

# **Centers for Disease Control and Prevention**

# NATIONAL CENTER FOR HIV, VIRAL HEPATITIS, STDS AND TB PREVENTION

Enhancing STI and Sexual Health Clinic Infrastructure (ESSHCI)

CDC-RFA-PS-23-0011

06/05/2023

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#### Part I. Overview

Applicants must go to the synopsis page of this announcement at <a href="www.grants.gov">www.grants.gov</a> and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-PS-23-0011. Applicants also must provide an e-mail address to <a href="www.grants.gov">www.grants.gov</a> to receive notifications of changes.

## A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

## **B.** Notice of Funding Opportunity (NOFO) Title:

Enhancing STI and Sexual Health Clinic Infrastructure (ESSHCI)

## C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at <a href="https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf">https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf</a>. Guidance on how CDC interprets the definition of research in the context of public health can be found at <a href="https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html">https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html</a> (See section 45 CFR 46.102(d)).

## **D.** Agency Notice of Funding Opportunity Number:

CDC-RFA-PS-23-0011

## **E.** Assistance Listings Number:

93.977

#### F. Dates:

## 1. Due Date for Letter of Intent (LOI):

05/05/2023

## 2. Due Date for Applications:

06/05/2023

11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

#### 3. Due Date for Informational Conference Call:

Informational call will be held on Monday, April 24, 2023, from 2:00-3:00 pm Eastern Standard Time. If interested, please register here:

https://www.zoomgov.com/webinar/register/WN\_qwMeRAPzTS-Sx9yBfOG11w

Additional details will be posted here: <u>Funding Opportunity Announcements (FOAs) | STDs |</u> CDC.

## **G.** Executive Summary:

## 1. Summary Paragraph

The purpose of this NOFO is to strengthen clinic infrastructure and expand access to comprehensive sexual health services. Strategy A (required strategy, Year 1 (Y1)) will foster community engagement and strategic partnerships to support expansion of sexual health services. Associated activities: engage priority populations disproportionately impacted by STIs, mobilize public health partners, and develop a plan to increase access to quality comprehensive sexual health services. Strategy B (required strategy, Years 1-5 (Y1-5)) will strengthen clinic infrastructure and provision of comprehensive sexual health services. Associated activities: conduct clinic infrastructure assessment, implement a plan to increase access to sexual health services, enhance clinic sexual health services, and assess and improve the patient clinic experience. Strategy C (optional strategy, Y1-5) will fund a subset of proposed short-term activities each budget period to expand access to STI prevention and other sexual health services supporting a syndemic approach. NOFO outcomes include increased community involvement in clinic-level planning, increased engagement with public health partners, increased access to & capacity to provide comprehensive sexual health services, improved patient clinic experience, increased identification of new STIs, and increased linkage to prevention and care services for co-occurring conditions.

## a. Eligible Applicants:

**Open Competition** 

## **b. Funding Instrument Type:**

CA (Cooperative Agreement)

# c. Approximate Number of Awards

25

## d. Total Period of Performance Funding:

\$50,000,000

#### e. Average One Year Award Amount:

\$500,000

The average one-year award will be \$300,000 - \$500,000. The award amount is dependent on the amount of funding available and which strategies are funded.

## f. Total Period of Performance Length:

5 year(s)

## g. Estimated Award Date:

September 29, 2023

## h. Cost Sharing and / or Matching Requirements:

No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

#### Part II. Full Text

## **A. Funding Opportunity Description**

## 1. Background

#### a. Overview

Preliminary data show 2.5 million reported cases of chlamydia, gonorrhea, and syphilis in 2021. During the second year of the COVID-19 pandemic (2021), gonorrhea rates increased 4.6%, chlamydia increased 3%, primary and secondary (P&S) syphilis rates among reproductive aged women increased 52.3%, and rates of congenital syphilis increased 34.2%. More than 2,855 babies were born with syphilis in 2021. Having an STI more than doubles the risk of acquiring or transmitting HIV during sex. STIs disproportionately occur in young people, and disparities persist in rates of STIs among racial and ethnic minority groups. The existing infrastructure of STI specialty clinics is insufficient to address the STI epidemic in the United States, including reducing STI and other related infection morbidity and disparities.

This NOFO, Enhancing STI and Sexual Health Clinical Infrastructure (ESSHCI), will increase clinic capacity to provide quality comprehensive sexual health services and increase access to quality, stigma-free STI care and comprehensive sexual health services, especially among applicant-identified priority populations. ESSHCI will also increase identification of new STIs by clinics, improve the patient clinic experience, and increase linkage to public health partners for prevention and care services for co-occurring conditions.

Syndemics are epidemics that interact with each other and by that interaction increase their adverse effects on the health of communities that face systemic, structural, and other inequities. Holistic, coordinated care is a hallmark of the syndemic approach. Activities under ESSHCI will expand access to STI prevention and other sexual health services supporting a syndemic approach that is essential to providing patients comprehensive sexual health care in clinic settings where they routinely receive care. If additional efforts are not taken to expand the breadth of sexual health services in the jurisdictions most impacted by STIs, the nation will continue to see an upward trajectory in these infections.

Involving community in a public health response promotes awareness in the community of the epidemic and builds capacity and understanding about how to respond. Community involvement also builds leadership and human resources, placing community advocates in positions to learn

about the epidemic, how to work with others in the community, how to articulate a position, etc. By involving community members, including people with lived experience, in a community engagement and planning process, NOFO funding recipients will be able to identify unaddressed challenges that contribute to STIs, reduce stigma, improve sexual health literacy, and facilitate opportunities to develop or enhance interventions that can contribute to better sexual health outcomes for the community.

This NOFO supports expanded access to comprehensive sexual health services through community engagement, strategic partnerships, and strengthened clinic infrastructure. ESSHCI is intended to establish a roster of pre-identified and pre-approved clinics for rapid funding to perform activities set forth by this funding opportunity. This NOFO will establish an Approved-But-Unfunded (ABU) list of recipients used to respond to programmatic and community needs as funds become available.

## **b. Statutory Authorities**

This program is authorized under Sections 317 and 318 of the Public Health Service Act, as amended [42 U.S.C. Sections 247b and 247c].

## c. Healthy People 2030

This program addresses the Healthy People 2030 focus area of Sexually Transmitted Infections (STI). See Sexually Transmitted Infections - Healthy People 2030 | health.gov

## d. Other National Public Health Priorities and Strategies

The ESSHCI NOFO supports activities included in CDC's <u>Division of STD Prevention 2022-2026 Strategic Plan</u>, the <u>STI National Strategic Plan 2021-2025</u> and the <u>NCHHSTP Strategic Plan 2022-2026</u>. The <u>National HIV/AIDS Strategy 2022-2026</u> and the <u>Viral Hepatitis National Strategic Plan 2021-2025</u> have similar objectives and embrace a federal syndemic approach. These strategies reflect new opportunities for disease prevention created by critical shifts in the national, state, and local economic and policy environments, including a continually evolving healthcare landscape that emphasizes accountability at every level, strategic allocation of resources, and the principles of high impact prevention.

#### e. Relevant Work

Ongoing relevant projects include:

- PS19-1901: Strengthening STD Prevention and Control for Health Departments (<u>STD</u> PCHD), including a Competitive Supplement for Decreasing Syphilis
- PS20-2004: National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers (NNPTC), with a supplement supported by Minority HIV/AIDS Fund
- PS20-2010: Integrated Programs for Health Departments to Support Ending the HIV Epidemic in the United States, <u>Component C</u>
- PS23-0007: Support Technical Assistance & Opportunities for Program, Policy, & Communications to Prevent STDs (STOP STDs)
- Community Engagement to Strengthen Approaches to Decreasing Syphilis (NACCHO RFAs)

# 2. CDC Project Description

## a. Approach

**Bold** indicates period of performance outcome.

CDC-RFA-PS-23-0011 Logic Model: Enhancing STI and Sexual Health Clinic Infrastructure (ESSHCI)

Strategies and	Short-term Outcomes	Intermediate	Long-Term
Activities	(Y1)	Outcomes (Y2-3)	Outcomes (Y4+)
Strategy A: Foster	Increased	Increased community	Reduced STI and
community	community	partner collaboration	other syndemic-
engagement and	involvement in	and communication to	related infection
partnerships	clinic-level planning	support provision of	morbidity
(Required strategy –	for provision of	comprehensive sexual	
Year 1)	comprehensive	health services	
- A1: Build	sexual health		Reduced STI
	services		disparities
community		Increased clinic	
connections to		capacity to provide	
identify, reach, and	Increased	quality	Increased
involve priority	engagement with	comprehensive	community, clinic,
populations affected by STIs and mobilize	public health	sexual health	and public health
public health partners	partners addressing	services	partner collaborations
to actively address	the STI epidemic		supporting a
STI epidemic			syndemic approach
STTeplucinic		Improved patient	
- A2: Develop an		clinic experience	
actionable,			
community-informed,			
clinic-level plan to		Increased	
increase access to		identification of new	
quality comprehensive		STIs by clinics	
sexual health services			
tailored to the affected			
community		Increased linkage to	
Strategy B:		public health	
Strengthen clinic		partners for	
infrastructure and		prevention and care	
provision of		services for co-	
comprehensive		occurring conditions	
sexual health			
services (Required		In among ad a sec 4-	
strategy – Years 1-5)		Increased access to quality, stigma-free	
- B1: Conduct clinic		STI care and	
infrastructure		comprehensive	
assessment to		sexual health	
document available		services, especially	
comprehensive sexual		among priority	
comprehensive sexual		among priority	<u> </u>

health services and identify and address gaps	populations affected by STIs	
- B2: Implement clinic-level plan to increase access to sexual health services		
- B3: Implement additional evidence- based approaches to enhance clinic sexual health services		
- B4: Assess and improve patient clinic experience and satisfaction		
Strategy C: Expand access to STI prevention & other sexual health services supporting a syndemic approach (Optional strategy – Years 1-5)		
- C1: Implement or expand alternative models of comprehensive sexual health service delivery		
- C2: Improve access to quality sexual health services based on local activity of interest		
- C3: Implement and evaluate demonstration projects that address emerging and unaddressed STI/HIV/viral hepatitis issues		

Note: The short-term and intermediate outcomes are based on Strategies A and B.

## i. Purpose

The purpose of this NOFO is to strengthen clinic infrastructure and expand access to comprehensive sexual health services in high burden and underserved areas. ESSHCI supports clinics to: 1) foster community engagement and strategic partnerships to support expansion of sexual health services, 2) strengthen clinic infrastructure and provision of sexual health services, and 3) conduct short-term activities to expand access to STI prevention and other sexual health services supporting a syndemic approach.

#### ii. Outcomes

Recipients must achieve the following outcomes by the end of the period of performance:

- increased community involvement in clinic-level planning for provision of comprehensive sexual health services,
- increased engagement with public health partners addressing the STI epidemic,
- increased clinic capacity to provide quality comprehensive sexual health services,
- increased access to quality, stigma-free STI care and comprehensive sexual health services, especially among priority populations affected by STIs,
- improved patient clinic experience,
- increased identification of new STIs by clinics, and
- increased linkage to public health partners for prevention and care services for cooccurring conditions.

# iii. Strategies and Activities

This NOFO serves communities with high STI burden and unmet need for STI clinical services. To address inequities and service gaps, applicants are expected to describe how the proposed service area is either high burden or medically underserved as indicated by:

- (Required): the proposed service area's population in total and by age, gender, race/ethnicity, as well as the proportion living under the federal poverty level;
- (Required): the number of cases and rates of HIV, gonorrhea, chlamydia, and primary and secondary (P&S) syphilis by gender, for the two most recent years of available data (resource: https://www.cdc.gov/nchhstp/atlas/index.htm);
- (Required): the current availability of STI and sexual health care services in the proposed service area;
- (Optional but recommended): the number of male HIV, gonorrhea, chlamydia, and P&S syphilis cases by sex of sex partners;
- (Optional but recommended): the number of urethral gonorrhea cases and number of P&S syphilis diagnoses for the provided time period and the proportion of these cases diagnosed in 1) emergency rooms/urgent cares; 2) primary care clinics; 3) STI/family planning clinics; or 4) other clinics.

Applicants are also expected to identify priority population(s) disproportionately impacted by STIs in their proposed clinics' catchment area (e.g., adolescents and young adults, racial, ethnic, sexual, and gender minorities, women of reproductive age, and/or persons experiencing incarceration and/or homelessness). Applicants must choose to focus on one or more of these

populations based on the STI health disparities in their jurisdictions. Applicant must describe knowledge of priority populations or plans to develop knowledge of priority populations.

# **Strategy A:** Foster Community Engagement and Partnerships (Required Strategy – Year 1)

Strategy A requires recipients to build active and meaningful engagements with communities of priority populations affected by the STI epidemic and mobilize public health partners to develop a clinic-level plan to increase access to quality comprehensive sexual health services. The strategy activities must be inclusive and representative of community input while supporting the expansion of sexual health services. Strategy A activities will take place in Year 1.

### Activities must include:

# Activity A1: Build community connections to identify, reach, and involve priority populations affected by STIs and mobilize public health partners to address the STI epidemic

## Recipients must:

- define the clinic catchment area and identify the priority population(s) affected by STIs within this area to participate in community engagement activities. There are communities within priority populations with unique cultural, social, racial, and ethnic attributes that are important to incorporate into engagement approaches when building community connections they must be considered to ensure that strategies are safe, inclusive, and relevant. As part of this process, create a relationship with the local health department, if one does not already exist.
- conduct formative data collection (e.g., assessments, surveys, listening sessions, focus
  groups), as needed, throughout the community engagement process to build community
  connections and inform the development of the recipient's clinic-level plan to increase
  access to quality comprehensive sexual health services, including the development or
  adaptation of existing interventions.
- design an <u>equitable process</u> to ensure meaningful community involvement (e.g., community advisory group(s) or task force, community liaisons, community partners) in developing the clinic-level plan. The role community members will participate in should be defined.
- engage with community advisory group(s) that reflect the priority population(s). Community advisory groups can be established by the recipient or leveraged through public health partners and other partnerships reflecting populations affected by STI disparities.
- leverage new and/or existing collaborations with public health partners and other partners (e.g., non-profits, community-based organizations, correctional facilities, academic institutions, social services, etc.) that work with both the identified priority populations and uninsured/underinsured populations disproportionately impacted by STIs to increase future linkage to ancillary services associated with improved sexual health outcomes (e.g., HIV treatment and pre-exposure prophylaxis (PrEP) referral, substance use treatment, mental health services, family planning services, reproductive health care providers, housing assistance, etc.) and any additional partnerships that support expansion of sexual health services.

# Activity A2: Develop an actionable, community-informed, clinic-level plan to increase access to quality comprehensive sexual health services tailored to the affected community

Members of the priority population(s) identified by applicants must be involved in the development of the clinic-level plan. Community representatives should have a defined role that supports efforts to increase access to quality comprehensive sexual health services in the catchment area. Clinic-level planning describes the operational and programmatic procedures and activities involved in providing and maintaining quality clinical sexual health services for patients and staff. Activities include (but are not limited to) staff diversity and training, development and dissemination of patient and community resources, community outreach activities, clinic assessments, implementation of sexual health services, patient clinic experiences and satisfaction, clinic space improvements, and improvement pilot projects.

- Using the insights and relationships developed in Activity A1, recipients must ensure that considerations and issues identified by partners and community representatives during the engagement process are addressed in the plan and shared with the community.
- The plan should focus on the recipient's priority populations, including as applicable persons who are uninsured and underinsured, medically underserved, adolescents and young adults, racial, ethnic, sexual, and gender minorities, women of reproductive age, and/or persons experiencing incarceration and/or homelessness, etc.
- In partnership with community members, community advisory board/groups, task force, and other entities, recipients must explore adaptable and innovative intervention strategies that can be utilized by the clinic to be responsive to prioritized population(s) including information, education, communication, social marketing strategies, accessibility strategies (e.g., language, transportation, childcare, food), and maintaining community engagement.
- Recipients will conduct (or utilize an existing and recently conducted) <u>community needs</u> <u>assessment among populations</u> disproportionately affected by STIs.
- Recipients must use the CDC's <u>Recommendations for Providing Quality STD Clinical Services (STD QCS)</u> to plan for provision of basic STI care with planned expansion to STI specialty care. (See Strategy B for additional guidance.)
- The plan must describe: (a) how clinic resources and services will be adapted to increase access to quality comprehensive sexual health services for persons who are uninsured, underinsured and other priority populations, and (b) community outreach activities to promote availability of comprehensive sexual health services upon implementation of the clinic-level plan and any related activities in Strategy B. Outreach activities must be informed by community members of the identified priority population(s). Examples of engagement activities include health education events, community events, virtual engagements using social media or other digital tools, or informal community listening sessions. Recipients are encouraged to consider creative and innovative activities to engage communities.

# <u>Strategy B:</u> Strengthen Clinic Infrastructure and Provision of Sexual Health Services (Required Strategy – Years 1-5)

This strategy expands and strengthens specialized STI care and sexual health services, particularly in areas with high STI burden and limited access to STI clinical services. Applicants may either propose to create a new sexual health clinic or expand a current clinic to include

specialized STI and sexual health services. The following guidance separates the anticipated outcomes by either the expansion of an existing clinic or the creation of a new clinic.

## For entities with an existing clinic:

**Years 1-2**: Concurrent with engaging the community in the process of expanding STI and sexual health services, leadership must develop a comprehensive clinical sexual health services plan starting with *Activity B1*, which is to conduct a clinic infrastructure assessment to document available sexual health services then identify and address gaps by conducting an inventory of current STI and sexual health services. Recipients should use CDC's Recommendations for Providing Quality STD Clinical Services (STD QCS) (see Table 1 below for an adapted summary), NACCHO-STD-QCS-Planning-Toolkit.pdf, STD Prevention Services Gap Assessment Toolkit, and the National Coalition for Sexual Health's Inclusive Sexual Health Services: Practical Guidelines for Providers & Clinics.

Address the following three activities in the comprehensive plan:

**Activity B2**: Implement the clinic-level plan developed in Y1 to increase access to basic STI and sexual health services.

**Activity B3:** Implement evidence-based approaches to enhance clinic sexual health services to provide STI specialty services in addition to activities included in Y1 plan.

Activity **B4**: Assess and improve the patient clinic experience, including patient satisfaction. Additional activities would include conducting a baseline assessment that could be repeated over time as part of process evaluation.

A clinic that is not currently meeting basic STI clinical services (first column of Table 1) must create a plan to meet basic services in Year 2. A clinic that is already meeting basic STI/sexual health clinical services must outline in the plan which additional services will be added in Years 2-5. Clinical services are not limited to those listed in the QCS or Table 1. The plan should include a timeline and a detailed discussion of the steps needed to move towards provision of specialized STI services.

The detailed plan should include:

- 1. An outline of the proposed clinical services that describes:
  - o the services that will be provided and the patient populations that will be served,
  - o how the services will be provided,
  - o a referral/linkage to care plan for specialty services not provided onsite,
  - o a continuous quality improvement framework or strategies to improve quality of care.
- 2. A laboratory services plan, particularly for the use of point of care (POC) testing services that describes:
  - o equipment that needs to be purchased,
  - o if the clinic needs to apply for a Clinical Laboratory Improvement Amendments (CLIA) waiver,
  - o the laboratory that will provide services for send out tests,
  - o who will perform microscopy (i.e., a laboratory technician or a provider). If a provider will perform microscopy and this is a new activity for providers in the

clinic, applicants must include a training plan. (Note: <u>NNPTC</u> has microscopy training courses.)

A detailed staffing strategy, including a clinical training plan for current providers, or for hiring new providers, with expertise in clinical care. STI and sexual health specialty providers need to provide culturally sensitive care for populations that have been marginalized, including lesbian, gay, bisexual, transgender, queer and intersex (LGBTQI+) people, youth and young adults and other disproportionately impacted individuals. The proposed clinical expansion could include a multi-disciplinary team to provide a syndemic approach to care for co-morbidities such as substance use disorders and other psychosocial issues. The staffing plan should:

- 1. Describe the size, demographics, and health needs of the projected patient population to determine the number and mix of clinical staff necessary to ensure reasonable access to services.
- 2. Include a training plan to provide culturally sensitive, trauma-informed, patient-centered care
- 3. Describe current clinical expertise in the diagnosis and management of bacterial, viral, and parasitic sexually transmitted pathogens or a training plan to achieve this level of expertise.
- 4. Include a training plan for testing proficiency if providers will perform POC tests.
- 5. Include a pharmacy plan for on-site administration of key medications such as injectables (penicillin G benzathine, ceftriaxone, gentamicin, and vaccines), and oral onsite medications such as rapid HIV PrEP starts, nonoccupational postexposure prophylaxis (nPEP), and expedited partner therapy (EPT) partner packs (see Table 1), describing:
  - o Physical on-site storage requirements,
  - o A pharmacy ordering plan,
  - o Inventory maintenance procedures.
- 6. Include an administrative plan discussing:
  - o Patient scheduling that allows for walk-in services and could include a plan for express services and/or telehealth visits (see Strategy C),
  - o A financial plan detailing billing practices and financial solvency, and
  - o Medical and administrative supervision of the clinic.
- 7. Describe medical and administrative supervision of the clinic.

Table 1: Clinical services that should be included for Basic and Specialty STD Care (adapted from CDC's QCS)

Category	Basic STD Services	STD Specialty Services
		(Include all basic care AND those under specialty care)
Sexual	Sexual History and Risk Assessment	Colposcopy
History and Physical Exam	Physical Exam (including pelvic exam) for patients presenting with STD-related	Anoscopy High resolution anoscopy (optional)

	symptoms, STD-related concerns or those at high behavioral risk for incident STDs	
Prevention	Condom Provision	Vaccination (add hepatitis A
	Vaccinations (hepatitis B virus, human papillomavirus)	virus and mpox) Provision of HIV PrEP and
	Counseling	nPEP
	Referral for HIV PrEP	
	HIV Linkage to care	
	Emergency Contraception	
Screening	Gonorrhea	Trichomonas
Tests Availability	Chlamydia	Anal cancer screening
Tivanaomity	Syphilis	(optional)
	HIV	
	Hepatitis B and C	
	Cervical Cancer Screening	
Onsite	pH paper	Phlebotomy
Diagnostic Availability	Thermometer	Pregnancy test
Tivanaomity		Microscopy
		Wet mount or POC vaginitis test (for bacterial vaginosis, trichomoniasis and vulvovaginal candidiasis)
		Gram Stain/Methylene Blue/Gentian Violet
		Rapid HIV test
		Rapid RPR (syphilis)
		Darkfield microscopy (optional)
		Urine dipstick
		Urinalysis with microscopy
		POC GC/CT test
		POC syphilis test

Partner Services	Guidance regarding notification and care of sex partners	Interactive counseling for partner notification		
	EPT (where legal and where local or state jurisdictions do not prohibit by regulation)	Health department Disease Intervention Specialist (DIS) elicitation of sex partner information (on site or by referral)		
Referral Plan	Immunoglobulin E (IgE) mediated allergies co (i.e., cephalosporins or penicillin)	unoglobulin E (IgE) mediated allergies compromising STD treatment cephalosporins or penicillin)		
	Complex gonorrhea cases (e.g., disseminated cephalosporin resistant cases)	gonococcal infections,		
	Complex chlamydia cases (e.g., neonatal ophthalmia)			
	Complex syphilis cases (e.g., lumbar puncture, ophthalmologic and otologic evaluation)			
	Complex vaginal discharge, trichomoniasis an	omplex vaginal discharge, trichomoniasis and candidiasis		
	Pelvic inflammatory disease requiring surgery (i.e., tubo-ovarian abscess)			
	Complex warts			
	Complex herpes (e.g., antiviral resistant cases)			
	Cervical intraepithelial neoplasia or cervical cancer			
	Sexual assault			
	Hepatitis B or C infection			
	New HIV diagnoses and previously diagnosed but out of care			
	Family planning and reproductive health care services and/or prenatal care	providers for contraception		

<sup>\*</sup>Information on the legal status of EPT for each state is available at https://www.cdc.gov/std/ept/legal/default.htm

Years 2-5: In Year 2, recipients will continue to refine the clinic expansion plan and begin implementation for what may become an iterative process. In Year 3, the clinic should begin providing all the required STI specialty services as outlined in the QCS (Table 1). If not before, by Years 4-5, the clinic should implement **Activity B4** to evaluate the program and the patient experience with a plan to make improvements based on the results, as needed. Examples of program and patient experience evaluation include:

- A time study to evaluate patient wait times, turn aways, and areas of bottlenecks,
- A patient satisfaction survey looking at the cultural competency of providers, the acceptability of services offered, etc.,
- Uptake and feasibility of specific clinical services (e.g., nPEP provision, contraception services, walk-in services versus scheduled patient visits, etc.), and

• An assessment of the quality of care, including the care environment.

# For Entities Proposing the Creation of a New Clinic (to align with activities B1-B4):

**Years 1-2**: In conjunction with community input from Strategy A, recipients will develop a plan for the delivery of basic level STI care. Basic level STI care must be implemented before the beginning of Year 3.

**Years 2-3**: The clinic should develop a plan to expand services to all the required STI specialty services as outlined in the QCS (Table 1).

**Year 4:** STI specialty services should be in place. Recipients standing up a new STI specialty clinic should follow the outline above for developing their plan. The difference is the timeline. New clinics will have one year longer to achieve full implementation.

**Year 5:** Year 5 should include plans for quality assurance/quality improvement and patient satisfaction surveys.

# <u>Strategy C:</u> Expand Access to STI Prevention & Other Sexual Health Services Supporting a Syndemic Approach (Optional Strategy, Competitive – Years 1-5)

Under Strategy C, applicants may propose one or more short-term activities (i.e., activities conducted within a given budget period) for activities C1-3 to expand access to STI prevention and other sexual health services in support of a syndemic approach. Strategy C is designed to optimize public health impact by facilitating the ability of CDC's Division of STD Prevention (DSTDP) to respond to emerging needs while remaining aligned with the scope of the NOFO. This strategy is optional and competitive.

While the purpose and general activities described under Strategy C will remain constant for the duration of the period of performance, CDC will describe emerging needs and program priorities under this strategy in the continuation guidance for each budget period. Recipients will be invited to submit applications in response to the solicitation.

Examples of Strategy C activities for Year 1 include:

# Activity C1: Implement or expand alternative models of comprehensive sexual health service delivery

Applicants can propose activities that increase access and engagement among persons who are medically underserved in priority populations by implementing or expanding alternative models of comprehensive sexual health service delivery. Examples of alternative models of service delivery include (but are not limited to):

- telehealth for HIV PrEP or other sexual health services.
- tele-mentorship to support new or existing providers that are addressing STI prevention and other sexual health service needs,
- engaging people who are medically underserved through:
  - o mobile health clinics,
  - o transgender care,
  - expanded field-based sexual health services provided by Disease Intervention Specialists (DIS),
  - o HIV/STI self-testing, including express clinic models,

o co-location of STI services in syringe services programs (SSPs), medication-assisted treatment (MAT) clinics, and opioid treatment programs (OTPs).

## Activity C2: Improve access to quality sexual health services based on local activity of interest

Applicants can propose activities of local interest that improve or increase access to quality sexual health services including integration of services and programs in support of a syndemic approach. Examples of alternative models of service delivery include (but are not limited to):

- expanding hepatitis C testing paired with referral/linkage to curative treatment or colocation of hepatitis C treatment in the clinic
- a syndemic-focused, local-level testing campaign
- improving integrated STI services/contraceptive/reproductive health care services in areas with high teen pregnancy rates or in areas/settings where contraceptive services may be harder to access, for women/people with a uterus of all ages

# Activity C3: Implement and evaluate demonstration projects that address emerging and unaddressed STI/HIV/viral hepatitis issues

Applicants can propose projects that address emerging and unaddressed STI/HIV/viral hepatitis issues. These projects may take shape as but are not limited to demonstration or pilot projects, needs or rapid assessments, evaluation, modeling and economic analysis, partner engagement, development of toolkits, best practices, and meetings, convenings, and consultations.

Examples of project areas include (but are not limited to):

- collaborations with health departments to utilize surveillance data, pharmacy fill data, clinic appointment data, and other treatment and care data to support the care continuum for HIV/viral hepatitis (e.g., build surveillance capacity for data to care assessing care cascades for HBV, HCV, HIV PrEP, etc.),
- outbreak response,
- antimicrobial resistance,
- diagnostic tests,
- prevention technologies and interventions (e.g., expansion of hepatitis B vaccination provision in clinic, collaboration between clinic and local emergency department [ED] providers to increase STI/HIV testing in ED, etc.),
- epidemiologic and policy analysis,
- cost and reimbursement, and
- social and structural determinants of health.

## 1. Collaborations

## a. With other CDC projects and CDC-funded organizations:

Recipients and their proposed clinic are encouraged to collaborate with the National Network of STD Clinical Prevention Training Centers (NNPTC), academic partner for training and capacity-building support. Recipients should collaborate with a regional STD prevention training center (PTC) to implement and promote quality sexual health services in their clinics in accordance with the STD QCS.

Recipients are expected to collaborate with communities and other syndemic-focused programs, not limited to community-based organizations, the STD Surveillance Network (SSuN), HIV, viral hepatitis, and HPV vaccine programs, reproductive health organizations and adolescent sexual and reproductive health programs, opioid prevention programs, outbreak response teams, and other programs funded by CDC. Recipients are encouraged to establish, build, and/or maintain working partnerships with other CDC-funded programs in their jurisdictions. Ensuring communication, collaboration, and coordination for the delivery of comprehensive sexual health services consistent with CDC standards and guidance may occur in collaboration with HIV and STD programs in health departments (e.g., state and local) in applicant jurisdictions, including recipients of PS19-1902 (Strengthening STD Prevention and Control for Health Departments) and, if appropriate, with a state or local public health laboratory.

Memoranda of agreement/memoranda of understanding (MOAs/MOUs) and/or data sharing agreements can be established. Applicants have the option to provide the MOU or MOA, as appropriate, naming the file "MOUs-MOAs", and uploading it as a PDF file in the application submitted through www.grants.gov.

## b. With organizations not funded by CDC:

Recipients must collaborate with organizations not funded by CDC that support the implementation of the proposed activities. Collaborations may include (but are not limited to) public health departments, community advocates, community members, youth serving organizations, local education agencies, local colleges and universities, non-CDC funded community-based and faith-based institutions, clinics and hospitals, and other interested organization ,entities, or groups that are interested in increasing access to quality comprehensive sexual health services. ESSHCI encourages innovative partnerships.

Memoranda of agreement/memoranda of understanding (MOAs/MOUs) and/or data sharing agreements can be established. Applicants have the option to provide the MOU or MOA, as appropriate, naming the file "MOUs-MOAs", and uploading it as a PDF file in the application submitted through www.grants.gov.

For applicants that are not the local public health agency, letters of collaboration from the local public health agency or other health care providers in the community, are strongly encouraged. Applicants should title this document, "Public Health LOS" and upload it as pdf at www.grants.gov.

#### 2. Target Populations

This NOFO serves communities with high STI burden and unmet need for STI clinical services. To address inequities and service gaps, applicants are expected to describe how the proposed service area is either high burden or medically underserved as indicated by:

- (Required): the proposed service area's population in total and by age, gender, race/ethnicity, as well as the proportion living under the federal poverty level;
- (Required): the number of cases and rates of HIV, gonorrhea, chlamydia, and primary and secondary (P&S) syphilis by gender, for the two most recent years of available data (resource: https://www.cdc.gov/nchhstp/atlas/index.htm);

- (Required): the current availability of STI and sexual health care services in the proposed service area;
- (Optional but recommended): the number of male HIV, gonorrhea, chlamydia, and P&S syphilis cases by sex of sex partners;
- (Optional but recommended): the number of urethral gonorrhea cases and number of P&S syphilis diagnoses for the provided time period and the proportion of these cases diagnosed in 1) emergency rooms/urgent cares; 2) primary care clinics; 3) STI/family planning clinics; or 4) other clinics.

Applicants must identify and describe the ability to reach priority population(s) disproportionately impacted by STIs in their proposed clinics' catchment area (e.g., adolescents and young adults, racial, ethnic, sexual, and gender minorities, women of reproductive age, and/or persons experiencing incarceration and/or homelessness). Applicants must focus on one or more of these populations based on the STI health disparities in their jurisdictions. Applicant must describe knowledge of priority populations or plans to develop knowledge of priority populations.

Applicants proposing the expansion of services within an existing clinic must include a table summarizing the following for the most recent year of available data:

- the number of clinic patient visits and
- the percent of clinic patients by gender, race/ethnicity, age distribution, sexual orientation and gender identity (if available).

Save the table as a file named "Documentation of clinic patient visits and demographic characteristics" and upload it as a PDF file in the application submitted through <a href="www.grants.gov">www.grants.gov</a>.

## a. Health Disparities

DSTDP supports efforts to improve the health of populations disproportionately affected by STIs by maximizing the health impact of public health services, reducing disease incidence, and advancing health equity through expanded access to STI clinical care. A health disparity occurs when a health outcome is seen to a greater or lesser extent between populations. Health disparities in STIs are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these infections and diseases.

Social determinants are conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of life-risks and outcomes (<a href="https://www.cdc.gov/socialdeterminants/index.htm">https://www.cdc.gov/socialdeterminants/index.htm</a>). These determinants include conditions for early childhood development; education, employment, and work; food security, health services, housing, income, and social exclusion. Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic challenges, requiring:

- Continuous efforts focused on elimination of health disparities, including disparities in health and in the living and working conditions that influence health, and
- Continuous efforts to maintain a desired state of equity after health disparities are eliminated.

Applicants should use data, including social determinants data, to identify communities within their jurisdictions that are disproportionately affected by STIs and related diseases and conditions, and plan activities to help eliminate health disparities. In collaboration with partners and appropriate sectors of the community, applicants should consider how racism may impact public health and influence how people access STD/HIV services, in addition to the social determinants of health in the development, implementation, and evaluation of program specific efforts and use culturally appropriate interventions and strategies that are tailored for the intended communities.

## iv. Funding Strategy

The average one-year award amount is \$300,000 - \$500,000, and is dependent on the amount of funding available and the strategies funded.

This NOFO has 3 strategies. Applicants must apply for Strategies A and B and have the option to apply for Strategy C. Applicants who do not include Strategies A and B in their application will be deemed non-responsive and their application will not be reviewed.

Applicants must clearly state the strategies to which they are applying in the Project Abstract Summary. When including this information in the Project Abstract Summary, please identify the strategies as they are used in the logic model; possible options are provided below.

- This application includes Strategies A and B.
- This application includes Strategies A, B, and C.

Funding for Strategy C activities is contingent on available federal funding and CDC's programmatic priorities (outlined in Strategies and Activities for Y1). For Y1, the highest scoring applicants for Strategies A & B may also be funded for Strategy C.

ESSHCI is also intended to establish a roster of pre-identified and pre-approved recipients for rapid funding to perform activities set forth by this funding opportunity. This NOFO will establish an Approved-But-Unfunded (ABU) list of recipients to respond to emerging STI prevention and other sexual health services needs and issues. ABUs will be considered but are not guaranteed funding since priority projects may change from year to year based on emerging needs. These funding decisions will consider various factors, including the specific STI prevention and other sexual health services need, the organizational capacity of the initial and/or ABU recipient, and agency and national priorities.

#### b. Evaluation and Performance Measurement

## i. CDC Evaluation and Performance Measurement Strategy

The evaluation and performance measurement strategy will demonstrate the achievement of program outcomes, build a stronger evidence base for specific program strategies, clarify the applicability of the evidence base to different populations, settings, and contexts, and drive continuous program improvement. Evaluation findings and performance measures will be used to demonstrate the value of the program and describe the effectiveness of NOFO implementation, including lessons learned and implications for future work. Evaluation and performance measurement findings will be systematically reviewed by CDC to (a) identify challenges encountered by recipients, (b) identify capacity-building assistance needs and actions needed to improve overall project performance, (c) compare methods and outcomes across recipients to identify promising practices for dissemination during the project period, (d)

demonstrate the value of the ESSHCI NOFO (e.g., improved public health outcomes, effectiveness of key strategies and activities), and (f) contribute to the evidence base for NOFO strategies and activities.

CDC requires ongoing evaluation and performance measurement under this NOFO. CDC expects recipients to maintain sufficient staffing and analytic capacity to meet these requirements. CDC will assess process, short-term and intermediate outcomes through the collection of qualitative and quantitative information through discussions with recipients and data reports. Additionally, recipients will provide process and outcome measures and additional documentation of program activities and outcomes.

For each of the NOFO's program strategies, a partial list of performance measures is presented below. A full list of proposed outcomes and measures will be provided by DSTDP project staff within the first six months of the start of the performance period. CDC will work with recipients to finalize their detailed Evaluation Plan, including a Work Plan and Data Management Plan (DMP), in accordance with CDC program guidance. CDC will finalize these measures, specific definitions, benchmarks, submission frequency, and submission templates in consultation with recipients within the first six months of the period of performance.

Recipients will submit biannual performance measures reports to CDC using the templates provided by the CDC evaluation team. Within two to three months after recipients report their data to CDC, CDC will provide them with a report that summarizes each recipient's performance as well as the performance of all other recipients. This report will be reviewed and discussed by the recipient and their assigned project officer, and among CDC staff involved in the ESSHCI NOFO.

### **Short-term and Intermediate Outcomes & Measures**

# Strategy A: Foster Community Engagement and Partnerships (Required Strategy – Year 1)

- Outcome 1: Increased community involvement in clinic-level planning for provision of comprehensive sexual health services
  - o Measure: Number and type of engagements with community advisory group
  - o Measure: Summary of actionable, community-informed, clinic-level plan to increase access to quality comprehensive sexual health services
- Outcome 2: Increased engagement with public health partners addressing the STI epidemic
  - o Measure: Total number and type (health provider, community-based organization, university, etc.) of community partners engaging in STI prevention collaboration
  - Measure: Assessment of partnerships and activities to address STIs (e.g., recipients can annually survey partners or complete surveys themselves assessing what occurred, such as exchanging contact info, making plans to exchange resources, making plans for formal collaboration)

Strategy B: Strengthen Clinic Infrastructure and Provision of Comprehensive Sexual Health Services (Required Strategy – Years 1-5)

- Outcome 1: Increased clinic capacity to provide quality comprehensive sexual health services
  - Measure: Total number of patients served by each clinic stratified by demographics and priority populations
  - Measure: Total number of eligible patients offered treatment as prevention (e.g., HIV PrEP or doxy-PEP prescriptions)
  - o Measure: List of findings for clinic infrastructure assessment to document available comprehensive sexual health services and identify and address gaps
  - Measure: Description of clinic-level plan developed to increase access to sexual health services
  - Measure: Description of strategies to improve clinic systems for referrals, lab systems, linkages to care, treatment, and/or record keeping
  - o Measure: Proportion of clinic staff who report that clinic has the capacity to provide quality comprehensive sexual health services to meet the demand
- Outcome 2: Improved patient clinic experience
  - Measure: Baseline and annual patient satisfaction survey or assessment plan established
  - o Measure: Patient satisfaction level with the clinic services and STI care
- Outcome 3: Increased identification of new STIs by clinic
  - o Measure: Number of new STI (syphilis, gonorrhea, chlamydia, mpox, HIV) cases identified by clinic stratified by demographics and priority populations
  - Measure: Number of new STI cases treated with recommended CDC treatment for each STI stratified by demographics and priority populations
- Outcome 4: Increased linkage to public health partners for prevention and care services for co-occurring conditions
  - Measure: Number of referrals to public health partners for prevention and care services for co-occurring conditions
  - Measure: Number of people testing positive for an STI (syphilis, gonorrhea, chlamydia, mpox, HIV) who were interviewed/offered partner services stratified by demographics and priority populations

# Strategy C\*: Expand Access to STI Prevention & Other Sexual Health Services Supporting a Syndemic Approach (Optional Strategy - Years 1-5)

- Outcome 1: Increased access to quality, stigma-free STI care and comprehensive sexual health services, especially among priority populations affected by STIs
  - Measure: Description of activity to improve/increase access to quality sexual health services of local interest.
  - Measure: Patient satisfaction level with the clinic services and STI care

## ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance

<sup>\*</sup>Additional measures will be developed to reflect proposed activities.

Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How the applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant)
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see <a href="https://www.cdc.gov/grants/additional-requirements/ar-25.html">https://www.cdc.gov/grants/additional-requirements/ar-25.html</a>.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

For the proposed performance measures listed above, describe:

- All available baseline measures (including definitions for numerators and denominators used and latest reporting year or timeframe),
- Source(s) of data needed to calculate the measures (i.e., which programs or agencies "own" the data),
- The use of the measures for program improvement and clinical capacity,
- Whether the applicant can report on the measures every six months,
- Anticipated barriers to obtaining and calculating the proposed measures,
- Any other comments or questions about the proposed measures.

Applicants should plan for sufficient staffing and resources to accomplish all activities related to evaluation and performance measurement for this NOFO, including planning, data management, reporting data to CDC, use of data for program improvement, development and dissemination of reports, and attendance at monitoring and evaluation meetings. Applicants must describe the current capacity, authority or shown/demonstrated capability, and process to implement any data

sharing agreement(s) needed to facilitate sharing of visit-level, deidentified records with CDC and the allocation of funds to support evaluation activities.

Applicants may propose additional key performance measures to collect and track. Applicants may list measures CDC should consider for inclusion in the final set of common performance measures, either in addition to, or in lieu of, those proposed in this NOFO.

CDC will work with recipients to finalize a Data Management Plan (DMP) in accordance with CDC program guidance. A data management plan is required for the proposed project will include:

- A description of the data to be collected or generated in the proposed project,
- Standards used for the collected or generated data,
- Mechanisms for, or limitations to, providing access to the data, including a description for the provisions of protection of privacy, confidentiality, security and intellectual property, or other rights,
- A statement of the use of data standards that ensure all documentation describes the method of collection and what the data represented,
- Plans for archiving and long-term preservation of the data, or an explanation for the reason why long-term preservation and access are not justified, and
- Plans for routine data sharing with CDC.

## c. Organizational Capacity of Recipients to Implement the Approach

Applicants must provide a staffing plan, including an organizational chart, CVs, position descriptions and project management structure that demonstrates the capacity to meet the goals of the proposed project and defines staff roles and reporting structure. Any planned consultancies or subcontracts should be included in the project management structure. The staffing plan must name a current medical director or health officer overseeing clinical staff and provide their CV. Applicants should provide the CVs/resumes, organizational chart, and staffing plan, as appropriate, naming the file "CVs/Resumes, Organizational Chart or Staffing Plan", and uploading it as a PDF file to the application submitted at <a href="https://www.grants.gov">www.grants.gov</a>.

Applicants must be providers of clinical services in the proposed service area, or plan to provide the majority of funds to provider(s) of clinical services in the proposed area. Applicants must describe the proposed clinic's organizational capacity to achieve the outcomes of the award. The clinic organizational capacity statement should describe in detail:

- the nature and scope of the clinical services that are provided,
- hours of operations,
- electronic health record functionality and interoperability,
- the number and composition of staffing, and
- the current state of services.

## Additional Requirements:

• Describe expertise and experience in program and performance management, quality improvement methods, partnership development, evaluation, personnel management including the authority and ability to hire or contract in a timely fashion and maintain adequate personnel resources with applicable skills and expertise.

- Describe relevant experience and capacity (management, technical, and clinical) to implement each of the required strategies and associated activities and achieve the project outcomes.
- Describe experience and capacity to coordinate with internal and external stakeholders, including local public health organization(s), to foster and coordinate community engagement.
- Describe experience and capacity to implement the evaluation plan, measure, and report on performance measures, and implement the data management plan.
- Describe the budget management and financial reporting capacity, including the management of travel requirements, the full capability, accountability and expertise to meet deadlines, track funds, submit reports, manage the required procurement efforts, and to write and award contracts in accordance with 45 CFR 75 by a given due date.

Non-clinical applicants, including state, local, and territorial health departments, must describe the relationship to the proposed clinic and describe how funds will be directed to the clinic, including mechanisms and timelines to obligate funds. CDC anticipates that at least 90% of the funds will be directed to the proposed clinic to support expanding access to comprehensive sexual health services through community engagement, strategic partnerships, and strengthened clinic infrastructure.

#### d. Work Plan

Applicants must provide a work plan that includes both a high-level overview of the entire five-year period of performance and a detailed description of the first year of the award. The work plan should incorporate all required Strategy A and B activities and any optional Strategy C activities that they are proposing. Applicants should propose specific, measurable, achievable, realistic, and time-based (SMART) process and/or outcome measures for each activity aligned with the related NOFO performance outcomes. The work plan should include training, capacity building, and TA activities to support the implementation of the proposed program. It should also include a concise description of how the recipient plans to implement and monitor each program activity.

The applicant should address the following outline in their work plan:

- Five-Year Overview of Project
  - o Intended outcomes for the entire period of performance
- Year 1 Detailed Work Plan
  - Program strategies and activities
  - Outcomes aligned with program strategies and activities
  - Outcomes aligned with performance targets (including quantitative baselines and targets, based on the proposed program, that lead to an increase, decrease, or maintenance over time)
  - o Activities aligned with program outcomes and measures
  - Timeline for implementation (including staffing of the proposed program, training, etc.)

Post-award, proposed work plan activities may be adjusted in collaboration with CDC to better address the overarching goals of the project.

A sample work plan format is presented below to show how a traditional work plan aligns with the logic model and project narrative.

• In this format, the table would be completed for each period of performance outcome. If a particular activity leads to multiple outcomes, it should be described under each outcome measure.

The work plan can be uploaded as a separate attachment to be submitted with the application. Name the file "Work Plan" and upload the document as a PDF file to the application submitted at www.grants.gov.

Period of Perfo Outcome: [from Outcome: logic model]	ormance s section and/or	Outcome Measure: [from Evaluation and Performance Measurement section]		[from Evaluation and Performance	
Strategies and Activities	Process Measure  [from Evaluation and Performance Measurement section]	Responsible Position / Party	Completion  Date		
1.					
2.					
3.					
4.					
5.					
6					

#### e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

CDC will monitor the cooperative agreement in partnership with the recipient to ensure mutual success in achieving the program outcomes, assess progress on objectives and make adjustments as needed to meet overall program objectives.

CDC will monitor the cooperative agreement through ongoing communication between CDC and the recipient via virtual/in-person meetings, conference calls, site visits, and the recipient's reporting (including work plan, process and outcome performance measures, monthly/annual summary reports, and financial reporting). CDC will assign at least one point of contact from DSTDP who will collaborate with the recipient through conference calls (at least monthly) and other routine communications. CDC will provide templates and guidance for monthly and annual summary reports. Post-award monitoring for cooperative agreements will include:

- Assessing the adequacy of the recipient's application in response to the NOFO description and requirements, working with the recipient to create a program implementation plan, and finalizing the evaluation plan,
- Monthly conference calls with the project primary investigator, completing monthly call reporting templates provided by CDC,
- Annual conference calls with the project business official, and
- Participation in webinars and recipient meetings.

## f. CDC Program Support to Recipients

In a cooperative agreement, CDC and the recipients share responsibility for successfully implementing the award and achieving identified project outcomes. As a result, recipient collaboration is required with CDC's DSTDP. CDC will provide substantial involvement beyond regular performance and financial monitoring during the period of performance. Substantial involvement means that the recipient can expect federal programmatic partnership to accomplish the effort under the award.

CDC will partner with the recipient to ensure the success of the cooperative agreement by:

Making subject matter experts available, including scientific leadership, program
planning, evaluation, and senior leadership to foster strategic discussions on the best
approaches to achieve program goals,

- Conducting an in-person or virtual kick-off meeting with DSTDP leadership and staff at the beginning of the five-year period of performance,
- Sharing scientific and policy reports, research publications, education media campaign updates, and other work,
- Providing data and expert opinion to inform project activities,
- Providing guidance and set standards on data collection, use, and submission requirements,
- Coordinating to improve the quality and effectiveness of the proposed program, including revising the work plan, evaluation strategy, products and services, and other elements,
- Fostering ongoing opportunities for networking, communication, coordination, and collaboration.
- Monitoring program performance using multiple approaches, such as standardized review
  of performance, recipient feedback and other data reports, to support program
  development, implementation, evaluation, and improvement,
- Facilitating program collaboration with other CDC programs and HHS offices to enhance and improve integration of services, and
- Collecting and disseminating information, best practices, lessons learned, and evaluation results (e.g., through conferences, guidance, material development, webinars, data sharing publications, other social media, participation in meetings, committees, and working groups related to the cooperative agreement).

#### **B.** Award Information

# 1. Funding Instrument Type:

CA (Cooperative Agreement)

CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

#### 2. Award Mechanism:

H25-Venereal Disease

#### 3. Fiscal Year:

2023

# 4. Approximate Total Fiscal Year Funding:

\$7,500,000

## **5. Total Period of Performance Funding:**

\$50,000,000

This amount is subject to the availability of funds.

**Estimated Total Funding:** 

\$50,000,000

## 6. Total Period of Performance Length:

5 year(s)

year(s)

## 7. Expected Number of Awards:

25

## 8. Approximate Average Award:

\$500,000

Per Budget Period

The average one-year award will be \$300,000 - \$500,000. The award amount is dependent on the amount of funding available and which strategies are funded.

## 9. Award Ceiling:

\$0

Per Budget Period

This amount is subject to the availability of funds.

#### 10. Award Floor:

\$0

Per Budget Period

## 11. Estimated Award Date:

September 29, 2023

## 12. Budget Period Length:

12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

### 13. Direct Assistance

Direct Assistance (DA) is not available through this NOFO.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

## C. Eligibility Information

## 1. Eligible Applicants

Eligibility Category:

- 00 (State governments)
- 01 (County governments)
- 02 (City or township governments)
- 04 (Special district governments)
- 05 (Independent school districts)
- 06 (Public and State controlled institutions of higher education)
- 07 (Native American tribal governments (Federally recognized))
- 08 (Public housing authorities/Indian housing authorities)
- 11 (Native American tribal organizations (other than Federally recognized tribal governments))
- 12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)
- 13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)
- 20 (Private institutions of higher education)
- 25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))
- 99 (Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility")

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)

Local governments or their bona fide agents

Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau

State controlled institutions of higher education

American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

Non-government Organizations

American Indian or Alaska native tribally designated organizations

# 2. Additional Information on Eligibility

All applicants must submit a letter (one page or less) from the clinical service provider where the work will be implemented. Title this document "Clinical Provider" and upload it as a PDF file in the application submitted at <a href="www.grants.gov">www.grants.gov</a>. Applicants who do not provide this statement will be considered non-responsive to this NOFO and will not receive further review.

Please note: Sections 317 and 318 of the PHS Act authorize funding to States, political subdivisions of States, and any other public and nonprofit private entities, but do not authorize awards to for-profit entities.

Applicants who do not include Strategies A and B in their application will be deemed non-responsive and their application will not be reviewed.

Applicants must clearly state the strategies to which they are applying in the Project Abstract Summary. When including this information in the Project Abstract Summary, please identify the strategies as they are used in the logic model; possible options are provided below.

- This application includes Strategies A and B.
- This application includes Strategies A, B, and C.

## 3. Justification for Less than Maximum Competition

N/A

# 4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:

No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

#### 5. Maintenance of Effort

Maintenance of effort is not required for this program.

# D. Application and Submission Information

## 1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the GSA website, SAM.gov, and Grants.gov- Finding the UEI.

## a. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number by registering in SAM.gov prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned to the registering organization.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-

recipients must provide their UEI numbers before accepting any funds.

# b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number and a Unique Entity Identifier (UEI). All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at <a href="SAM.gov">SAM.gov</a> and the <a href="SAM.gov">SAM.gov</a> Knowledge Base.

## c. Grants.gov:

The first step in submitting an application online is registering your organization at <a href="www.grants.gov">www.grants.gov</a>, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at <a href="www.grants.gov">www.grants.gov</a>.

All applicant organizations must register at <a href="www.grants.gov">www.grants.gov</a>. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	Award	Ingua an activa <b>S</b> A M account	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/ fsd-gov/ home.do Calls: 866-606-8220
2	Grants.gov	Authorized Organization Representative (AOR)  2. Once the account is set up the E-BIZ POC will be notified via email	SAM) to receive a UEI (SAM) which will allow you to register with Grants.gov and apply for federal funding.	Register early! Applicants can register within minutes.

4. This authorizes the AOR to	)
submit applications on behalf	of
the organization	

## 2. Request Application Package

Applicants may access the application package at www.grants.gov.

## 3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this notice of funding opportunity at <a href="https://www.grants.gov">www.grants.gov</a>.

## 4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

## a. Letter of Intent Deadline (must be emailed)

Due Date for Letter Of Intent 05/05/2023

05/05/2023

## **b.** Application Deadline

Due Date for Applications 06/05/2023

06/05/2023

11:59 pm U.S. Eastern Time, at <a href="www.grants.gov">www.grants.gov</a>. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which Grants.gov operations resume.

#### **Due Date for Information Conference Call**

Informational call will be held on Monday, April 24, 2023, from 2:00-3:00 pm Eastern Standard Time. If interested, please register here:

https://www.zoomgov.com/webinar/register/WN\_qwMeRAPzTS-Sx9yBfOG11w

Additional details will be posted here: <u>Funding Opportunity Announcements (FOAs) | STDs |</u> CDC.

## 5. Pre-Award Assessments

## Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at

https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a

review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at <a href="https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf">https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf</a>, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and UEI.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents \_ Procurement Policy.

## **Duplication of Efforts**

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

## 6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at <a href="https://www.grants.gov">www.grants.gov</a>.

#### 7. Letter of Intent

The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applicants.

In the LOI, please state whether you plan to apply for 1) strategies A and B only, or 2) strategies A, B, and C.

LOI must be sent via email to:

Ted Castellanos

Deputy Branch Chief, Program Development and Evaluation Branch

CDC/Division of STD Prevention

ipq1@cdc.gov

#### 8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at <a href="https://www.grants.gov">www.grants.gov</a>.

# 9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at <a href="www.grants.gov">www.grants.gov</a>. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at <a href="www.grants.gov">www.grants.gov</a>.

## 10. Project Narrative

(Unless specified in the "H. Other Information" section, maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. This includes the work plan. Content beyond the specified page number will not be reviewed.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at <a href="www.grants.gov">www.grants.gov</a>. The Project Narrative must include all of the following headings (including subheadings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section. Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

## a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

## b. Approach

## i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

#### ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

## iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan how these strategies will be evaluated over the course of the project period. See the Strategies and Activities section of the CDC Project Description.

#### 1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

## 2. Target Populations and Health Disparities

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Target Populations and Health Disparities requirements as described in the CDC Project Description.

## c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

 How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see <a href="http://www.hhs.gov/ocio/policy/collection/">http://www.hhs.gov/ocio/policy/collection/</a>.

- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

## d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

#### 11. Work Plan

(Included in the Project Narrative's page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

## 12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits

- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs could include the cost of collecting, managing, sharing and preserving data.

Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and upload it as a PDF file at <a href="https://www.grants.gov">www.grants.gov</a>. If requesting indirect costs in the budget, a copy of the indirect cost-rate

agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at <a href="https://www.grants.gov">www.grants.gov</a>.

The budget must follow the budget preparation guidance found here: <a href="https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.pdf">https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.pdf</a>

## 13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

## 14. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

## 15. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be

made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

# **16. Funding Restrictions**

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
  - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
  - o the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See <u>Additional Requirement (AR) 12</u> for detailed guidance on this prohibition and <u>additional guidance on lobbying for CDC recipients</u>.

- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.
- CDC funds may be used for laboratory costs to screen or monitor PrEP per CDC Guidelines for uninsured or underinsured people receiving PrEP in not-for-profit or governmental clinics.
- CDC funds may be used for mobile units and other novel engagement strategies.
- CDC funds cannot be used to cover the costs of antiretroviral medication, including PrEP
- Federal funds used for the purchase of supplies or equipment related to injection drug use must comply with current federal law.
- Recipients may not use funds to purchase family planning medications.
- Recipients may use funds to screen, diagnose, or treat STIs in persons who are uninsured and underinsured.
- Funds cannot be used to purchase medication for treatment of hepatitis C.

## 17. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:

https://www.cdc.gov/grants/additional-requirements/ar-25.html.

# 18. Other Submission Requirements

#### a. Electronic Submission:

Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

- **b. Tracking Number:** Applications submitted through <a href="www.grants.gov">www.grants.gov</a> are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when <a href="www.grants.gov">www.grants.gov</a> receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.
- **c. Validation Process:** Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to

applicants will then be generated by <a href="www.grants.gov">www.grants.gov</a> that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact <a href="www.grants.gov">www.grants.gov</a>. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.

https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=Get\_Started%2FGet\_Started.htm

- **d. Technical Difficulties:** If technical difficulties are encountered at <a href="www.grants.gov">www.grants.gov</a>, applicants should contact Customer Service at <a href="www.grants.gov">www.grants.gov</a>. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at <a href="support@grants.gov">support@grants.gov</a>. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.
- **e. Paper Submission:** If technical difficulties are encountered at <a href="www.grants.gov">www.grants.gov</a>, applicants should call the <a href="www.grants.gov">www.grants.gov</a> Contact Center at 1-800-518-4726 or e-mail them at <a href="support@grants.gov">support@grants.gov</a> for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

- 1. Include the www.grants.gov case number assigned to the inquiry
- 2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
- 3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application via email.

#### E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

#### a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants

Management Officials and Program Officials. <u>Non-responsive applications will not advance to Phase II review</u>. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

#### **b.** Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

- i. Approach
- ii. Evaluation and Performance Measurement
- iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements

i. Approach Maximum Points: 35

The review panel will assess eligible applications using the following review criteria which applies to both Strategies A and B. The review panel will evaluate the extent to which the applicant:

- (10 points) Describes their ability to reach priority population(s) disproportionately impacted by STIs in their proposed clinic's catchment area (e.g., adolescents and young adults, racial, ethnic, sexual, and gender minorities, women of reproductive age, and/or persons experiencing incarceration and/or homelessness).
  - Applicants must choose to focus on one or more of these populations based on the STI health disparities in their jurisdiction.
- (10 points) Describes their ability to reach communities with high STI burden and high need for STI clinical services by providing the following statistics for the two most recent years of available data:
  - o (Required): the proposed service area's population in total and by age, gender, race/ethnicity, as well as the proportion living under the federal poverty level,
  - o (Required): the current availability of STI and sexual health care services in the proposed service area,
  - o (Required): the number of cases and rates of HIV, gonorrhea, chlamydia, and primary and secondary (P&S) syphilis by gender,
  - (Optional but recommended data points, will consider as provided): the number of male HIV, gonorrhea, chlamydia, and P&S syphilis cases by sex of sex partners, and
  - (Optional but recommended data points, will consider as provided): the number of urethral gonorrhea cases and number of P&S syphilis diagnoses for the provided time period and the proportion of these cases diagnosed in 1) emergency rooms/urgent cares; 2) primary care clinics; 3) STI/family planning clinics; or 4) other clinics.
- (3 points) Presents outcomes that are consistent with the period of performance outcomes described in the CDC Project Description and logic model.

- (3 points) Describes an overall approach and activities consistent with the CDC Project Description and logic model.
- (3 points) Describes activities that are achievable, appropriate to achieve the outcomes of the project, and evidence-based (to the degree practicable).
- (3 points) Shows that the proposed use of funds is an efficient and effective way to implement the activities and attain the period of performance outcomes.
- (3 points) Presents a work plan aligned with the strategies/activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC.

#### ii. Evaluation and Performance Measurement

**Maximum Points: 30** 

The review panel will evaluate the extent to which the applicant:

- (15 points) Proposes an evaluation plan that is realistic, consistent with the work plan and the CDC evaluation performance strategy, can demonstrate performance outcomes, successes and areas for improvement.
- (10 points) Describes how performance measurement and evaluation findings will be reported and used to demonstrate the outcomes of the NOFO and for continuous program quality improvement.
- (5 points) Describes for the proposed performance measures listed in the CDC Evaluation and Performance Measurement Strategy section:
  - Available baseline measures (including definitions for numerators and denominators used and latest reporting year or time frame),
  - Source(s) of data to calculate the measures (i.e., which programs or agencies "own or control" the data),
  - o The use of the measures for program improvement and clinical capacity,
  - o The ability to report on the measures every six months, and
  - o Anticipated barriers to obtaining and calculating the proposed measures.

# iii. Applicant's Organizational Capacity to Implement the Approach

**Maximum Points: 35** 

The review panel will evaluate the extent to which the applicant:

- (10 points) Provides an adequate staffing plan, including an organizational chart, CVs, position descriptions and project management structure that demonstrate sufficient capacity to meet the goals of the proposed project and defines staff roles and reporting structure. Any planned consultancies or subcontracts should be included in the project management structure.
  - o Describes their authority and ability to hire or contract in a timely fashion for and maintain adequate personnel resources with applicable skills and expertise.
- (10 points) Describes relevant experience and capacity (management, technical, and clinical) to implement each of the required strategies and associated activities and achieve the project outcomes.
  - Non-clinical applicants, including state, local, and territorial health departments, must describe the capacity for the proposed clinic(s). Applicants should describe

the relationship to the proposed clinic(s) and describe how funds will be directed to the clinic(s), including mechanisms and timelines to obligate funds.

- (5 points) Describes experience and capacity to coordinate with internal and external stakeholders, including local public health organization(s), to foster and coordinate community engagement.
- (5points) Describes experience and capacity to implement the evaluation plan, measure, and report on performance measures, and implement the data management plan.
- (5 points) Describes the budget management and financial reporting capacity, including the management of travel requirements, the full capability, accountability and expertise to meet deadlines, track funds, submit reports, manage the required procurement efforts, and to write and award contracts in accordance with 45 CFR 75 by a given due date.

Budget Maximum Points: 0

The budget will not be scored; however, the budget will be assessed to determine whether it aligns with the proposed work plan.

#### c. Phase III Review

Phase III Review will be conducted after CDC's internal objective review process. The following factors may affect the funding decision and CDC's decision not to fund in order by score and rank.

- Preference to applicants demonstrating highest need and burden in their jurisdictions:
  - o Lowest number of STD clinics per 1,000,000 persons
  - Highest number of cases of urethral gonorrhea per 1,000 persons and/or P&S syphilis per 1,000 persons
  - o Highest percentage of urethral gonorrhea or P&S syphilis diagnosed in emergency department/urgent care (if data is provided by applicant)
- Preference to avoid duplication of services, especially for organizations currently receiving funding from any federal funding sources to provide similar sexual health services.
- Preference for applicants proposing to serve underserved populations and priority populations that are not addressed in other applications.

## Review of risk posed by applicants.

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs

or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

- (1) Financial stability;
- (2) Quality of management systems and ability to meet the management standards prescribed in this part;
- (3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards:
- (4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
- (5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

# 2. Announcement and Anticipated Award Dates

Awards are anticipated to be made by September 29, 2023.

#### F. Award Administration Information

#### 1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to annual SAM Registration and Federal Funding Accountability And Transparency Act Of 2006

(FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt.

# 2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at <a href="https://www.cdc.gov/grants/additional-requirements/index.html">https://www.cdc.gov/grants/additional-requirements/index.html</a>.

The HHS Grants Policy Statement is available at <a href="http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf">http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf</a>.

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: <a href="https://www.archives.gov/federal-register/cfr">https://www.archives.gov/federal-register/cfr</a>

*The following Administrative Requirements (AR) apply to this project:* 

# **Generally applicable ARs**:

#### NOTE: AR-37 is required on all NOFOs

- *AR-9: Paperwork Reduction Act Requirements*
- AR-10: Smoke-Free Workplace Requirements
- *AR-11: Healthy People 2030*
- *AR-12: Lobbying Restrictions*
- AR-14: Accounting System Requirements
- AR-24: Health Insurance Portability and Accountability Act Requirements
- AR-25: Data Management and Access
- AR-26: National Historic Preservation Act of 1966
- AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009
- <u>AR-30: Information Letter 10-006, Compliance with Section 508 of the Rehabilitation</u> Act of 1973
- *AR-31: Research Definition*
- AR-32: Enacted General Provisions
- AR-34: Accessibility Provisions and Non-Discrimination Requirements
- AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020

## ARs applicable to HIV/AIDS Awards:

- AR-4: HIV/AIDS Confidentiality Provisions
- AR-5: HIV Program Review Panel Requirements
- AR-6: Patient Care

# Organization-specific ARs:

- AR-8: Public Health System Reporting Requirements
- *AR-15: Proof of Non-profit Status*
- AR-23: Compliance with 45 CFR Part 87

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR 75, can be found at: <a href="https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75">https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75</a>

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which you agree, as a condition of receiving the grant, to administer your programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <a href="https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html">https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html</a>.

- For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see <a href="https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html">https://www.lep.gov</a>.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see <a href="http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html">http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html</a>.
- HHS funded health and education programs must be administered in an environment free
  of sexual harassment, see <a href="https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html">https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html</a>.
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <a href="https://www.hhs.gov/conscience/conscience-protections/index.html">https://www.hhs.gov/conscience/conscience-protections/index.html</a> and <a href="https://www.hhs.gov/conscience/religious-freedom/index.html">https://www.hhs.gov/conscience/religious-freedom/index.html</a>.

## 3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the project period. Also, reporting is a requirement for recipients

who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	At least twice within the budget period. CDC will provide guidance related to reporting frequency and analysis of data to inform program improvement.	Yes
Federal Financial Reporting Forms	90 days after the end of the budget period.	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes

#### a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

#### Performance Measurement

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching target populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

#### **Evaluation**

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publicly available website.
- How evaluation findings will be used to ensure continuous quality and program improvement.
- How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

#### **b.** Annual Performance Report (APR) (required)

The recipient must submit the APR via <a href="www.Grantsolutions.gov">www.Grantsolutions.gov</a> no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- Evaluation Results: Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- Work Plan: Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.

#### Successes

 Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.

- Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
- Recipients must describe success stories.

#### Challenges

- Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
- Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

## CDC Program Support to Recipients

 Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.

# • Administrative Reporting (No page limit)

- o SF-424A Budget Information-Non-Construction Programs.
- Budget Narrative Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- o Indirect Cost Rate Agreement.

The recipients must submit the Annual Performance Report via <u>www.Grantsolutions.gov</u> no later than 120 days prior to the end of the budget period.

# c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

For each of the NOFO's program strategies, a partial list of performance measures is presented above. A full list of proposed outcomes and measures will be provided by DSTDP project staff within the first 6 months of the start of the performance period. CDC will work with recipients to finalize their detailed Evaluation Plan, including a Work Plan and Data Management Plan (DMP), in accordance with CDC program guidance. CDC will finalize these measures, their specific definitions, benchmarks, submission frequency, and submission templates in consultation with recipients within the first six months of the period of performance.

Recipients will submit biannual performance measures reports to CDC using the templates provided by the CDC evaluation team.

#### d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated

obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

# e. Final Performance and Financial Report (required)

The Final Performance Report is due 90 days after the end of the period of performance. The Final FFR is due 90 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

## 4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, <a href="http://www.USASpending.gov">http://www.USASpending.gov</a>.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over \$25,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf,
- https://www.fsrs.gov/documents/ffata\_legislation\_110\_252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA.

# **5.** Reporting of Foreign Taxes (International/Foreign projects only)

- A. Valued Added Tax (VAT) and Customs Duties Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.
- B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) ("United States foreign assistance funds"). Outlined below are the specifics of this requirement:
- 1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]
- 2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.
- 3) Terms: For purposes of this clause:
- "Commodity" means any material, article, supplies, goods, or equipment;
- "Foreign government" includes any foreign government entity;
- "Foreign taxes" means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.
- 4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.
- 5) Contents of Reports: The reports must contain:
- a. recipient name;
- b. contact name with phone, fax, and e-mail;
- c. agreement number(s) if reporting by agreement(s);
- d. reporting period;
- e. amount of foreign taxes assessed by each foreign government;
- f. amount of any foreign taxes reimbursed by each foreign government;
- g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

## 6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

- (1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award:
- (2) By the HHS awarding agency or pass-through entity for cause;
- (3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or
- (4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

# **G.** Agency Contacts

Email:

ipq1@cdc.gov

CDC encourages inquiries concerning this notice of funding opportunity.

#### **Program Office Contact**

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	For programm:	aric	technical	i accictance	contact.

First Name:
Ted
Last Name:
Castellanos
Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
Address:
Telephone:
770-488-3665

#### **Grants Staff Contact**

# For financial, awards management, or budget assistance, contact:

First Name:

Rhonda

Last Name:

Burton

**Grants Management Specialist** 

Department of Health and Human Services

Office of Grants Services

Address:

District Chamblee, Bldg. 2900 TCU-3

Atlanta, GA 30341

Telephone:

770-488-1381

Email:

bgr2@cdc.gov

For assistance with **submission difficulties related to** <u>www.grants.gov</u>, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

#### **H.** Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at <a href="www.grants.gov">www.grants.gov</a>. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

#### For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

Resumes / CVs

Position descriptions

Letters of Support

**Organization Charts** 

Non-profit organization IRS status forms, if applicable

Indirect Cost Rate, if applicable

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

Bona Fide Agent status documentation, if applicable

- Letter stating that applicant is a clinical service provider
- Letter of support from local public health agency, if applicable
- Table summarizing clinic patient visits and demographic characteristics (from applicants with an existing clinic)

#### **Reference Materials:**

Overview References:

- 1. National Center for HIV, Viral Hepatitis, STD, and TB Prevention. (2021, September 1). *Preliminary 2021 Surveillance Data*. Centers for Disease Control and Prevention. <u>Preliminary 2021 STD Surveillance Data (cdc.gov)</u>
- 2. Kreisel, et al. (2021). Sexually Transmitted Infections Among US Women and Men: Prevalence and Incidence Estimates, 2018. *Sex Transm Dis*, 2021;48(4):208-214.

#### I. Glossary

**Activities:** The actual events or actions that take place as a part of the program.

# Administrative and National Policy Requirements, Additional Requirements (ARs):

Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see <a href="https://www.cdc.gov/grants/additional-requirements/index.html">https://www.cdc.gov/grants/additional-requirements/index.html</a>. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

**Approved but Unfunded:** Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

**Assistance Listings:** A government-wide collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

**Assistance Listings Number:** A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

**Award:** Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

**Budget Period or Budget Year:** The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

**Carryover:** Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

**Competing Continuation Award:** A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the "life" of the award).

**Continuous Quality Improvement:** A system that seeks to improve the provision of services with an emphasis on future results.

**Contracts:** An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

**Cooperative Agreement:** A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

**Cost Sharing or Matching:** Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

**Direct Assistance:** A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. <a href="https://www.cdc.gov/grants/additional-requirements/index.html">https://www.cdc.gov/grants/additional-requirements/index.html</a>.

**Evaluation (program evaluation):** The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

**Evaluation Plan:** A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is

used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

**Federal Funding Accountability and Transparency Act of 2006 (FFATA):** Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at <a href="https://www.USAspending.gov">www.USAspending.gov</a>.

**Fiscal Year:** The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

**Grant:** A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

**Grants.gov:** A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at <a href="www.grants.gov">www.grants.gov</a>.

**Grants Management Officer (GMO):** The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

**Grants Management Specialist (GMS):** A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

**Health Disparities:** Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

**Health Equity:** Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

**Health Inequities:** Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

**Healthy People 2030:** National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

**Inclusion:** Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention

will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

**Indirect Costs:** Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

**Letter of Intent (LOI):** A preliminary, non-binding indication of an organization's intent to submit an application.

**Lobbying:** Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

**Logic Model:** A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

**Maintenance of Effort:** A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

## Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA):

Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

**Nonprofit Organization:** Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

**Notice of Award (NoA):** The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

**Objective Review:** A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant

aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

**Outcome:** The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

**Performance Measurement:** The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

**Period of performance –formerly known as the project period - :** The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

**Period of Performance Outcome:** An outcome that will occur by the end of the NOFO's funding period

**Plain Writing Act of 2010:** The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

**Program Strategies:** Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

**Program Official:** Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

**Public Health Accreditation Board (PHAB)**: A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation <a href="http://www.phaboard.org">http://www.phaboard.org</a>.

**Social Determinants of Health:** Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

**Statute:** An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

**Statutory Authority:** Authority provided by legal statute that establishes a federal financial assistance program or award.

**System for Award Management (SAM):** The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing <a href="www.grants.gov">www.grants.gov</a> to verify identity and pre-fill organizational information on grant applications.

**Technical Assistance:** Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

**UEI:** The Unique Entity Identifier (UEI) number is a twelve-digit number assigned by SAM.gov. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a UEI number as the Universal Identifier. UEI number assignment is free. If an organization does not know its UEI number or needs to register for one, visit <a href="https://www.sam.gov">www.sam.gov</a>.

**Work Plan:** The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

## **NOFO-specific Glossary and Acronyms**

**Sexual health services:** Sexual health services cover broad preventive and treatment approaches related to sexual health including taking a sexual history and risk assessment; education and counseling; testing and treatment for HIV and other STIs; hepatitis B and C screening; PrEP/nPEP for HIV prevention; contraception; condoms; and recommended vaccinations.