, and viral load measurements, as applicable. Applicants will also help evaluate geographies with higher burden of HIV/HCV/STI and assist communities in targeting interventions.

B. Project Objective(s), Work Plan, and Approach (25 Points)

a. Clearly identify the operational strategies to be addressed by the applicant. Include objectives that are Specific, Measurable, Attainable, Relevant, and Time-bound (also known as SMART). In addition, the IHS encourages applicants to assume relevant objectives from (1) The National Strategic Plan: A Roadmap to End the Epidemic for the United States | 2021–2025;²³ and (2) The Viral Hepatitis National Strategic Plan for the U.S.: A Roadmap to Elimination 2021–2025.²⁴

b. Activities in at least two of three ETHIC’s key operational strategies (Diagnose, Treat, Prevent) must be planned for completion within the

²³ <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>.

²⁴ <https://www.hhs.gov/hepatitis/viral-hepatitis-national-strategic-plan/national-viral-hepatitis-action-plan-overview/index.html>.

program period (indicate these two activities in bold).

c. Applicants will outline their approach for addressing the operational strategies in the work plan or logic model. Outline overarching activities, short-term, and long-term outcomes. Make note of proposed timelines and partners who will be involved in each activity.

Recipient Activities

Proposals must include the following activities:

1. Coordination Operational Strategy

i. Recipients will send at least one representative to the annual IHS HIV meeting. The budget should include travel and associated costs for participation.

ii. Recipients will participate in the IHS National AI/AN STI Prevention workgroup.

iii. Recipients will provide technical assistance and/or support to AI/AN communities by developing or sharing analytical reports that examine the burden of HIV/HCV and other relevant co-morbidities such as STIs in Native communities.

2. Diagnosis Operational Strategy

The recipients will collaborate with communities to increase local capacity to expand the availability of HIV/HCV/STI testing in health centers, emergency departments, substance abuse prevention and treatment programs, mobile units, as well as community-based organizations and non-traditional settings such as bars, parks, and during community festivals to diagnose all people with HIV/HCV/STIs as early as possible.

3. Treatment Operational Strategy

The recipients will provide support to communities in the development of enhanced activities and expanded capacity to identify and better serve people who are not in HIV/HCV/STI care by working with health care providers, Ryan White clinics and I/T/U health centers, state and local health departments, and other partners to expand capacity, strengthen systems, establish new programs and services, and forge new partnerships to tailor and implement these approaches as appropriate in their communities.

4. Prevention Operational Strategy

The recipients will develop local plans with community member input to guide the scale-up of proven prevention interventions and strategies that increase the access to and availability of PrEP and safe syringe programs (SSPs)—

where permitted by local laws—in the communities where these services are needed most.

PrEP is a pill that reduces the risk of getting HIV when taken as prescribed. However, of the estimated 1 million Americans at substantial risk for HIV who could benefit from PrEP, fewer than 1 in 4 actually use it. HHS agencies will support states and local communities to implement strategies to increase access to and use of PrEP—especially among populations disproportionately affected by HIV.

C. Program Evaluation (30 Points)

a. Clearly identify plans for program evaluation to ensure that objectives of the program are met at the conclusion of the funding period.

b. Include evaluation criteria based on SMART objectives.

c. Evaluation should minimally include summaries of activities in each of the proposed key operational strategies.

D. Organizational Capabilities, Key Personnel, and Qualifications (30 Points)

a. Include an organizational capacity statement that demonstrates the ability to execute program strategies within the program period.

b. Provide a project management and staffing plan. Detail that the organization has the current staffing and expertise to address each of the program activities. If current capacity does not exist, please describe the actions that the applicant will take to fulfill this gap within a specified timeline.

c. Applicant must demonstrate a plan to work with Tribal Epidemiology Centers and local partners on the proposed efforts.

d. Demonstrate that the applicant has previous successful experience providing technical or programmatic support to Tribal communities.

E. Categorical Budget and Budget Justification (5 Points)

a. Provide a detailed budget and accompanying narrative to explain the activities being considered and how they are related to proposed program objectives.

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

- Work plan, logic model, and 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 (if applicable).
- 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 the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, project period limit) will not be referred to the ORC and will not be funded. The applicant will be notified 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 DCCS within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the 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, and the budget/project period. 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-2020-title45-vol1/pdf/CFR-2020-title45-vol1-part75.pdf>.

- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp&SID=2970eec67399fab1413ede53d7895d99&mc=true&n=pt45.1.75&r=PART&ty=HTML&se45.1.75_1372#se45.1.75_1372.

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.

E. Audit Requirements

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” at 45 CFR part 75 subpart F.

F. As of August 13, 2020, 2 CFR 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. 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 grant 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 45 CFR 75.414(f) Indirect (F&A) costs, "any non-Federal entity (NFE) [i.e., applicant] that has never received a negotiated indirect cost 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 75.403, 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 only applies to applicants that have never 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 grant.

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 call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443-5204.

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 grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of

payment. Continued failure to submit required reports may result in 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 awardee 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 see the Agency Contacts list in Section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required quarterly. 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 90 days of expiration of the period of performance.

B. Financial Reports

Federal Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services at <https://pms.psc.gov>. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Federal Financial Reports are due 30 days after the end of each budget period, and a final report is due 90 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, the Federal Cash Transaction Report, and the Federal Financial Report.

C. Data Collection and Reporting

The recipient must report their progress quarterly towards data points in their ETHIC objectives and activities via a standardized form co-developed with the IHS program officer.

The recipient and the IHS will jointly develop the report for the data and objectives proposed in the application. The recipient will then report on these data points annually. Due dates for these reports will be included in the Terms & Conditions in the NoA. The

recipient will participate in quarterly calls with the program office.

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 grants 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

Should you successfully compete for an award, recipients of Federal financial assistance (FFA) from HHS must administer their programs in compliance with Federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please 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>.

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://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 \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part

75, 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 of 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: Paul Gettys, Deputy 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: Paul.Gettys@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. Rick Haverkate, Public Health Advisor, Office of Clinical and Preventive Services, Division of Clinical and Community Services, Indian Health Service, 5600 Fishers Lane, Mailstop: 08N34A, Rockville, MD 20857, Phone: (954) 909-4834, Email: Richard.Haverkate@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Willis Grant, Grants Management Specialist, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2214, Email: Willis.Grant@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Deputy Director, Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Email: Paul.Gettys@ihs.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.

Elizabeth A. Fowler,

Acting Director, Indian Health Service.

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BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Minnesota Chippewa Tribe, Minnesota, Mille Lacs Band of Ojibwe

AGENCY: Indian Health Service, Health and Human Services.

ACTION: Final notice.

SUMMARY: Notice is hereby given that the Indian Health Service (IHS) has decided to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Mille Lacs Band of Ojibwe in the State of Minnesota to include the Minnesota counties of Crow Wing and Morrison in the State of Minnesota. The final PRCDA for the Mille Lacs Band of Ojibwe is now the Minnesota counties of Aitkin, Crow Wing, Kanebec, Mille Lacs, Morrison, and Pine. Mille Lacs Band of Ojibwe members residing outside of the PRCDA are eligible for direct care services, however, they are not eligible for Purchased/Referred Care (PRC) services. The sole purpose of this expansion is to authorize additional Mille Lacs Band of Ojibwe members and beneficiaries to receive PRC services.

DATES: This expansion is effective as of the publication date of this notice.