

Centers for Disease Control and Prevention

National Center for HIV-AIDS, Viral Hepatitis, STD, and TB Prevention

Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States

CDC-RFA-PS20-2010

Application Due Date: 03/25/2020

Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-PS20-2010. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Notice of Funding Opportunity (NOFO) Title:

Integrated HIV Programs for Health Departments to Support Ending the HIV Epidemic in the United States

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 https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html (See section 45 CFR 46.102(d)).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-PS20-2010

E. Assistance Listings (CFDA) Number:

93.940

F. Dates:

1. Due Date for Letter of Intent (LOI): **N/A**

Is a LOI: Not Applicable

Letters of Intent (LOI) are not requested or required as part of the application for this NOFO.

2. Due Date for Applications: **03/25/2020**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Date for Informational Conference Call: **02/04/2020**

Component A: Tuesday, February 4, 2020 at 2:00 pm (EST)

Registration Link: https://globalmeetwebinar.webcasts.com/starthere.jsp?ei=1280904&;tp_key=90383bbac

Component B: Wednesday, February 5, 2020 at 2:00 pm (EST)

Registration Link: https://globalmeetwebinar.webcasts.com/starthere.jsp?ei=1280906&;tp_key=88f751d0ae

Component C: To Be Announced

G. Executive Summary:

1. Summary Paragraph:

The CDC announces the availability of fiscal year 2020 funds for a Notice of Funding Opportunity (NOFO) to support the development and implementation of programs tailored to

ending the HIV epidemic in America. Recent scientific advances in HIV prevention and treatment have made ending the HIV epidemic in America a realistic possibility. Under the leadership of President Trump, the Department of Health and Human Services (DHHS) has set an ambitious goal of reducing all new HIV infections by 75% in 5 years and by 90% by 2030. Reaching this target requires a coordinated national effort that will focus first on the 50 most affected U.S. jurisdictions- 48 counties, Washington DC, and San Juan PR as well as seven states.

With funding from DHHS, this NOFO for the "Ending the HIV Epidemic" (EHE) initiative is intended to build on the on-going activities funded through *PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments* to strategically advance (i.e., initiate new or expand existing) HIV prevention efforts. The strategies proposed herein embody discrete areas of activity, which, based on the best available scientific evidence and experience, CDC believes will most rapidly accelerate efforts to reduce new HIV infections and merit undertaking. CDC recognizes that local public health must be responsive to local circumstances. Thus, in response to each strategy, CDC strongly encourages applicants to propose disruptively innovative activities unique to their jurisdiction's local context. Component A is the core component of this NOFO and therefore is required. Funding levels will be determined by formulas reflecting a base funding amount, HIV disease prevalence, number of counties within the health department jurisdiction (if applicable), and program performance (in subsequent years). Funding for Components B and C are contingent upon submission of application for funding under Component A. Applicants should submit one application that is responsive to the requirements outlined under each of the components for which they intend to apply.

Funding is subject to the availability of appropriated funds. Funding availability in subsequent fiscal years will be determined by satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government. The amount available, in addition to the ceiling amounts stated, is based on current projections. Future year ceiling and award amounts may be adjusted to reflect any changes. CDC may require recipients to submit a revised budget and work plan, as necessary, to appropriately reflect the actual funding amounts provided in the Notice of Award(s).

a. Eligible Applicants: Limited

b. NOFO Type: Cooperative Agreement

c. Approximate Number of Awards: 48

Component A: 32

Component B: 8 (beginning in Year 2)

Component C: 5 - 8

d. Total Period of Performance Funding: $109,000,000

e. Average One Year Award Amount: $0

Component A: Not applicable. Funding will be determined by formulas reflecting a base funding amount, HIV disease prevalence, number of counties within the health department jurisdiction (if applicable), and program performance (in subsequent years). Funding will vary by jurisdiction.

Component B: $450,000 - $725,000; Funding begins in Year 2

Component C: $400,000 - $800,000

f. Number of Years of Award: 5
g. Estimated Award Date: 06/01/2020
h. Cost Sharing and / or Matching Requirements: N

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

For more than 35 years, HIV has affected millions of Americans of whom more than 700,000 have died. In recent years, deaths among persons with HIV have declined, while the number of people with HIV has increased. According to CDC, an estimated 1.1 million persons are living with HIV and approximately 15% are unaware they have HIV. [1, 2] Unless effectively treated to achieve viral suppression, HIV can be transmitted to others and leads to premature death. However, persons with HIV who use antiretroviral therapy (ART) and reach and maintain an undetectable viral load in their blood can have a nearly normal life expectancy and have effectively no risk of transmitting HIV to others through sex.[3]

The Administration's approach to reducing HIV infections in the United States - or High Impact Prevention (HIP) - focuses on a strategic combination of scientifically proven, cost-effective, and scalable structural, behavioral, and biomedical interventions that target persons both with and without HIV in geographic areas where infections are most concentrated. Reaching and maintaining viral suppression among people with HIV is the most effective way to reduce new infections. Efforts that uniquely target HIV-negative persons, such as behaviors that minimize risk, pre-exposure prophylaxis (PrEP), non-occupational post-exposure prophylaxis (nPEP), and comprehensive syringe service programs (SSPs), are critical supplements to effective treatment. Behavioral strategies (e.g., use of condoms, reduced number of sexual and injection-sharing partners) are proven effective strategies to reduce risk of HIV transmission in both those with and without HIV.[5] Community partners are uniquely positioned to complement and extend the reach of HIV prevention efforts implemented by state and local health departments. Thus, it is critical that health departments consider the most productive means for reaching out and engaging the community and other partners.

Since the late 1980s, CDC has formally partnered with state and local health departments to conduct HIV surveillance and expand the impact and reach of HIV prevention in affected communities. Additional HIV prevention partners include primary and HIV-specialty care providers, tribal governments and/or tribally designated organizations, community and faith-based organizations, and education agencies, among others. Together with the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Service Administration (SAMHSA), the National Institutes of Health (NIH), Indian Health Service (IHS), and the Office of the Assistant Secretary for Health, CDC seeks to ensure every

American knows their HIV status and is durably linked to and engaged with comprehensive and effective HIV prevention and treatment services.

b. Statutory Authorities

Section 318(b-c) of the Public Health Service Act (42 USC § 247c(b-c)), as amended, and the Consolidated Appropriation Act of 2016 (Pub. L. 114-113).

c. Healthy People 2030

This NOFO addresses the Healthy People 2030 focus on HIV: http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=22

d. Other National Public Health Priorities and Strategies

Other National Public Health Priorities

Ending the HIV Epidemic: A Plan for America: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

The HHS Strategic Plan, FY 2018-2022: https://www.hhs.gov/about/strategic-plan/strategic-goal-2/index.html

National HIV/AIDS Strategy: Update 2020: https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update

CDC Division of HIV/AIDS Prevention Strategic Plan 2017-2020: https://www.cdc.gov/hiv/pdf/dhap/cdc-hiv-dhap-external-strategic-plan.pdf

CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Strategic Plan Through 2020: https://www.cdc.gov/nchhstp/docs/NCHHSTP-Strategic-Plan-through-2020-508.pdf

HIV Care Continuum: https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum

e. Relevant Work

PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments

PS19-1906: Strategic Partnerships and Planning to Support Ending the HIV Epidemic in the United States

PS19-1901: Strengthening STD Prevention and Control for Health Departments (STD PCHD)

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

Strategies and Activities	Short-Term Outcomes	Intermediate Outcomes
Component A: Ending the HIV Epidemic Initiative (EHE) - Core		
Diagnose • Expand or implement routine opt-out HIV screening in healthcare and other institutional settings in high prevalence communities • Develop locally tailored HIV testing programs to reach persons in non-healthcare settings • Increase at least yearly re-screening of persons at elevated risk for HIV per CDC testing guidelines, in healthcare and non-healthcare settings	• **Increased routine opt-out HIV screenings in healthcare and other institutional settings** • **Increased local availability of and accessibility to HIV testing services** • **Increased HIV screening and re-screening among persons at elevated risk for HIV**	• **Increased knowledge of HIV status** • **Reduced new HIV diagnoses**
Treat • Ensure rapid linkage to HIV medical care and antiretroviral therapy (ART) initiation for all persons with newly diagnosed HIV • Support re-engagement and retention in HIV medical care and treatment adherence, especially for persons who are not recipients of Ryan White HIV/AIDS Programs	• **Increased rapid linkage to HIV medical care** • **Increased early initiation of ART** • **Increased immediate re-engagement to HIV prevention and treatment services for PWH who have disengaged from care** • **Increased support to providers for linking, retaining, and re-engaging persons with HIV (PWH) to care and treatment**	• **Increased receipt of HIV medical care among persons with HIV** • **Increase viral suppression among persons living with diagnosed HIV**
Prevent • Accelerate efforts to increase pre-exposure prophylaxis (PrEP) use, particularly for populations with the highest rates of new HIV diagnoses and low PrEP use among those with indications for PrEP • Increase availability, use, and access to and quality of comprehensive syringe services programs (SSPs)	• **Increased screening for PrEP indications among HIV-negative clients** • **Increased referral and rapid linkage of persons with indications for PrEP** • **Increased access to SSPs**	• **Increased PrEP prescriptions among persons with indications PrEP** • **Increased knowledge about the services and evidence-base of SSPs in communities** • **Increased quality of evidence-based SSP service delivery**
Respond • Develop partnerships, processes, data systems, and policies to facilitate robust, real-time cluster detection and response • Investigate and intervene in networks with active transmission • Identify and address gaps in programs and services revealed by cluster detection and response	• **Increased health department and community engagement for cluster detection and response** • **Improved surveillance data for real-time cluster detection and response** • **Improved policies and funding mechanisms to respond to and contain HIV clusters and outbreaks**	• **Improved response to HIV transmission clusters and outbreaks**
Component B: HIV Incidence Surveillance		
• Work with stakeholders (e.g., community, laboratories, and providers) to identify best practices for implementing a recency-based incidence surveillance • Conduct recency-based HIV incidence surveillance in selected jurisdictions • Review incidence results from a CD4 depletion model and a recency-based assay model	• Improved coordination with stakeholders including community, laboratory, and clinical providers to develop recency-based incidence surveillance • Increased capacity to collect recency-based assays from all persons aged 13 years and older with a new HIV diagnosis	• **Estimate HIV incidence in selected jurisdictions using a recency-based assay** • Review HIV incidence using a CD4 depletion model and a recency-based assay model.
Component C: Scaling up HIV prevention services in STD clinics		
• Conduct assessment of clinic infrastructure to document current HIV/STD prevention services, identify gaps, and assess service quality • Implement evidence-based approaches to scale up capacity for sexual risk assessments, self-collected STD testing, timely treatment, and HIV-related tests • Expand capacity of STD clinics to offer PrEP/nPEP and strengthen clinic and laboratory capacity for recommended follow-up visits • Optimize linkage to, retention in, and re-engagement in HIV medical care • Facilitate partnerships with community HIV clinical providers, health departments and community based organizations for implementation of the EHE	• **Increased identification of new HIV and STD infections in STD specialty clinics** • **Increased rapid linkage to care for individuals newly diagnosed with HIV at STD specialty clinic** • **Increased identification of virally unsuppressed people in STD specialty clinics** • **Increased re-engagement to care for persons living with HIV who are not virally suppressed** • **Increased screening for PrEP/nPEP indication in STD specialty clinics** • **Increased PrEP-eligible individuals in STD specialty clinics who are offered and initiate PrEP, if indicated**	• Increased knowledge of HIV status • Increase viral suppression among persons living with diagnosed HIV • Increase persons receiving PrEP/nPEP.

i. Purpose

The purpose of this NOFO is to implement comprehensive HIV programs, that complement programs, such as the Ryan White program and other HHS programs, designed to support ending the HIV epidemic in America by leveraging powerful data, tools and resources to reduce new HIV infections by 75% in 5 years.

ii. Outcomes

The program is expected to demonstrate measurable progress toward addressing the short-term and intermediate outcomes that appear in bold in the NOFO logic model. Indicators that quantify these outcomes are described in the section entitled CDC Evaluation and Performance Measurement Strategy.

Expected short-term and intermediate outcomes include the following:

Component A:
Diagnose

- Increased routine opt-out HIV screenings in healthcare and other institutional settings
- Increased local availability of and accessibility to HIV testing services
- Increased HIV screening and re-screening among persons at elevated risk for HIV
- Increased knowledge of HIV status (Intermediate Outcome)
- Reduced new HIV diagnoses (Intermediate Outcome)

Treat

- Increased rapid linkage to HIV medical care
- Increased early initiation of ART
- Increased immediate re-engagement to HIV prevention and treatment services for PWH who have disengaged from care
- Increased receipt of HIV medical care among persons with HIV (Intermediate Outcome)
- Increased viral suppression among PWH (Intermediate Outcome)

Prevent

- Increased screening for PrEP indications among HIV-negative clients
- Increased referral and rapid linkage of persons with indications for PrEP
- Increased access to SSPs
- Increased PrEP prescriptions among persons with indications for PrEP (Intermediate Outcome)
- Increased knowledge about the evidence-base of SSPs in communities (Intermediate Outcome)
  Increased quality of evidence-based SSP service delivery (Intermediate Outcome)

Respond

- Increased health department and community engagement for cluster detection and response
- Improved surveillance data for real-time cluster detection and response
- Improved policies and funding mechanisms to respond to and contain HIV clusters and outbreaks
- Improved response to HIV transmission clusters and outbreaks (Intermediate Outcome)

Component B:

- Estimate HIV incidence in selected jurisdictions using a recency-based assay

Component C:

- Increased identification of new HIV infections in STD specialty clinics
- Increased rapid linkage to care for individuals newly diagnosed with HIV infection at STD specialty clinic
- Increased identification of virally unsuppressed people in STD specialty clinics
- Increased re-engagement to care for persons living with HIV infection who are not virally suppressed
- Increased screening for PrEP/nPEP indication in STD specialty clinics
- Increased PrEP-eligible individuals in STD specialty clinics who are offered and initiate PrEP, if indicated

iii. Strategies and Activities

Component A: Ending the HIV Epidemic Initiative (EHE) - Required Core Component

The strategies and activities included in Component A of this NOFO are designed to be complementary to the strategies and activities funded by *PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments*. Jurisdictions should carefully evaluate their existing PS18-1802 supported prevention and surveillance portfolio to ensure that activities are being brought to scale and focused on specific populations based upon disease burden, and as outlined by the EHE initiative. If needed, programmatic changes should be made to maximize the impact of available resources in the targeted jurisdictions. Examples included below represent possible activities. However, jurisdictions should consider innovative strategies that better align with the needs of their local jurisdiction. Any proposed new activity should include the rationale for the approach or a brief summary of the evidence that justifies its inclusion. The process of identifying innovative strategies will occur in collaboration with CDC during the first 3 months of the project. When applicable, jurisdictions are encouraged to use and adapt HHS, CDC, HRSA, IHS, or other campaigns to increase knowledge about and promote HIV prevention, including PrEP effectiveness, availability and uptake, and decrease misinformation about PrEP to a broad population. CDC anticipates that jurisdictions may collaborate on the development of communications materials, resources, and other products. HHS/CDC and funded jurisdictions may find it advantageous to co-brand these materials. In such cases, the funding recipient will work with HHS/CDC to assure that all appropriate permissions are obtained, and materials are appropriately reviewed and approved by

HHS/CDC. All newly developed co-branded materials and/or materials that include the HHS and CDC logos must be prepared with substantial involvement from CDC.

The strategies and activities included in Component A were strategically selected to maximize the ability of all jurisdictions to reach the goals of the EHE initiative and to focus efforts and facilitate transfer of knowledge and best practices from the Phase 1 jurisdictions (see the *Eligibility Information* section for a list of Phase 1 jurisdictions) to other jurisdictions so that EHE goals can be achieved by 2030. CDC's expectations are that all strategies and activities will be implemented using the principles of High-Impact Prevention (HIP). However, a jurisdiction will have the opportunity to opt-out of some activities (e.g., implementation is not currently feasible due to local or state laws), with the exception of any requirements listed as mandatory. A jurisdiction requesting to opt-out of an activity will be required to provide CDC with a full justification that is included in the application for funding, before a waiver will be approved. Proposed strategies and activities should be consistent with and responsive to EHE plans newly developed or enhanced using funds awarded under *PS19-1906: Strategic Partnerships and Planning to Support Ending the HIV Epidemic in the United States*.

Additionally, this program allows each jurisdiction to maximize the impact of federal HIV prevention funding, strengthen implementation of HIP, align resources to better match the geographic burden of HIV infections, and improve data collection for public health action. CDC strongly encourages applicants to coordinate with partners such as HRSA HIV/AIDS Bureau and Bureau of Primary Health Care funded recipients, IHS funded recipients, tribal governments and/or tribally designated organizations, STD, viral hepatitis, and TB programs, other surveillance programs, laboratory units, other health agencies, community-based and faith-based organizations, community health centers, lesbian, gay, bisexual and transgender (LGBT) health centers, STD and TB clinics, local education agencies, hospitals, specialty clinics, other non-governmental organizations, and criminal justice and correctional facilities to implement comprehensive HIV programs within the jurisdiction.

Health department funding recipients are required to establish a new or expand an existing EHE advisory group or committee, as a standing or ad hoc committee, as allowed by planning group policies, procedures, and/or bylaws, to: 1) advise the health department funding recipient on EHE-related priorities and activities; and 2) ensure ongoing representation from the community throughout the 5-year project period. Additionally, health department funding recipients must adhere to guidance provided in the EHE Planning Program Guidance when establishing criteria for recruiting advisory group or committee members. At a minimum, the composition of the advisory group or committee must be inclusive of representatives from the Phase 1 counties (e.g., health department staff, community members) and members of local communities affected by or living with HIV who may not have been fully heard or may not have felt fully engaged in the past. The proposed structure and role and responsibilities of the group must be described in the EHE plan as well as the PS20-2010 application for funding.

Applicants are eligible to use up to **10%[a]** of the approved total funding amount to:

1. enhance and expand integrated screening activities (e.g., screening for STDs, viral hepatitis, and/or TB), conducted in conjunction with HIV testing, with accompanying referral for prevention and care services; and/or
2. diagnose and treat STDs for uninsured or underinsured people receiving care in not-for-

profit or governmental clinics, when conducted in conjunction with HIV testing and provided that these facilities document their ability to provide safety-net STD clinical preventive services as per CDC guidance. At a minimum, clinics receiving assistance should have the capacity to rapidly diagnose and treat bacterial STDs.[b]

HIV surveillance data are essential for monitoring HIV trends; detecting HIV clusters; identifying persons in need of critical services, including partner services and linkage to care; assessment for enhanced support services; and guiding public health action. Moreover, HIV surveillance provides data critical to monitoring the success of efforts to end the HIV epidemic. In accordance with existing surveillance standards, recipients should strengthen HIV surveillance systems, including developing secure means for timely and accurate reporting of HIV diagnoses and other HIV-related laboratory test results (within two months of the specimen collection date) for assessment of patient needs to maximize real-time linkage to partner services, care, and essential support services. This is a mandatory program requirement and jurisdictions cannot opt out of this program requirement. Failure to implement and maintain comprehensive collection and reporting of HIV laboratory data will result in the restriction of funds.

EHE Health Department Jurisdictions with One or More Phase One Counties

Recipients with one or more Phase 1 counties must ensure that at least 70% of the total resources received are directed to the local EHE jurisdiction(s). Recipients may use the remaining funds to support: 1) infrastructure, 2) activities and services, that will be provided by the recipient, and 3) the anticipated support the recipient will provide to the Phase 1 counties within their respective jurisdictions. If a Phase 1 county health department(s) does not have the capacity to manage the funds, the recipient may request to provide less than 70% of funding to ensure adequate oversight and implementation of program activities within the Phase 1 counties. However, the recipient must submit, with the application, a letter of concurrence or agreement (LOC/LOA), obtained from each Phase 1 county in the health department jurisdiction, indicating: 1) the current inability to manage the funds and/or fully implement the required EHE activities, in accordance with the NOFO; and 2) their preference for the recipient to retain full or partial funding until a time in which the necessary capacity is established. Additionally, the recipient must describe in detail how they will assist with building the capacity of the Phase 1 county over the 5-year project period. Included must be a timeline for the transition of fiscal and/or programmatic management and oversight to the Phase 1 county, if applicable and deemed appropriate. Official approval will be granted via written response from CDC. To ensure that resources are reaching the Phase 1 counties, each funded jurisdiction will be required to report annually to CDC on the amount of funding allocated to these areas. Additionally, funding should be allocated in a manner that ensures services are targeted to appropriate areas and expand and/or enhance the ability of local areas to increase access to services where challenges currently exist.

Note: The following documents do not count toward the page limit for the Project Narrative. Applicants must file LOC/LOA with the Phase 1 County(s), as appropriate, name the file(s) LOC," and upload the document(s) as a PDF file under "Other Attachments Forms".

EHE Health Department Jurisdictions without Phase One Counties

For the seven states that do not have identified counties, efforts should be made to allocate

funding according to the epidemiologic, surveillance, and other available data sources to inform program efforts and assist in program planning, implementation and evaluation. Recipients are encouraged to use the most current epidemiological profile to inform local program efforts and assist in program planning, implementation, and evaluation. Specifically, to ensure resources reach the areas (e.g., county, city, etc.) of greatest need, adequate resources should be allocated to areas that have at least **30%** of the state's HIV burden. Recipients should utilize local epidemiologic, surveillance, and other available data as well as locally developed funding formulas to determine the appropriate amount of funding to be allocated to each area. Funded jurisdictions will be required to report annually to CDC the amount of funding allocated to the above-referenced areas. Additionally, funding should be allocated in a manner that ensures services are targeted to appropriate areas and expand and/or enhance the ability of local areas to increase access to services where challenges currently exist, such as rural parts of the state.

Community Engagement

Community engagement processes involve the collaboration of key stakeholders and communities who collaboratively identify strategies for increased coordination of HIV programs throughout the state and local health jurisdictions. Ultimately, an effective collaboration should result in a collective vision that assists the jurisdiction in achieving the goals of the EHE Initiative. Furthermore, engaging the community is a key factor in the recipients' ability to successfully implement their EHE programs. Therefore, all recipients must allocate **at least 25%** of the total funds directed to the local EHE jurisdiction(s) to support planning and implementation of EHE activities by community organizations. Recipients are encouraged to establish new funding relationships with community organizations that have traditionally not received funding and that:

- have experience working with communities most affected by HIV, including experience addressing the social determinants that influence populations most severely affected by HIV; and
- possess the capacity to implement the EHE activities.

Furthermore, recipients may continue funding relationships with community organizations that have proven experience working with communities most affected by HIV, including experience addressing the social determinants that influence populations most severely affected by HIV. Recipients should also consider funding various community organizations, located in other parts of the jurisdiction, that have the capacity to expand their services to the Phase 1 counties where traditional HIV-focused CBOs do not exist or do not have the capacity to support implementation of EHE activities. For the purposes of this NOFO, community organizations include non-profit public or private organizations, American Indian/Alaska Native tribally designated organizations (e.g., tribal health programs, tribal organizations, urban Indian health programs, etc.), community-based organizations, faith-based organizations, hospitals, and health centers, including federally qualified health centers.

Although not direct recipients of this funding, private sector entities are important partners in achieving success under the EHE initiative. Recipients are encouraged to seek out opportunities to ensure private sector entities are engaged in ways that maximize the impact of the EHE initiative. Examples of engagement, may include, but are not limited to: promoting routine HIV testing as standard of care and building capacity for reimbursement through third party payers,

increasing awareness of and capacity to screen for and prescribe PrEP, as well as PEP, or referring patients to substance use disorder treatment and SSPs.

Additionally, recipients are expected to have a robust evaluation plan and should allocate appropriate funds to support evaluation staff and activities. See the Applicant Evaluation and Performance Measurement Plan section for guidance on funding to support evaluation staff and activities.

In anticipation of continued advancements and the availability of new tools and resources, recipients are expected to apply best practices and lessons learned to the implementation of their programs. Thus, jurisdictions should be prepared to revise their programmatic approaches based on advances in science and the dissemination of best practices and lessons learned. In addition, recipients should conduct ongoing reviews of existing data to identify and prioritize social and structural barriers that may be impeding the successful implementation of the NOFO activities, focusing on addressing those with the largest impact as well as the highest likelihood of implementation success.

Strategy 1: Diagnose all people with HIV as early as possible

An HIV test is the first step to HIV medical care and treatment for those who test positive and provides a gateway to HIV prevention services such as PrEP for those who test negative but remain at risk for HIV. In 2006, CDC recommended all persons age 13 to 64 be screened for HIV in healthcare settings; however, uptake has been suboptimal. CDC has funded a wide variety of clinical and non-clinical HIV testing activities through other funding mechanisms, including PS18-1802. In order to end the HIV epidemic, health departments are encouraged to propose new and innovative HIV testing strategies, like those described in this section, or improve the reach of existing programs. Impactful programs should be locally tailored to develop a mix of testing options, with the main goals to make HIV testing accessible and routine, and reduce the time from HIV infection to diagnosis. By so doing, those with undiagnosed HIV, as well as those previously testing positive but not engaged in HIV medical care or virally suppressed, can be identified and referred to HIV medical care and treatment services. A negative HIV test should lead to referrals for preventive services, such as PrEP and SSPs. Therefore, proposed *Diagnose* activities should include a description of how HIV testing encounters will be leveraged to improve the provision of comprehensive HIV medical care and preventive services, and ways in which HIV testing services can be integrated into Response.

<u>Strategy 1A: Expand or implement routine opt-out HIV screening in healthcare and other institutional settings located in high prevalence communities</u>

- Identify and select healthcare facilities using criteria developed during the local planning process, such as geographic location and populations served, that have not already implemented routine HIV screening, and automate HIV test orders for eligible patients at key healthcare encounters (e.g. emergency department visits, annual physical exams).
- Promote routine opt-out screening as part of medical intake evaluation in jails, particularly in large jails located in high prevalence communities, as well as in prison systems if HIV testing is not yet routinely performed, in accordance with state and local policy.
- Identify "champions" or key staff (e.g. nurses/other medical staff performing intake medical examinations) to lead activities to routinize HIV screening at intake.

- Modify the electronic medical records to routinize the offer of screening and screen all patients (at least once) for HIV regardless of risk.
- Establish mechanisms for rapid linkage to HIV medical care and prevention (i.e., PrEP and SSP) services for persons screened for HIV in all healthcare settings.
    - Rapid linkage to care for persons newly diagnosed with HIV is defined as, ensuring rapid linkage to care and starting antiretroviral therapy, within 7 days.

Strategy 1B: Develop locally tailored HIV testing programs to reach persons in non-healthcare settings

Activities may include, but are not limited to the following:

- Normalize HIV testing in non-traditional settings (e.g., pharmacies and retail venues) by advertising broadly and providing residents multiple options to receive HIV tests in venues that do not traditionally promote tests.
    - Examples include, but are not limited to a combination of "brick-and-mortar" buildings, mobile units, etc.
- Promote rapid HIV self-test distribution programs, mobile testing units, and technology-based partner services and social network recruiting strategies.
- Implement testing at health fairs or pop-up testing events where appropriate (including in rural and resource scarce environments), whereby HIV testing is offered as a service bundled with screening for other conditions relevant to the local population (e.g., STD testing, HBV and HCV testing, blood pressure screening, BMI assessment) in order to reduce stigma and normalize HIV testing.
    - Incorporate strategies to rapidly link persons to HIV medical care and prevention (i.e., PrEP and SSP) in all non-traditional settings.
- Collaborate with laboratories to determine appropriate tests and improve the quality of testing in non-healthcare settings.

Strategy 1C: Increase at least yearly re-screening of persons at elevated risk for HIV per CDC testing guidelines, in healthcare and non-healthcare settings

- Establish systems whereby patients with elevated risk are routinely identified and HIV tests are ordered at least yearly. In some settings, annual screening of all patients could be considered.
- Identify "champions" (e.g., physicians, nurses, etc.) who can lead all activities in healthcare settings needed to routinize identification of persons at ongoing risk for HIV and conduct at least annual HIV screening for this population
- Modify the electronic medical records to routinize the offer of annual screening for those at ongoing risk for HIV.
- Promote rapid HIV self-test programs in both healthcare and non-healthcare settings that can offer HIV rapid self-tests to persons at ongoing risk. This could include self-tests that clients can take away for themselves or distribute to others in their network.
- Implement novel approaches to make HIV tests widely available in non-healthcare settings where marginalized populations, including people experiencing homelessness and/or those injecting drugs congregate (e.g., homeless shelters, mobile clinics and

laboratories, and SSPs).

Strategy 2: Treat people with HIV rapidly and effectively to reach viral suppression

HIV treatment has transformed the HIV prevention landscape and dramatically improved the health, quality of life, and life expectancy of people with HIV. In addition, research has shown the profound impact of HIV treatment in preventing the sexual transmission of HIV. Keeping patients in regular, ongoing care can support antiretroviral therapy (ART) adherence, maintain decreased viral load and increased CD4 count, lower rates of progression to AIDS, improve overall health and reduce the risk of HIV transmission. Current treatment guidelines recommend ART for all people with HIV regardless of CD4 count. While ART can reduce HIV-related morbidity and mortality when taken consistently, in the U.S. only 53% of all persons with HIV are virally suppressed.

The *Treat* strategy is focused on comprehensive strategies to enhance linkage to and engagement in HIV medical care, expand re-engagement and retention in care and improve viral suppression among persons with HIV.

Strategy 2A: Ensure rapid linkage to HIV medical care and antiretroviral therapy (ART) initiation for all persons with newly diagnosed HIV
Examples may include, but are not limited to the following:

- Develop a robust network (supported by interagency/facility agreements) for rapid linkage (within 7 days) to clinical care and essential support services.
- Report all new HIV diagnoses to health departments, as rapidly as possible, in accordance with state and local policy by establishing or expanding secure electronic methods or on-call hotline(s) (including after-hours).
- Conduct a rapid needs assessment (housing, transportation etc.) for all persons with new HIV diagnoses and link to a disease intervention specialist and/or case manager as needed.
- Develop programs to support and promote rapid linkage (within 7 days) and early ART initiation by HIV medical care and treatment providers in non-Ryan White HIV/AIDS Program facilities.

Strategy 2B: Support re-engagement and retention in HIV medical care and treatment adherence, especially for persons who are not recipients of Ryan White HIV/AIDS Programs
Examples may include, but are not limited to the following:

- Develop, expand and scale up Data to Care programs using surveillance data and other data sources including Medicaid administrative claims and pharmacy refill data (D2C Rx), to identify patients not in care and develop re-engagement strategies (e.g. utilizing linkage specialists, disease intervention specialists).
- Develop electronic based approaches (e.g., text messaging, virtual case management) to support retention in care activities, patient navigation and distribution of strengths-based case management (e.g., ARTAS) via phone.
- Create and maintain an easily accessible provider-initiated retention in care support service (e.g., encrypted online reporting system) for providers to request health department support when patients miss appointments or appear to be lost to follow up.

- Provide locally informed, evidence-based incentives (non-monetary) to PWH for retention in care and viral suppression.
- Develop robust telemedicine programs that use electronic information and telecommunications technologies (e.g., videoconferencing, the internet, store-and-forward imaging, streaming media) to support and promote long-distance clinical health care and patient health-related education. Please reference the Other Information section for additional resources specific to telemedicine.

Strategy 3: Prevent new HIV transmission by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs)

Pre-exposure prophylaxis (PrEP), when used consistently, is a highly effective HIV prevention tool. However, slow uptake has hindered its full potential for reducing new HIV infections in high incidence areas. The intent of the following strategies includes increasing overall PrEP use, while simultaneously focusing on addressing PrEP uptake in communities with the highest need (e.g., African-American men who have sex with men). All activities to expand PrEP care and increase its use should incorporate elements to increase non-occupation post-exposure prophylaxis (nPEP) awareness and access when appropriate, including activities with clinicians, non-clinical CBOs, and persons at risk for HIV acquisition.

HHS supports the implementation of comprehensive SSPs as an effective public health approach to reduce the spread of infectious diseases. SSPs have been associated with a reduced risk of infection with bloodborne diseases such as HIV and viral hepatitis. In addition to improving access to sterile injection equipment, SSPs often provide other services important in supporting persons who inject drugs (PWID). SSPs offer risk reduction counseling and are an important venue for HIV, viral hepatitis, STD, and TB testing; hepatitis A and hepatitis B vaccination; linkage to care and treatment; the provision of naloxone; and referrals to substance use treatment. More information for applicants is provided at the following link: https://www.cdc.gov/ssp/index.html. Refer to the HHS Syringe Services Programs (SSP) Implementation Guidance at https://www.hiv.gov/sites/default/files/hhs-ssp-guidance.pdf. The CDC Program Guidance for Implementing Certain Components of Syringe Services Programs, 2016, provides specific procedures for CDC-funded grantees: https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-syringe-exchange-services.pdf

Additionally, the desired outcome for the Prevent strategy's syringe services programs (SSPs) strategy is to develop programs that provide comprehensive service delivery. However, in situations where foundational elements may not exist for developing comprehensive SSP service delivery, applicants may prioritize specific "building block" components that can lead to more robust service delivery.

Strategy 3A: Accelerate efforts to increase PrEP use, particularly for populations with the highest rates of new HIV diagnoses and low PrEP use among those with indications for PrEP.

Examples may include, but are not limited to the following:

- Support development and delivery of PrEP services in clinical and nonclinical sites in communities with the highest rates of new HIV diagnoses. Ensure adequate scale-up of PrEP use among MSM of all races, and particularly young African American and Hispanic/Latino gay and bisexual men, transgender persons, and other communities that

would benefit most from its use. Efforts should also be made to co-locate nPEP with PrEP services to prevent possible HIV infections from recent exposure.
    - Examples of clinical and non-clinical sites include, but are not limited to a combination of "brick-and-mortar" buildings (e.g., health centers), and mobile vans.
- Increase PrEP training among private and safety-net clinical providers by increasing the number of trained PrEP detailers (i.e., clinical educators) through collaboration with organizations that have demonstrated success in providing ongoing training and support (e.g., AIDS Education Training Centers, The National Resource Center for Academic Detailing), and adapting resources from CDC and others to meet local provider training needs (e.g., materials from the Prescribe HIV Prevention campaign).
- Incentivize PrEP provision that is appropriate to locally specific demographics of persons with new HIV diagnoses while maintaining provision of PrEP to all persons with indications for its use. Examples may include, but are not limited to: annual awards or incentives for clinical sites that exceed annual goals for providing PrEP (not already funded by the HRSA Bureau of Primary Health Care) for success in reducing disparities (i.e., matching the provision of PrEP to the local demographics of persons with new HIV diagnoses).
- Support the formation of a locally-driven peer network of African American and Hispanic/Latino persons who are PrEP users, to educate on PrEP and support PrEP uptake and continued PrEP use among persons in their social networks.
- Develop and implement locally-specific insurance and cost-assistance navigation protocols for PrEP patients.
- Support client access to existing traditional PrEP care delivery systems (e.g., community health centers) and non-traditional PrEP care delivery systems. This may include active referral and linkage to: home test kits for some visits, PrEP care in community pharmacies, and use of telemedicine services especially in rural communities.
- Disseminate approaches proven effective to support adherence and persistence. Examples include certified health coaches or nurse educators, certified community health workers, PrEP navigators, use of eHealth technology, and pharmacist- based PrEP services. Priority should be given to services that are fiscally sustainable (e.g., billable).

CDC funds may be used to support limited personnel costs related to the provision of PrEP medication if coupled with other supportive PrEP services, e.g., eligibility assessments, risk reduction education, referral/navigation support to other essential services, etc. These activities must be a well-defined set of duties that are in addition to writing prescriptions and provision of clinical care. The funded percentage for these duties may not exceed 75% of the FTE. Other sources of funding are needed to support any duties specifically related to clinical care.

- CDC funds may be used for laboratory costs for screening or monitoring 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.

- CDC funds may not be used for clinical care except as allowed by law.[c]

Strategy 3B: Increase availability, use, and access to and quality of comprehensive Syringe Services Programs (SSPs)

Use of funds to support proposed SSPs must be in accordance with federal law and CDC guidance. Additionally, resources awarded as part of this NOFO may be used to support efforts to build or expand SSPs, but only when certain conditions are met. In consultation with CDC, state and local health departments must first demonstrate that the jurisdiction or area they are serving is at risk for, or experiencing, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use. Recipients can initiate the Determination of Need (DON) request at any time during the project period. However, funds cannot be allocated to support SSPs until concurrence with the DON has been received. More information can be found at https://www.aids.gov/pdf/hhs-ssp-guidance.pdf.

Examples may include, but are not limited to the following:

- Ensure that SSPs provide clients with the following standard services: needs-based access to sterile needles and syringes and other injection equipment (e.g., sterile water, cookers), condoms, syringe disposal, HIV and HCV testing, linkage to HIV and HCV care, linkage to PrEP, naloxone distribution, and linkage to medication-assisted treatment.
    - Condom distribution efforts, including the promotion of and provision of condoms, within communities, venues, and other settings, should be included as a component of the SSPs.
- Ensure that SSPs have the following additional services provided directly to clients or available through formal, active referral arrangements facilitated by patient navigators:
    - Infectious disease prevention, detection, care, and treatment; including HIV, viral hepatitis (HAV, HBV, and HCV), sexually transmitted infections (syphilis, gonorrhea, and chlamydia) and wound care.
    - Substance use disorder care and treatment; including low threshold medication-assisted treatment and evidence-based psychological and behavioral treatments (e.g., talk therapies).
    - Essential support services, including housing, transportation; mental health/substance use counseling.
- Promote and establish SSPs strategically distributed across communities with the highest number of new HIV diagnoses attributed to injection drug use, highest number of new HCV diagnoses, and/or highest rates of drug overdose.
    - Examples include, but are not limited to a combination of "brick-and-mortar" buildings, mobile vans, vending machines, and peer-delivery systems.
    - For jurisdictions that do not currently have laws in place to support SSPs, educate stakeholders about the evidence which has shown that SSPs reduce the transmission and spread of infectious diseases.
- Increase access to sterile needles and syringes for persons who inject drugs (PWID) through non-prescription syringe sales in community pharmacies, where allowed by law.
- Educate the community about the availability and evidence-base of SSP services, including through the use of evidence-based consumer materials and content.

- Develop and implement a quality management program to continuously evaluate and improve SSP service delivery according to evidence-based practices defined by HHS.

Strategy 4: Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them

Cluster and outbreak detection and response are relatively new activities in 2019 that have not yet been widely implemented. Therefore, the benefit has not been fully realized. Responding quickly to clusters and outbreaks in which HIV is spreading quickly offers an opportunity to interrupt that spread. The presence of a cluster indicates gaps in prevention services, which must be addressed to improve access to services such as HIV testing, ART, and PrEP in order to stop transmission. In this way, response is closely related to other strategies described here, as cluster response uses traditional HIV prevention approaches in a more focused way.

Successful cluster response depends on strong partnerships, processes, data systems, and policies. The activities included in the first strategy (4A) focus on these fundamental building blocks to help ensure successful response; for this reason, it is critically important that recipients prioritize and complete these activities to promote success in cluster response.

Strategy 4A: Develop partnerships, processes, data systems, and policies to facilitate robust, real-time cluster detection and response

- Establish new or expand an existing standing committee that meets routinely to guide cluster response. Include health department leadership and staff with diverse areas of expertise and authority to implement change; routinely review cluster data, prioritize clusters, guide cluster response, review response data, and modify and improve responses as needed.
- Actively involve members of local communities in planning, implementation, and evaluation. Include people with or at risk for HIV, local HIV services providers, Ryan White HIV/AIDS Program facility leadership, community-based organizations, HIV planning groups, and, as applicable, correctional and military facilities, tribal organizations, behavioral health providers, housing providers, etc.
- Update mechanisms or processes to expedite reporting and entry of case, laboratory, risk, vital status, and other key data into surveillance systems to ensure accurate surveillance data for real-time decision-making.
- Implement approaches to provide real-time information on cluster detection and response. Rapidly analyze, integrate, visualize, and share data from diverse sources, including surveillance, partner services, Ryan White HIV/AIDS Program, STD, and HIV testing.
- Create and maintain flexible funding mechanisms capable of supporting cluster response efforts. Examples may include, but are not limited to the following:
    - Developing mechanisms that allow health departments to instruct their subcontractors to redirect a portion of funding to support jurisdictional HIV cluster response efforts, with prior approval from CDC.
    - Setting aside resources that can easily be directed to entities that can support a response effort.

Strategy 4B: Investigate and intervene in networks with active transmission

- Understand the networks: Train key staff to implement methods to identify and understand the entire network, including enhanced partner services, social network strategies, rapid ethnographic assessment, and other innovative approaches.
- Provide linkage to critical services to network members. Prioritize network members for enhanced linkage to services including: testing and future re-testing for HIV, HCV, HBV, and STDs; PrEP; SSPs; HIV medical care; including rapid start of ART and PrEP; and other essential support services (e.g., housing, social services).

Strategy 4C: Identify and address gaps in programs and services revealed by cluster detection and response

- Identify and address programmatic gaps: Review cluster information to identify specific gaps in programs such as testing, care, PrEP, partner services, SSPs, other support services, collaborations, and communication, and address these gaps swiftly during cluster response.
- Use cluster information to guide future program activities.

Component B: HIV Incidence Surveillance (Optional)- Begins in Year 2

Applicants can enhance their surveillance programs by requesting funding to implement Component B. Component B will assess efforts to prevent new infections by estimating HIV incidence using a recency assay. A select set of jurisdictions can enhance their programs by requesting funding to implement HIV incidence surveillance. The project would employ a recent infection testing algorithm (RITA) to assess incidence using recency testing results along with clinical data from persons with newly diagnosed HIV collected through surveillance. Routinely collected HIV surveillance data will be used to calculate CD4-based incidence estimates for the same jurisdictions in parallel. The Ending the HIV Epidemic initiative will bring increased attention to incidence estimation, specifically, to address whether anticipated increases in HIV diagnoses represent new infections or diagnosis of long-standing chronic infections finally being identified. Given these circumstances, and technological improvement in recency assays, reassessment of recency assay-based incidence estimation is warranted.

Based on previous experience conducting incidence surveillance activities, having reliable CD4-based incidence estimates and geographic focused EHE areas eight recipients are eligible to apply for funding for these supplemental HIV incidence surveillance funds: Alabama, District of Columbia, Florida, Houston, New York City, Michigan, South Carolina, and Texas. Implementation of HIV incidence surveillance in these jurisdictions will allow for comparison to CD4-based incidence estimates for the same jurisdictions in parallel and provide an interpretation of diagnosis trends.

Project proposals must address how the applicant will implement and evaluate HIV incidence surveillance activities over the project period (up to four years), with more detailed information for activities conducted during the first year of funding.

Strategy B1: Work with stakeholders to identify best practices for implementing a recency-based HIV incidence surveillance.

A strong foundation of community engagement is critical to the success of incidence surveillance. Applicants shall propose to engage a diverse group of key partners and

stakeholders, including community groups, HIV testing providers, and laboratories, about health department activities surrounding HIV incidence surveillance activities and use of incidence data to support efforts of the Ending the HIV Epidemic initiative. Community engagement shall be conducted prior to implementing incidence surveillance activities and continue as an ongoing process that responds to community needs and concerns. Stakeholders will be made aware of any changes in incidence procedures and can discuss questions and concerns to ensure responsible implementation and support for the program.

Strategy B2: Conduct recency-based HIV incidence surveillance in selected jurisdictions.

In a manner consistent with CDC's guidance, collect results from a recent infection testing algorithm, or other methods as they become available, necessary for the statistical estimation of HIV incidence. RITA results will be obtained through required submission of remnant samples from HIV diagnostic tests for testing at a CDC-designated laboratory. Therefore, for all newly diagnosed HIV infections reported to HIV surveillance, funded health departments are required to:

- Secure remnant specimens from the original diagnostic HIV test or other HIV-related test performed within one month of diagnosis by public or private laboratories (within and outside the state). Remnant specimens from diagnostic HIV testing may be either blood serum or plasma.
- Coordinate with public and private HIV testing laboratories (within and outside the state) to arrange transport of remnant specimens to a selected laboratory for storage and eligibility assessment.
- Identify and locate specimens eligible for recency testing for persons with newly diagnosed HIV that are reported to the state or local surveillance system and inform the appropriate laboratory of the need to ship specimens to the laboratory designated by CDC for recency testing. Establish procedures for tracking specimen shipments as well as receipt of recency testing results from the CDC-designated laboratory and results submission to the National HIV Surveillance System.

Establish regular communication between the public health, private, and commercial laboratories; the CDC-designated laboratory; and HIV incidence surveillance staff. As future assays to determine recency of HIV infection become available, programs must adapt to CDC guidance for the collection of blood, serum, or plasma specimens for recency testing and submission of test results from these specimens to the National HIV Surveillance System. All eligible remnant specimens should be made available to CDC for additional RITA-related testing upon request.

Strategy B3: Review incidence results from a CD4 depletion model and a recency-based assay model.

For persons with a new diagnosis of HIV that have been reported to HIV surveillance, along with other data routinely collected for HIV surveillance, consistent with CDC's guidance, applicants will conduct all relevant activities required to obtain and submit data to CDC for incidence estimation. This includes ensuring integration of HIV incidence surveillance activities with routine HIV surveillance activities. Applicants will submit data, as specified by CDC, by using CDC approved software and by complying with data submission standards consistent with the requirements of CDC's Data Security and Confidentiality Guidelines and conduct systematic

data quality and evaluation of HIV incidence surveillance. They also will calculate and disseminate routine population-based HIV incidence estimates, review results from a CD4 depletion model and a recency-based assay model, and promote the use of HIV incidence data for prevention and health services planning. The following data are essential for incidence estimation:

- HIV testing history (e.g., dates, tests used, results)
- Antiretroviral (ARV) drug exposure history (including for treatment, for pre- or post-exposure prophylaxis, or for any other purpose/reason)
- Viral load (VL) results from specimens collected within one month after diagnosis (ideally from the same specimen as the diagnostic specimen/remnant specimen for RITA) to confirm presence of untreated HIV infection (e.g., VL >1,000 copies/mL)

Provide a program description to include annual program goals and SMART objectives for the proposed project and activities that will be conducted to meet the objectives. Include process and outcome evaluation to measure performance, effectiveness and potential impact of the project.

- Include a timeline for implementation of the proposed project. The timeline should include planning, implementation and evaluation phases.
- Describe collaboration with CDC, and consultation with staff conducting HIV incidence surveillance
- Provide a plan for community engagement, including communicating with key partners and stakeholders.
- Provide evidence that the applicant has the experience and capacity to implement the HIV incidence surveillance. Provide any anticipated capacity building needs.
- If desired, applicants can request collaboration with CDC on the development and analysis of HIV incidence surveillance data and use information from analyses, as well as from ongoing use of program monitoring data, to assess and improve performance.
- Develop and submit to CDC a detailed final report to include process, outcome, impact, cost and, if available, cost-effectiveness data, qualitative and quantitative findings, including successes, challenges, and lessons learned from HIV incidence surveillance.

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (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 project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

Component C: Scaling Up HIV Prevention Services in STD Clinics (Optional)

Applicants can enhance their programs by requesting funding to implement strategies and activities focused on scaling up HIV prevention services in STD clinics. STD clinics serve populations who are not engaged in HIV prevention programs or the primary health care system for their STD and HIV prevention care. As a result, STD clinics are suitable settings to reach

populations at high risk of acquiring HIV who could benefit from PrEP/nPEP or individuals living with HIV who are either unaware of their status or are not virally suppressed and could benefit from linkage or re-engagement in care.[7,8] STD incidence among MSM who do not have HIV is a marker for extremely high vulnerability to HIV infection among this population.[9]

State and local health departments (LHD) in the U.S. have supported dedicated public STD clinics since the 1910s and STD clinics have remained a large component of public health safety-net STD services provided by local and state governments.[10] Historically, they have been an important health-care setting for clients who may not otherwise have access to health-care services, including those who are uninsured and at high risk for HIV, and individuals who seek confidential services. Moreover, STD clinics have become a primary source of STD and HIV prevention services for men who do not have a usual source of care.[11] and include confidential comprehensive STD testing and timely on-site treatment, risk reduction counseling and partner services; HIV testing and linkage to care for those who test positive for HIV; and support STD and HIV prevention activities for the community.

STDs are associated with a higher risk of acquiring HIV, both because the presence of an STD might enhance transmission of HIV and because of shared modes of transmission of both STDs and HIV.[9] STDs are a marker of condomless sexual activity, which may result in HIV transmission. HIV negative individuals with an STD are at higher risk of acquiring HIV, and those with a concurrent HIV and STD are more likely to transmit HIV to their partners. Primary and secondary (P&S) syphilis diagnoses are strongly and consistently associated with a high risk for HIV acquisition.[12] In 2017, 46% of P&S syphilis cases were reported among MSM with HIV. In a retrospective study of MSM who sought care in STD clinics participating in the STD Surveillance Network (SSuN), investigators estimated that MSM with a diagnosis of P&S syphilis on or after the first negative HIV test had a higher (7.2/100 person-years (PY)) new HIV diagnosis rate compared with MSM who did not have a P&S syphilis diagnosis (2.8/100 PY).[13] Also, MSM who tested positive for rectal gonorrhea (6.3/100 PY) or rectal chlamydia (5.6/100 PY) had higher rates of new HIV diagnosis when compared with those with negative test results.[13] Rectal STDs (especially rectal gonorrhea), are of considerable public health concern because they confer the highest risk of HIV acquisition. Also, a recent study estimated that approximately 10% of incident HIV infections among MSM in the U.S. are attributable to Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) infections [14]. Of additional concern is that co-infection with syphilis in people living with HIV (PLWH) has been associated with decreased CD4 cell counts and increased HIV viral load, which may lead to a greater risk of transmitting HIV to a negative partner and possibly a worse health outcome if the syphilis infection is not diagnosed and treated.[15]

In January 2020, CDC released Recommendations for Providing Quality STD Clinical Services (STD QCS) that will enable STD clinics to scale up and improve the quality of HIV and STD prevention services.

The purpose of Component C, "Scaling up HIV Prevention Services in STD Specialty Clinics[d] to Support the Ending HIV Epidemic (EHE) Initiative," is to strengthen the infrastructure of STD clinics serving a high proportion of racial/ethnic and sexual minorities to support the EHE Initiative. To be able to enhance and scale up quality HIV prevention services in an STD specialty clinic located in a city, county, parish or district, CDC expects that no less than 90% of Component C funds will be directed to a local health department and their STD specialty clinic to: (1) increase the number and percentage of STD clinic visits in which patients who are diagnosed with an acute STD and are not known to have HIV are tested for HIV; (2) increase uptake of PrEP/nPEP for those with acute STDs and are vulnerable for acquiring HIV; (3) establish cost effective models for PrEP/nPEP services; and (4) optimize linkage to, retention in, and re-engagement in HIV medical care and prevention services for patients who are HIV-positive and not in care or not virally suppressed. These funds can be used to screen or test, uninsured and underinsured people for HIV and STDs, and to treat those persons who are diagnosed with STDs, but cannot be used to cover the costs of antiretroviral medication, including PrEP.

Overall goals for this project are to increase the capacity of STD specialty clinics in providing culturally sensitive HIV preventive clinical services and linkage to care; and to increase the number of STD specialty clinics providing PrEP. Component C will support the five strategies described below.

Implementation of all strategies and activities described below is required by all applicants. Applicants can request to opt out of selected required activities by providing a strong justification, which must be based on program priorities, resources, and/or local policies. Approval will be considered after review of the application. Applicants are encouraged to implement additional innovative activities and to conduct additional evaluation, if resources are available.

Strategy C1: Conduct assessment of the clinic infrastructure to document HIV and STD prevention services, identify gaps, and assess service quality.

STD specialty clinics should develop efficient, integrated approaches for delivering care that enhances value for the patients they care for and the populations they serve. Participating clinics will conduct an assessment of the clinic infrastructure to document HIV and STD prevention services that are currently provided, as well as a gap analysis. For this project, infrastructure includes: the physical, technical, organizational and systems-level components or assets that are necessary to deliver quality HIV and STD prevention services. Quality HIV and STD prevention services should include PrEP services, viral load testing, and linkage to other services that are not available at the STD clinic, such as care and treatment for HIV and other co-occurring conditions, including substance use disorders, family planning, intimate partner violence, and housing assistance. Clinic and laboratory components may include management, physical structure, supply systems, technical equipment, information technology (including electronic heath records), clinical services, staffing and organizational structure, and data. The assessment and gap analysis will be conducted in collaboration with CDC and should include:

- Review of the documentation of clinic practices, including policies and procedures, clinical protocols, inventory of services and laboratory procedures, organizational structure, patient satisfaction and quality assurance procedures.

- Review procedures for record keeping and identify barriers and cost of adoption of electronic health records, billing and electronic case reporting, if not available.
- Assess patient flow and determine the clinic's capacity to increase patient volume. Identify new testing and prevention strategies (e.g. STD specimen self-collection, express STD testing services, viral load testing comprehensive sexual health services including HCV screening and HBV, HAV and HPV vaccination) and wrap around follow-up services for PrEP patients, if applicable to the clinic.
- Examine best strategies for the integration and/or co-location of STD specialty and PrEP services, if not currently available.
- Review staff credentials, skills and identify training needs. Assess adequacy of existing staff to scale up and expand service capacity. Clinics must identify opportunities for PrEP and nPEP clinical management, viral suppression and basic treatment as prevention training for physicians, nurses, social workers, patient navigators, Disease Intervention Specialists (DIS) and other allied health professionals on their staff through the National Network of STD Clinical Prevention Training Centers (NNPTC) or the AIDS Education and Training Centers or other local academic partners.
- Assess existing ancillary and laboratory service capacity including specimen self-collection, POC testing, and rapid turnaround time for results, and, if necessary, establish agreements for laboratory services.
- Work with the National Network of STD Clinical Prevention Training Centers (NNPTCs) in the implementation of the provision of STD Quality Clinical Services (QCS). STD QCS includes recommendations for STD and HIV prevention services such as PrEP/nPEP, viral load testing, and strong strategies for linkage to HIV medical care and co-occurring conditions such as substance use disorder, family planning, intimate partner violence, and housing assistance as the new standard of care for STD specialty or sexual health clinics. Additionally, work with NNPTCs on protocols and providing necessary training to staff.

Strategy C2: Implement evidence-based approaches to scale up capacity, sexual risk assessments, self-collected STD testing and treatment, and HIV testing and viral load assessment.

Participating STD clinics will identify innovative and evidence-based approaches that will allow staff to serve patients in a timely manner, improve patients flow, conduct walk-in client initiated sexual risk assessments and specimen self-collection to increase capacity to test for STDs at all anatomic sites, provide timely treatment, test for HIV and do viral load assessments and other HIV-related laboratory tests, as recommended by CDC[e] Some of the approaches may include the use of tablets or other mobile technology for intake and express STD services. Express visit services have the potential to play a key role in increasing access to testing and treatment by optimizing clinic efficiency. In express services, asymptomatic patients are routed to less intensive clinical services through standing orders and no physical examination. While express services models vary, there are a number of core elements seen across models:

- Triage to route patients to express or traditional provider visit
- No physical examination
- Patient self-collects specimens, including swabs and urine, while a nurse, DIS or

phlebotomist collects serum
- Aided by technology/automation for triaging, faster lab turnaround times, and notification of results
- Reliance on diverse staffing to allow healthcare professionals to work at the top of their licenses

The process of identifying innovative strategies will occur in collaboration with CDC during the first 3 months of the project. Although it is expected that programs and their partners will use substantial discretion, interventions will be validated through existing research or evaluation (i.e., promising, emerging and best practices) and implemented in the context of existing resources and care for racial and ethnic minorities, including MSM and transgender females, and other high-risk individuals.

Strategy C3: Expand the capacity of STD clinics to offer PrEP, nPEP, and strengthen clinic and laboratory capacity for recommended follow-up visits for individuals.

Participating clinics will identify, tailor and implement innovative strategies to offer comprehensive PrEP and nPEP services for high-risk racial/ethnic and sexual minorities for whom it is appropriate and desired, especially MSM. Targeting PrEP to MSM who do not have HIV, and diagnosed with an STI may be cost-effective compared to alternative behavioral risk reduction strategies for those with PrEP indications.

Participating clinics must follow the CDC guidelines for PrEP implementation, which recommend that PrEP be considered for:

- people who are HIV-negative and in an ongoing sexual relationship with an HIV-positive partner;
- individuals who are not in a mutually monogamous relationship with a partner who recently tested HIV-negative;
- gay or bisexual men who had anal sex without using a condom or have been diagnosed with an STD in the past 6 months;
- heterosexual men or women who do not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk for HIV (for example, people who inject drugs or women who have bisexual male partners).

PrEP is also recommended for people who have injected drugs in the past 6 months and have shared needles or works or been in drug treatment in the past 6 months. Clinics without capacity to retain patients on PrEP must have formal agreements with clinicians who can provide follow up services, as needed.

Clinics should also strengthen clinic and laboratory capacity for recommended PrEP care including follow-up visits that include recommended STD testing at relevant anatomical sites along with other recommended wrap around services. Participating clinics might need to work in partnership with their state and local HIV prevention programs to identify and possibly modify existing delivery approaches to scale-up PrEP and nPEP services and reduce structural and other perceived system barriers. For example, strategies to increase awareness among racial and ethnic minority populations to address availability of services, any misinformation about side effects of PrEP, and financial limitations; to the extent permitted by law, expand the scope of practice of nurse practitioners and other clinic providers; reach high risk populations --such

as sex partners of persons diagnosed with HIV or STD-- through new media and mobile technologies; and implement express services for ongoing monitoring of patients on PrEP.[23,24] In addition, the STD clinics may consider expanding partnerships with other community-based organizations in their catchment areas to address linkage for other co-occurring conditions, such as HBV and HCV.

Strategy C4: Optimize linkage to, retention in, and re-engagement with HIV medical care.

Participating clinics should consider testing for viral loads all patients who test positive for HIV and patients living with HIV and not engaged in HIV medical care. Patients with newly diagnosed HIV and those not virally suppressed should be rapidly linked to HIV medical care within 7 days. STD clinics will work with health department HIV/STD prevention personnel DIS, Linkage Coordinators, Patient Navigators, HIV providers and other community providers, such as behavioral health, family planning, intimate partner violence, and housing assistance to:

- Facilitate active linkage to HIV medical care and treatment for patients who are newly diagnosed; and facilitate re-engagement in care for patients who were not virally suppressed and lost to care.
- Facilitate linkage to care and other services for co-occurring conditions, such as HBV and HCV.
- Provide support to help patients remain in care.
- Provide support for expanded Partner Services in participating STD clinics following the Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection, 2008 (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5709a1.htm) for patients who are diagnosed with HIV, syphilis and rectal gonorrhea or chlamydia and their sexual partners. Partner services should include a broad array of services that are offered to persons with HIV and their sexual or needle-sharing partners. For example, embedded health department HIV/STD prevention staff can work with STD clinic patients who could benefit from partner services, including confidentially notifying their partners of a possible HIV and/or STD exposure, and offering partners HIV and STD testing and treatment, PrEP, if indicated, and linkage to a range of medical, prevention, and psychosocial services for co-occurring conditions, if needed.

These activities should also include coordination and partnership with the HIV prevention program and other providers in the community and development of a linkage/referral roster of providers, by specialty, who provide culturally informed care for vulnerable populations especially LGBTQ+ and racial/ethnic minorities.

Strategy C5: Facilitate the development of partnerships with other community HIV clinical providers and health department and community-based organizations providing HIV prevention services and collaborating in the implementation of the EHE.

STD clinics, with support from the NNPTCs and CDC, will partner and collaborate with health department HIV prevention and Ryan White Care providers, community-based organizations, as well as other governmental and external experts in the development of local EHE community plans to identify system efficiencies and improve access to quality HIV prevention services. System efficiencies may include:

- implementation of locally targeted communication strategies, including support for PrEP and integrated HIV and STD prevention social marketing campaigns for providers and potential users, development of information websites with locators for PrEP providers, comprehensive STD specialty clinics and sexual health clinics;
- data sharing across jurisdictional STI and HIV providers and STI and HIV surveillance systems, in accordance with NCHHSTP Data Security and Confidentiality Guidelines;
- training for "insurance navigator" and agreements with quality preventive, healthcare, social and support services in the community;
- integration or co-location of STI and HIV services;
- implementation of PrEP patient support systems, including insurance assistance, health literacy education, medication adherence counseling services, and other supportive services; and
- community engagement.

1. Collaborations

Component A and B

CDC expects recipients to coordinate with Health Resources and Services Administration (HRSA) funded entities, sexually transmitted disease (STD) programs, viral hepatitis programs, TB programs, school-based programs, other surveillance programs, laboratory units, other health agencies, tribal governments and/or tribally designated organizations, community-based organizations, community health centers, Bureau of Primary Health Care funded recipients, lesbian, gay, bisexual and transgender (LGBT) health centers, STD and TB clinics, hospitals, specialty clinics, other non- governmental organizations, and criminal justice and correctional facilities to implement comprehensive HIV programs focused on ending the HIV epidemic in the respective jurisdictions.

In addition, recipients are encouraged to consider collaborating with grantees funded by the National Institutes of Health to conduct implementation research with state and local health departments. These NIH grantees will be funded to support implementation research as part of EHE, and they will be supported by either one of the Centers for AIDS Research (CFAR) or one of the AIDS Research Centers (ARC)

Component C

Recipients are expected to collaborate with the NNPTCs to implement and promote quality and recommended STD clinical services in their clinic. STD clinics are also encouraged to strengthen collaboration with other EHE-funded programs in their jurisdiction; HIV and primary care providers with a large volume of HIV or PrEP patients to enhance STD testing, especially three-site testing in HIV and PrEP care; and with other providers with a large volume of patients at risk for HIV who need syphilis and three-site gonorrhea and chlamydia screening as biomarkers of HIV risk to identify who could benefit from PrEP, especially MSM.

Applicants must describe how funds will flow to the selected STD clinic and/or city, county, parish or district to fulfill the requirements of the supplement in a timely fashion with a proposed timeline. State applicants must submit a letter of collaboration or MOU from the local

county health officer(s) and this file should be named "County Letter of Collaboration or MOU" and State and local (city, county or district) applicants must submit a letter of collaboration or MOU from the medical director of the STD clinic and this file should be named "Medical Director Letter of Collaboration or MOU." Both files should be uploaded as a PDF file under "Other Attachment Forms" on www.grants.gov.

Applicants should also describe how they intend to collaborate with state and local HIV prevention programs, local CBOs and HIV and primary care providers, and if appropriate with a state or local laboratory. In addition, applicants must describe how they propose to work with training organizations such as academic institutions, the NNPTC and /or AETCs and other EHE-funded programs in their community. Letter of collaborations with local health care organizations, training centers and maternal-child health programs are strongly encouraged.

a. With other CDC programs and CDC-funded organizations:

CDC expects recipients to establish, build, and/or maintain working partnerships with CDC and other CDC-funded organizations and projects (e.g., directly funded CBOs, STD programs, Viral Hepatitis and TB programs, Medical Monitoring Project) to ensure communication, collaboration, and coordination for the delivery of a comprehensive HIV program that is consistent with CDC standards and guidance. For implementing activities, applicants should collaborate with local CBOs, tribal governments and/or tribally designated organizations, local health departments, medical institutions, federally qualified health centers (FQHCs), LGBT health centers, STD clinics, hospitals, specialty clinics, institutions of higher education, faith-based institutions, correctional institutions, etc. Recipients are expected to collaborate with other health departments (e.g., state and local) within the jurisdiction. If necessary, memoranda of agreements/memoranda of understandings (MOAs/MOUs), should be established.

Additionally, recipients are encouraged to include the local education agencies (LEA) within their county in the implementation efforts, where feasible to address primary prevention activities for school-age youth. Where multiple school districts exist, recipients are encouraged to align with school districts of highest disease burden. In counties where CDC currently provides funding support through CDC-RFA-PS18-1807 to promote adolescent health through school-based HIV prevention, recipients should include the LEAs in the planning process.

Note: The following documents do not count toward the page limit for the Project Narrative. Applicants must file MOUs/MOAs with other providers, as appropriate, name the file(s) MOUs," and upload the document(s) as a PDF file under "Other Attachments Forms".

b. With organizations not funded by CDC:

CDC expects recipients to establish, build, and/or maintain collaborative relationships with organizations not funded by CDC that will support the implementation of the proposed program. Consideration should be given to developing strategic partnerships with the following types of organizations: federal agencies (e.g., the Health Resources and Services Administration, the Centers for Medicaid and Medicare Services, Substance Abuse and Mental Health Services Administration, Indian Health Services) and their recipients; public health departments; tribal governments and/or tribally designated organizations; local and state education agencies; colleges and universities; non-CDC funded CBOs; capacity building assistance organizations; faith-based organizations; for-profit organizations; clinics and

hospitals; non-governmental organizations; state and local governments; community advocates; community members; foundations; and other stakeholders that may have a vested interest in promoting health through HIV prevention, care, and treatment. If necessary, memoranda of agreements/memoranda of understandings (MOAs/MOUs), should be established.

Note: The following documents do not count toward the page limit for the Project Narrative. Applicants must file MOUs/MOAs with other providers, as appropriate, name the file(s) MOUs," and upload the document(s) as a PDF file under "Other Attachments Forms".

2. Target Populations

Component A

Target populations may vary. Applicants must tailor HIV prevention activities to target population(s) among those identified within their local or state Integrated HIV Prevention and Care Plan, recently submitted EHE plan or other locally developed plans, Needs Assessment, and/or Epidemiologic Profile as being people with and at greatest risk for HIV. Applicants are also expected to include social determinants data to identify communities that are disproportionately affected by HIV and plan activities to reduce or eliminate these disparities. Disparities by race, ethnicity, gender identity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions should be considered.

Component B

The target population for this component is persons with newly diagnosed HIV infection, including racial/ethnic and sexual minorities.

Component C

The target population for this component is STD specialty clinic patient population, including racial/ethnic and sexual minorities.

Applicants must describe the patient population and HIV and STD morbidity in the proposed STD clinic. Specifically, the application must include a table summarizing for 2018, the number of STD clinic patient visits, the percent of STD clinic patients by gender, race/ethnicity, age distribution and sexual orientation and gender identity (if available) and the number of new HIV infections, and diagnoses of primary and secondary syphilis and gonorrhea by anatomic site (if available). This table must be uploaded as a PDF in Grants.gov under "Other Attachment Form" and labeled: Documentation of STD specialty clinic patient visits, demographic characteristics and 2018 HIV and STD morbidity.

a. Health Disparities

Health disparities in HIV are inextricably linked to a complex blend of social determinants that influence populations most severely affected by this disease. Health equity is a desirable goal that entails special efforts to improve the health of those who have experienced social or economic disadvantage. Social determinants of health affect disparities in HIV, viral hepatitis, STD and TB. Environmental factors such as housing conditions, social networks, and social support are also key drivers for acquisition and transmission of HIV, viral hepatitis, STDs, and TB. This NOFO supports efforts to improve the health of populations disproportionately affected by HIV by maximizing the health impact of public health services, reducing disease

prevalence, and promoting health equity.

The recipient must devise a process and allocate resources, as needed, to assist the jurisdictions with the use of epidemiologic and social determinants data to identify communities within their jurisdictions disproportionately affected by HIV and related diseases and conditions. Likewise, the recipient should use data describing the social determinants of diseases in their coverage areas to accurately focus activities for reducing health disparities and to identify strategies to promote health equity. Based on the local epidemiologic and social determinants data, and in collaboration with partners and appropriate sectors of the community, the recipient should select metrics to monitor observed disparities in HIV and related diseases and conditions over time and should set specific targets and timelines for reducing such disparities. In collaboration with partners and appropriate sectors of the community, the recipient should also consider social determinants of health in the development, implementation, and evaluation of program-specific efforts and use culturally appropriate prevention messages, strategies, and interventions that are tailored for the communities for which they are intended. For additional resources to identify disability social determinants of health, visit the Disability and Health Data System website (https://www.cdc.gov/ncbddd/disabilityandhealth/dhds/index.html).

Details of the health equity strategy and approach are outlined in the NCHHSTP Social Determinants of Health White Paper (https://www.cdc.gov/nchhstp/socialdeterminants/docs/SDH-White-Paper-2010.pdf) and updates on the approach are described in Public Health Reports special supplement (Dean HD, Williams KM, Fenton KA. From Theory to Action: Applying Social Determinants of Health to Public Health Practice. Public Health Reports. 2013;128(Suppl 3):1-4.).

iv. Funding Strategy (for multi-component NOFOs only)

Note: Applicants must submit one application inclusive of the components (i.e., Components A, B, and/or C) for which they are applying.

Component A: Ending the HIV Epidemic Initiative (EHE)- Core Component

Visit the PS20-2010 website for detailed information on the funding ranges for each applicant.

CDC will distribute cooperative agreement funds based on a data driven formula, in order to better align funding with the ending the HIV epidemic initiative. This formula ensures that resources are distributed in a reliable manner, and that the federal investment in HIV prevention programs is based on need. Funding levels will be determined by formulas reflecting a base funding amount, HIV disease prevalence, number of counties within the health department jurisdiction (if applicable), and program performance (in subsequent years). Please note funding availability in subsequent fiscal years will be determined by satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, CDC can process applications and award funds in a timely manner. In the event that future fiscal year appropriation or other statute fails to authorize this activity, no awards will be made. Final award amounts may be less than requested. Funding availability in subsequent fiscal years is subject to the availability of appropriated funds.

Component B: HIV Incidence Surveillance

No funding allocated for this activity in Year One. Funding availability in subsequent fiscal years is subject to the availability of appropriated funds. Estimated Incidence funding and Laboratory Specimen Process/Storage funding per Jurisdiction is determined based on number of new HIV diagnoses. Estimated Incidence funding and Laboratory Specimen Process/Storage funding per Jurisdiction is determined based

Component C: Scaling Up HIV Prevention Services in STD Clinics

Eligible applicants include all jurisdictions applying for Component A of this NOFO (PS20-2010). Applicants must demonstrate the capacity to bill in the proposed STD specialty clinic or those who provide detailed plans to sustain this project through billing, or partnering and leveraging resources with other partners in the community; and to applicants with a functional STD specialty clinic that has the following services available onsite:

- STAT syphilis test
- Microscope for STAT Gram stain/Methylene Blue/Gentian Violet and wet mount
- Gonorrhea culture capacity
- Benzathine Penicillin LA
- Ceftriaxone

Average one year award: $500,000 - $800,000. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, CDC can process applications and award funds in a timely manner. In the event that future fiscal year appropriation or other statute fails to authorize this activity, no awards will be made. Final award amounts may be less than requested. Funding availability in subsequent fiscal years is subject to the availability of appropriated funds.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

CDC's Division of HIV/AIDS Prevention (DHAP) approach to monitoring, evaluation, accountability, and quality assurance for PS20-2010 includes the following components:

CDC evaluation and performance measurement ? will use data to (a) monitor and evaluate the PS20-2010 project, overall; (b) determine if NOFO strategies and activities are being implemented as expected; (c) assess whether intended short-term and intermediate outcomes are being achieved; (d) assess the effectiveness of key prevention strategies; (e) drive continuous program and system improvement; and (f) improve overall project performance.

Monitoring and accountability of individual recipients ? will ensure quality and accountability by using data to track implementation of recipient strategies and activities (process monitoring) and to determine progress toward achieving the outcomes (outcome monitoring).

Local (recipient) evaluation and performance measurement ? will involve use of data by recipients at the local level to monitor, evaluate, and continuously improve program performance.

CDC will use multiple methods for this approach, such as collection and analysis of quantitative

and qualitative data on program implementation and performance submitted by recipients to DHAP and DSTDP; tracking of key, standardized performance indicators; review of Annual Performance Reports; conference calls with recipients; and site visits.

Required data will include, but are not limited to, National HIV Surveillance System, Annual Performance Reports, National HIV Prevention Program Monitoring and Evaluation (NHM&E) data, and aggregated local health department data (e.g., county-level data). Recipients will collect the required quantitative and qualitative data using CDC approved applications (software) and submit to CDC, according to an established schedule and via CDC approved systems. These data will be used by CDC to calculate indicators and generate Rapid Feedback Reports (RFRs) regarding program accomplishments related to this NOFO and the EHE. Guidance on data collection, reporting, and analysis is provided in the HIV Surveillance Technical Guidance for HIV Surveillance Programs and the National HIV Prevention Program Monitoring and Evaluation (NHM&E) Data Collection and Reporting Guidance.

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 or innovative practices for dissemination during the project period, (d) demonstrate the value of the NOFO (e.g., improved public health outcomes, effectiveness of key prevention strategies and activities), and (f) contribute to the evidence base for NOFO strategies and activities.

Recipients will be expected to demonstrate progress toward achieving the intended short term, intermediate, and long-term outcomes that are bolded in the logic model. Progress towards achieving the short-term and intermediate outcomes should align with overall progress towards meeting the goals of the EHE initiative. The overarching goals for the EHE initiative are listed below.

For each of the NOFOs program components and strategies, a partial list of outcomes and indicators is presented below. A full list of proposed outputs, outcomes, and measures or indicators will be included in the CDC PS20-2010 Evaluation and Performance Measurement Strategy which will be provided by CDC at the beginning of the project. CDC will work with awardees to develop additional project specific outputs, outcomes, and measures. The CDC PS20-2010 Evaluation and Performance Measurement Strategy template is optional and can be used by recipients as a guide to assist with the development of the jurisdictional Evaluation and Performance Measurement Plan (EPMP). Recipients can use their own template. CDC will work with recipients to finalize their detailed EPMP, including a Work Plan and Data Management Plan (DMP), in accordance with CDC program guidance. Additionally, CDC will provide guidance to support the development of jurisdictional level targets for all EHE strategies for which racial and ethnic sub-targets will be developed.

Component A

Long Term Outcome: Reduced new HIV infections

- Measure: Estimated number of new infections among persons ≥13 years during the measurement period (EHE target: reduction ≥75% by 2025) (EHE target: reduction ≥90% by 2030) (EHE national target: ≤3,000 by 2030 (fewer than 1:100,000))

Strategies, Short-term and Intermediate Outcomes, Measures

Outcomes:

1.1: Increased routine opt-out HIV screenings in healthcare and other institutional settings

- Measure: Percentage of health care facilities identified as priority for routine opt-out HIV screening
- Measure: Percentage of persons tested in health care facilities identified as priority for routine opt-out screening

1.2: Increased local availability of and accessibility to HIV testing services

- Measure: Of all tests conducted in the county, the percentage conducted in other venues identified as a priority for the EHE HIV testing services (e.g., pharmacies, retail venues, other alternative settings)
- Measure: Percentage of all persons tested linked to appropriate HIV medical care and prevention services

1.3: Increased HIV screening and re-screening among persons at elevated risk for HIV

- Measure under development

1.4: Increased knowledge of HIV status (Intermediate Outcome)

- Measure: Percentage of people with HIV ≥13 years old who know their serostatus (EHE target: at least 95% by 2025)

1.5: Reduced new HIV diagnoses (Intermediate Outcome)

- Measure: Number of diagnoses among persons aged ≥13 years during the measurement period

Outcomes:

2.1: Increased rapid linkage to HIV medical care

- Measure: Percent linked to HIV medical care within 1 month after diagnosis among persons aged ≥13 years old with newly diagnosed HIV during the measurement period (EHE target: at least 95% by 2025)

2.2: Increased early initiation of ART

- Measure: Percentage of persons ≥13 years of age with HIV diagnosed in the measurement period and with viral suppression ≤ 6 months after HIV diagnosis (EHE target: at least 95% by 2025)

2.3: Increased immediate re-engagement to HIV prevention and treatment services for PWH who have disengaged from care

- Measure: Percentage of presumptively not-in-care PWH with an investigation opened (initiated) during a specified 6-month evaluation time period, who were confirmed within 90 days after the investigation was opened not to be in care
- Measure: Percentage of PWH confirmed during a specified 6-month evaluation time period not to be in care, who were linked to HIV medical care within 30 days after being confirmed not to be in care
- Measure: Percentage of PWH linked to HIV medical care during a specified 6- month evaluation time period, who achieved HIV viral suppression within six months (180 days) after being linked to care

2.4: Increased support to providers for linking, retaining, and re-engaging PWH to care and treatment

- Measure under development

2.5 Increased receipt of HIV medical care among persons with HIV (Intermediate Outcome)

- Measure: Percentage of persons ≥13 years living with diagnosed HIV who received any HIV medical care as measured by documentation of ≥1 CD4 or viral load tests performed during the measurement period (EHE target: at least 95% by 2025)

2.6: Increased viral suppression among persons living with diagnosed HIV (Intermediate Outcome)

- Measure: Percent of persons ≥13 years living with diagnosed HIV who are virally suppressed at last test (EHE target: at least 95% by 2025)

Outcomes:

3.1: Increased screening for PrEP indications among HIV- negative clients

- Measure: Number of HIV-negative clients who are screened for PrEP

3.2: Increased referral and rapid linkage of persons with indications for PrEP

- Measure: Number and percentage of HIV-negative clients who are linked to PrEP

3.3 Increased PrEP prescriptions among persons with indications for PrEP (Intermediate Outcome)

- Measure: Number of persons prescribed PrEP among those with indications for PrEP
- Measure: Percent of persons using PrEP (defined as filling prescriptions) among those with indications for PrEP (EHE target: at least 50% by 2025)

3.4: Increased access to SSPs

- Measure: Number of SSP delivery sites

- Measure: Number of encounters served by SSPs

3.5: Increased knowledge about the services and evidence-base of SSPs in communities (Intermediate Outcome)

- Measure under development

3.6: Increased quality of evidence-based SSP service delivery (Intermediate Outcome)

- Measure under development

Outcomes:

4.1: Increased health department and community engagement for cluster detection and response

- Measure: Number of meetings of standing committee to guide cluster response (at least quarterly)
- Measure: Number of meetings per year with a wide range of community members to engage them in cluster response (at least quarterly)
- Measure: Number of agreements for community-based organizations to be involved in cluster response

4.2: Improved surveillance data for real-time cluster detection and response

- Measure: Of all diagnoses, the percentage entered into the local surveillance system within the time specified in the HIV surveillance guidance
- Measure: Of all diagnoses, the percentage of duplicates identified in the Soundex application prior to entry into the surveillance system
- Measure: Of all labs with a specimen collection date in the reporting year, ≥85% are loaded in the surveillance system within two weeks of the specimen collection date

4.3: Improved policies and funding mechanisms to respond to and contain HIV clusters and outbreaks

- Measure under development

4.4: Improved response to HIV transmission clusters and outbreaks (Intermediate Outcome)

- Measure: Number and percentage of persons in cluster network who were located and interviewed within 7 days of identification as part of a cluster

<u>Component B</u>

Outcome: Estimate HIV incidence in selected jurisdictions using a recency-based assay

- Measure: Improved coordination with stakeholders including community, laboratory, and clinical providers to conduct recency-based incidence surveillance
- Measure: Increased capacity to collect recency-based assay results from all persons aged

13 years and older with a new diagnosis of HIV
- Measure: Estimated HIV incidence in selected jurisdictions using a recency-based assay

Component C

Outcome: Increased identification of new HIV and STD infections in STD specialty clinics

- Measure: Number of persons who were screened with a lab-based 4th generation HIV test
- Measure: Number of HIV-negative persons or unknown HIV status who were tested for HIV
- Measure: Number of HIV-negative persons who received three site and syphilis testing

Outcome: Increased rapid linkage to care for individuals newly diagnosed with HIV infection at STD specialty clinic

- Measure: Number of persons diagnosed with HIV who were linked to care within 7 days of diagnosis
- Measure: Number of persons diagnosed with HIV who were initiated on ARVs within 7 days of diagnosis

Outcome: Increased identification of virally unsuppressed people in STD specialty clinics.

- Measure: Number of patients living with HIV or newly diagnosed with HIV who were tested for viral load

Outcome: Increased re-engagement to care for persons living with HIV infection who are not virally suppressed

- Measure: Percentage of PWH linked to HIV medical care during a specified 6-month evaluation time period, who achieved HIV viral suppression within six months (180 days) after being linked to care

Outcome: Increased screening for PrEP/nPEP indications in specialty clinics

- Measure: Number of persons with a risk event showing within 72 hours of the event who received nPEP provider on the same day
- Measure: Number of persons with a negative HIV test and at substantial risk for HIV who were evaluated for PrEP

Outcome: Increased PrEP-eligible individuals in STD specialty clinics who are offered and initiate PrEP, if indicated

- Measure: Number of persons eligible from PrEP who started PrEP
- Measure: Number of PrEP patients who received recommended three site and syphilis testing

Cost Estimates: STD clinics will work with CDC to develop a cost analysis plan and

identify appropriate data collection instruments and methods. Additional studies may be conducted by CDC to assess the cost-effectiveness of specific interventions and service delivery models.

Specialized Evaluation Studies and Quality Improvement

We expect that specific evaluation questions and performance measures, data sources, and program targets for the required activities will be developed swiftly post-award in collaboration with CDC. We expect that sites will conduct evaluation studies using program evaluation techniques to test the impact of the intervention packages they propose.

Sites should also consider continuous quality improvement (CQI) approaches. CQI is an approach for improving service provision that emphasizes reaching and maintaining maximum quality. CQI requires analysis of all steps in a process of service provision (e.g., intervention delivery) against a relevant outcome or goal. Revised processes are analyzed for improvements against the baseline and further changes can be hypothesized and tested. When changes cease producing improvements, processes are finalized and institutionalized. For this proposal, the relevant outcomes are gaps and time delays in cascades of care.

CDC will work with recipients to finalize a Data Management Plan (DMP) in accordance with CDC program guidance

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 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.
- 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), if applicable, for accuracy throughout the lifecycle of the project. 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 https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

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 a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

Jurisdiction evaluation and performance measurement involves use of data by recipients at the jurisdiction level to monitor, evaluate, and continuously improve program performance. This will be conducted by recipients, based on the jurisdictional EPMP they develop. CDC will provide an optional template that can be used to develop the jurisdictional EPMP or a recipient can use their own template.

The jurisdictional EPMP will address all major program elements and include all indicators required by CDC, plus additional indicators useful to program managers. The jurisdictional EPMP findings should be reviewed by recipients at least quarterly and used to monitor, evaluate, and continuously improve program processes and performance.

As part of their jurisdictional evaluation, recipients may conduct in-depth evaluation of selected program activities to compare the effectiveness of different approaches used to accomplish project activities and identify the most effective methods for accomplishing project outcomes in their specific context and circumstances.

Applicants should plan for sufficient staffing and resources to accomplish all activities related to CDC and jurisdictional EPMPs, including planning, data collection, data entry, data management, reporting data to CDC, data analysis and interpretation, use of data for program improvement, development and dissemination of reports, and attendance at monitoring and evaluation meetings. Recipients must describe how funds will be allocated to support evaluation activities.

Applicants may also propose additional key outcome or performance measures that they plan to collect and track for themselves. Applicants are encouraged to list measures that they believe CDC should consider for inclusion in the final set of common performance measures for this NOFO, either in addition to, or in lieu of, the ones proposed in this NOFO.

All recipients are expected to comply with the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs (2011). All standards included in the NCHHSTP Data Security and Confidentiality Guidelines should be implemented by recipients, unless otherwise justified. A Certification of Compliance statement signed by an overall responsible party or parties (ORP) will be submitted annually to the CDC Project Officer at the same time the Annual Performance Report (APR) is submitted. For information on the data security and confidentiality guidelines and example certification statement, please refer to: https://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf.

Component C only

Performance measures

For the proposed outcome (not process) measures listed above, applicants should describe:

- Any 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)
- How useful the measures would be to the applicant
- How feasible it would be for the applicant to report on the measures, and to do so every 6 months
- Any anticipated barriers to obtaining and calculating the proposed measures
- Any other comments or questions the applicant has about the proposed measures at this time.

Applicants may also propose additional key outcome or performance measures that they plan to collect and track for themselves. Applicants are encouraged to list measures that they believe CDC should consider for inclusion in the final set of common performance measures for this NOFO, either in addition to, or in lieu of, the ones proposed in this NOFO.

c. Organizational Capacity of Recipients to Implement the Approach

Component A

All applicant organizations must demonstrate their existing or forthcoming capacity to successfully execute all proposed strategies and activities to meet the program requirements. Applicants must demonstrate expertise, experience, and/or capacity to develop, implement, and evaluate the required program strategies and activities. Applicants must also demonstrate the ability of their fiscal and programmatic systems to rapidly implement these EHE activities working with state, tribal, local, and/or territorial health departments, community health centers, health care providers, private/commercial/public laboratories, and other stakeholders within the jurisdiction is integral to program implementation. Applicants should describe their mission, organizational structure, overall organizational budget and funding sources, staff size and expertise, the nature and scope of their work and capabilities, long-term sustainability plan, and other information that would help CDC assess the organization's infrastructure and capacity to implement the proposed program. Applicants should address the physical infrastructure as it relates to equipment, electronic information and data systems, ensuring data security and confidentiality, and communication systems to implement the award.

Workforce Capacity

Applicants must provide details on their workforce capacity, competence, expertise and experience as they relate to all specific program strategies and activities. Applicants must have a strategy to ensure that the development, implementation, and delivery of comprehensive programs are appropriate to meet the needs of the population served within the jurisdiction and comply with existing laws and regulations. Details include experience and expertise related to the implementation of the required strategies and activities, recent examples of HIV program development and implementation, and demonstrated outcomes or benefits related to the HIV services provided. Applicants should provide a description of their current CDC funded HIV programs.

Having the appropriate workforce in place is a critical part of any plan to end the HIV epidemic. CDC's overarching approach to supporting a competent and adequate workforce to address the goals of EHE include the following principles:

- The workforce must be culturally competent, appropriate to the community and properly trained to meet the needs of those at risk for or with HIV.
- Workforce solutions must allow for flexibility of approach.
- Workforce solutions must focus on a multi-disciplinary approach based on local gaps and needs.
- The goal of workforce efforts is to increase staffing levels to support EHE activities funded under this NOFO. Therefore, rapid recruitment and retention of staff is critical.

Additionally, workforce capacity and development should focus on enhancing the skill sets of the community to support the hiring of individuals who are representative of the communities being served.

The following settings should be the focus of workforce enhancement efforts associated with this NOFO:

- Public Health-State, county or other jurisdictional health departments as well as other public health organizations or entities.
- Community-based -Settings focused on serving community members (e.g., community service and advocacy organizations, community centers, faith-based organizations, schools, etc.).
- Clinical - Private and public clinics, medical offices, and hospitals.
- Laboratories- public and private laboratories.

Furthermore, recipients must adhere to the additional requirements listed below when developing the appropriate workforce structure.

Oversight and Management:

- Recipients must designate, at a minimum, a specific individual at 100% effort to coordinate all EHE activities funded under this NOFO. The EHE Coordinator must be part of any committee or coalition mentioned in other activities under Component A, particularly the Response Pillar.

Using Existing Staff

- If recipients choose to fund salary/fringe of existing programmatic and scientific staff through this NOFO, staff should be dedicated at no less than 50% of time to EHE activities funded by the NOFO.

Additional Staff:

- Recipients are encouraged to identify additional staff for the EHE activities and may do so in a variety of ways, including, but not limited to:
    - Direct hiring of staff using NOFO funds

    - Contracting or temporary hiring through a third party (local or national)
    - Conversion of Financial Assistance (FA) to Direct Assistance (DA), if available
    - Use of Public Health Associate Program (PHAP) Associates and/or Graduates, if available
    - Other mechanisms provided by CDC or state/local governments
    - Other innovative solutions approved by the CDC Project Officer.
- Recipients are encouraged to hire staff who reflect the communities and/or populations being served by the activities funded in this NOFO.
- Additional programmatic and/or scientific staff should be funded at no less than 50% of dedicated time to EHE activities funded this NOFO.

Training and Capacity Building:

- Recipients must provide local training to new staff working on EHE activities. Training must be relevant to their position using CDC guidance, when available.
- Recipients must also allow new staff working on EHE activities to access training from Federal partners and other sources (i.e., CBA training, AIDS Education and Training Centers (AETCs) etc.).
- Recipients should also access existing training and capacity building resources.

Furthermore, applicants must provide evidence of adequate program management/staffing plans, performance measurement, evaluation, financial reporting, management of travel requirements, and workforce development and training. Applicants should identify key staff, including program management, with expertise in prevention and surveillance programs (Principal Investigator or Co-Principal Investigator) and must have a plan to ensure that program staff, including Public Health Associate Program (PHAP) graduates, have adequate skills and relevant experience and capacity to implement the activities and achieve the project outcomes, including the evaluation plan.

The staffing plan and project management structure should be sufficient to achieve the project outcomes (e.g., staff technical expertise, data management and data analysis capacity, and a plan for accessing capacity building assistance to support workforce development), inclusive of subcontractors and consultants if applicable, throughout the duration of the five-year project. Staff must have the breadth of subject matter expertise and experience required to conduct all proposed work. Applicants should describe how they will assess staff competencies and develop a plan to address gaps through organizational and individual training and development opportunities.

Additionally, a curriculum vitae or resume must be submitted for each existing key personnel who will be affiliated with this program. Applicant organizations are also required to provide an agency-wide organizational chart and an organizational chart for the proposed program.

Component B

In addition to the organizational capacity requirements described above for Component A, Component B applicants must also:

- Demonstrate the ability of their fiscal and programmatic systems to rapidly implement the described EHE activities working with private/commercial/public laboratories.

- Demonstrate workforce capacity by describing in detail recent examples of implementation of similar surveillance activities, collaborative relationships with providers and laboratories, dissemination and uses of data to inform HIV program development and implementation.

Component C

The applicant must clearly and concisely describe the program activities and methods the applicant intends to use to meet the budget and performance period outcomes. The applicant should outline their experience to date with each of the five activities, as well as a planned approach to strengthening their work for each activity under this award. Applicants must include a description of the proposed STD specialty clinic and how the proposed approaches will identify individuals who could benefit from HIV prevention services, will achieve the goals of the award and alleviate health disparities; and how the clinic proposes to determine health insurance status. While funds from Component C can be used to screen, diagnose, or treat STDs for uninsured and underinsured patients, they cannot be used to cover the costs of antiretroviral medication, including PrEP. Applicants must describe plans to sustain this project through billing, or partnering and leveraging resources with other HIV prevention providers in the community. Additionally, applicants should describe plans to reach out to minority populations in their target local jurisdiction.

Applicants must describe the HIV and STD health department programs' in the proposed local jurisdiction and describe the proposed STD specialty clinic's organizational capacity to achieve the outcomes of the award. The STD clinic organizational capacity statement should specifically describe the nature and scope of the clinical services that are provided, hours of operations, electronic health record functionality and interoperability and the number and composition of staffing. The STD clinic capacity statement should also describe the current state of HIV prevention services including known infrastructure and system level barriers to expansion and full implementation.

In addition, applicants must report:

- The number of new HIV infections reported by the local jurisdiction for 2016 and 2017 as a marker of transmission in the jurisdiction
- The percent decline in the number of new HIV infections reported in the local jurisdiction from 2011 to 2017 as a marker of local HD efforts and infrastructure to address their HIV epidemic.

These local health jurisdiction data must be summarized in a table and uploaded as PDF in www.grants.gov under "Other Attachment Form" and labeled: Documentation of Local Health Jurisdiction reported HIV cases in 2016 and 2017 and recent percent declines from 2011 to 2017.

State health department applicants must describe the HIV and STD health department programs relationship to the local health department (LHD) and STD specialty clinic proposed for this project and describe how funds will be directed to the STD clinic, including mechanisms and timelines to obligate funds. CDC anticipates that no less than 90% of the funds will be directed to strengthening infrastructure and systems to enhance and scale up HIV prevention services in

the proposed STD specialty clinic.

Local health department applicants must describe the HIV and STD health department programs relationship to the STD specialty clinic proposed for this project and describe how funds will be directed to the STD clinic. In addition, applicants must describe data transfer/sharing process between participating entities. Applicants must also include:

- The agency, LHD and STD clinic organizational charts, clearly identifying the organizational placement and management structure of the STD and the HIV prevention programs and the STD clinic within the State and/or local health department
- Key local and clinic staff
- HIV case management, linkage services, partner services or other collaborative activities relevant to the supplement.

Applicants should name the file "Organizational Charts" and upload as a PDF file under "Other Attachment Forms" on www.grants.gov.

Applicants should specify who will have day-to-day responsibilities for state, local and clinic leadership of the project, monitoring the project's on-going progress, preparation of reports, and communication with CDC and other partners; and the proposed staffing plan and project management structure that will be in place to achieve the project outcomes, inclusive of subcontractors and consultants if applicable, throughout the duration of the project.

Management and staffing plan

Applicants must provide details on their workforce capacity, competence, expertise and experience as they relate to the required program strategies and activities. Staff must have the breadth of subject matter expertise and experience required to conduct all proposed work and the capacity and skills to effectively manage a diverse STD program portfolio. Finally, applicants must demonstrate an effective approach to supporting workforce development over the course of the period of performance. To that end, applicants should describe:

- Their general approach to assessing workforce training and development needs, and their approach to meeting those needs
- Their primary approach to providing training to staff
- Any known workforce capacity or skills gaps that may affect their ability to implement the strategies in year one, and
- Their highest priorities for workforce development and training in the first year of this program and any plans in place already to meet those needs

d. Work Plan

Applicants are required to provide a work plan that provides both a high-level overview of the entire five-year project period and a detailed description of the first year of the award. The work plan should be a direct response to issues, strategies and activities outlined in local EHE or other previously submitted/developed plans. The work plan can be integrated with the jurisdiction EPMP, should be broken out by program component, and incorporate all NOFO-related program strategies and activities. Applicants should propose specific, measurable, achievable, realistic, and time-based (SMART) process and/or outcomes for each activity

aligned with the related NOFO performance outcomes, including NOFO performance targets. The work plan should include training, capacity building, and TA needs to support the implementation of the proposed program. In addition, a concise description on how the recipients plans to implement and monitor each program activity should be included in the work plan.

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

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

- Five-Year Overview of Project (include narrative)
    - Intended outcomes for the entire project period
- 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)
    - Activities aligned with program outcomes and measures
    - Timeline for implementation (including staffing of the proposed program, training, etc.)

Below is a sample work plan format to show the alignment with the logic model and narrative. The table would be completed for each project period outcome. If a particular activity leads to multiple outcomes, it should be described under each outcome measure: Project Period Outcome: [from Outcomes section and/or logic model]		Outcome Measure: [from Evaluation and Performance Measurement section]	
Strategies and Activities	Process Measures [from Evaluation and Performance Measurement section]	Responsible Position/Party	Completion Date

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(s) as a PDF file under "Other Attachments".

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.

Monitoring may also include other activities deemed necessary to monitor the award, if applicable. After review of the first annual performance report, if the awardee is not conducting required recipient activities or not meeting process or outcome standards, CDC will provide or facilitate technical/capacity building assistance for program improvement. Recipients performing at a less than sufficient level to achieve program objectives within stated timeframes will be placed on a time-phased Programmatic Improvement Plan (PIP) developed by the CDC Project Officer/Project Consultant/Epidemiologist in collaboration with the awardee. The PIP is a comprehensive tool used to assist recipients to improve program performance through identifying factors contributing to less than sufficient performance and developing specific action steps to address areas in need of improvement. If placed on a PIP, the awardee will have an opportunity to document a plan of action to improve the performance of program activities. In subsequent budget periods, funding may be affected based on performance.

Monitoring and reporting activities are outlined in Chapter 2.01.101 of the HHS Grants Policy Administration Manual (GPAM) that assists grants management staff (e.g., grants management officers [GMOs] and specialists [GMS], and project officers) in the identification, notification, and management of high-risk recipients.

f. CDC Program Support to Recipients (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In a cooperative agreement, CDC staff are substantially involved in the program activities, above and beyond routine grant monitoring. CDC activities for this program are as follows:

1. Collaborate to ensure coordination and implementation of strategies to support the

implementation of comprehensive HIV surveillance and prevention activities.

2. Provide guidance and coordination to funded organizations to improve the quality and effectiveness of work plans, evaluation strategies, products and services, and collaborative activities with other organizations.
3. Collaborate to ensure coordination and provide policy and program information for rapid dissemination and implementation.
4. Work with recipients to identify and address capacity building assistance (CBA) and TA needs that are essential to the success of the project.
    - Provide access to training and TA that will strengthen staff capacity relevant to all required strategies and activities of the program.
5. Provide guidance to the recipient and set standards on data collection, use, and submission requirements.
6. Provide technical advice in the development of systems to implement and advance CDC policies, initiatives and programs.
7. Collaborate to ensure coordination and implementation of technical assistance services to state and local health department HIV program staff.
8. Collaborate in assessing progress toward meeting goals/outcomes and in establishing measurement and accountability systems for documenting outcomes, such as increased performance improvements and best or promising practices
9. Provide guidance and coordinate with the recipient to improve the quality and effectiveness of the proposed program. This may include revision of the work plan, evaluation strategy, products and services, among others.
10. Foster and support ongoing opportunities for networking, communication, coordination, and collaboration.
11. Provide consultation in planning, operating, analyzing and evaluating HIV programs, including HIV prevention planning, CDC special initiatives, (e.g., program integration, comprehensive HIV prevention programs, and program evaluation activities.)
12. Monitor recipient 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.
13. Provide support and facilitate program collaboration with other CDC programs and HHS offices to enhance and improve integration of services.
14. Assist in assessing program operations and in evaluating overall effectiveness of programs.
15. Provide capacity building assistance where identified or as needed to the recipient.
16. Collect and disseminate 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).
17. Provide requirements and expectations for standardized and other data reporting and support monitoring and evaluation activities.

B. Award Information

1. Funding Instrument Type:	Cooperative Agreement CDC's substantial involvement in this

program appears in the CDC Program Support to Recipients Section.

2. Award Mechanism: U62

3. Fiscal Year: 2020

Estimated Total Funding: $109,000,000

4. Approximate Total Fiscal Year Funding: $109,000,000

This amount is subject to the availability of funds.

5. Approximate Period of Performance Funding: $109,000,000

Estimated $109,000,000 in Year One. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, CDC can process applications and award funds in a timely manner. In the event that future fiscal year appropriation or other statute fails to authorize this activity, no awards will be made. Final award amounts may be less than requested. Funding availability in subsequent fiscal years is subject to the availability of appropriated funds.

6. Total Period of Performance Length: 5

Component A and C: 5 years

Component B: 4 years

7. Expected Number of Awards: 48

Component A: 32

Component B: 8 (beginning in Year 2)

Component C: 5 - 8

8. Approximate Average Award: $0 Per Budget Period

Component A: Not applicable. Funding will be determined by formulas reflecting a base funding amount, HIV disease prevalence, number of counties within the health department jurisdiction (if applicable), and program performance (in subsequent years). Funding will vary by jurisdiction.

Component B: $450,000 - $725,000; Funding begins in Year 2

Component C: $400,000 - $800,000

This amount is subject to the availability of funds.

9. Award Ceiling: $0 Per Project Period

Not applicable; The ceiling is subject to the availability of funds.

10. Award Floor: $0 Per Project Period

Component A: $1,800,000

Component B: $450,000 (beginning in Year 2)

Component C: $400,000

11. Estimated Award Date: 06/01/2020

Throughout the period of performance, 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 (period of performance) 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).

12. Budget Period Length: 12 month(s)

13. Direct Assistance

Direct Assistance (DA) is available through this NOFO.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments

Additional Eligibility Category:

Government Organizations:

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.

2. Additional Information on Eligibility

Component A:

Eligible applicants include state, local, and territorial health departments or their Bona Fide Agents identified in Phase 1 of the Ending the HIV Epidemic (EHE) Initiative and that have a current direct funding relationship with CDC. Eligibility for funding to implement the above

described program is contingent upon the existence of a comprehensive EHE plan.

The Ending the HIV Epidemic: A Plan for America is a new initiative announced by the President in February 2019. The Phase 1 jurisdictions represent more than 50% of new HIV diagnoses only 48 counties, Washington, DC, and San Juan Puerto Rico. In addition, seven (7) states have a substantial rural burden with over 75 cases and 10% or more of the diagnoses in rural areas.

Eligible Phase I jurisdictions and corresponding CDC funded health department	
Phase 1 State or County	***Eligible Entity***
Alabama	Alabama Health Department
Arkansas	Arkansas Health Department
Arizona	
Maricopa County	Arizona Health Department
California	
Los Angeles County	Los Angeles County Health Department
San Francisco County	San Francisco Health Department
Alameda County	California Health Department
Orange County	California Health Department
Riverside County	California Health Department
Sacramento County	California Health Department
San Bernardino County	California Health Department
San Diego County	California Health Department
Florida	
Broward County	Florida Health Department
Duval County	Florida Health Department
Hillsborough County	Florida Health Department
Miami-Dade County	Florida Health Department
Orange County	Florida Health Department
Palm Beach County	Florida Health Department
Pinellas County	Florida Health Department

Georgia	
Cobb County	Georgia Health Department
DeKalb County	Georgia Health Department
Fulton County	Georgia Health Department
Gwinnett County	Georgia Health Department
Illinois	
Cook County	City of Chicago Health Department
Indiana	
Marion County	Indiana Health Department
Kentucky	Kentucky Health Department
Louisiana	
East Baton Rouge Parish	Louisiana Health Department
Orleans Parish	Louisiana Health Department
Maryland	
Baltimore City	Baltimore City Health Department
Montgomery County	Maryland Health Department
Prince George's County	Maryland Health Department
Massachusetts	
Suffolk County	Massachusetts Health Department
Michigan	
Wayne County	Michigan Health Department
Mississippi	Mississippi Health Department
Missouri	Missouri Health Department
Nevada	
Clark County	Nevada Health Department
New Jersey	
Essex County	New Jersey Health Department
Hudson County	New Jersey Health Department

New York	
Bronx County	New York City Health Department
Kings County	New York City Health Department
New York County	New York City Health Department
Queens County	New York City Health Department
North Carolina	
Mecklenburg County	North Carolina Health Department
Ohio	
Cuyahoga County	Ohio Health Department
Franklin County	Ohio Health Department
Hamilton County	Ohio Health Department
Oklahoma	Oklahoma Department of Health
Pennsylvania	
Philadelphia County	City of Philadelphia Health Department
South Carolina	South Carolina Health Department
Tennessee	
Shelby County	Tennessee Health Department
Texas	
Harris County	Houston Health Department
Bexar County	Texas Health Department
Dallas County	Texas Health Department
Tarrant County	Texas Health Department
Travis County	Texas Health Department
Washington	
King County	Washington State Health Department
Washington, DC	District of Columbia Health Department
Puerto Rico	
San Juan Municipio	Puerto Rico Territorial Health Department

Jurisdictions with both eligible state and local (city or county) health departments listed in the table above must collaborate on and discuss: (1) the proposed program approach being implemented by the state and local health departments, (2) how the state and local area will collaborate during the project period to ensure appropriate provision of services and document any agreements reached in a letter of agreement/letter of concurrence (LOA/LOC), which must be submitted by both parties as part of their application; and (3) ensure that fiduciary arrangements specify that the funding resources are directed towards the Phase 1 local county, as appropriate.

Component A applicants must file letters of agreement/letters of concurrence, as appropriate, name the file(s) "LOA," and upload the document(s) as a PDF file under "Other Attachments Forms".

Component A applicants must file Bona Fide Agent agreements, as appropriate, name the file(s) "Bona Fide Agent" and upload the document(s) as a PDF file under "Other Attachments Forms".

Component B:

Eligible recipients must meet the following criteria:

- *Ending the HIV Epidemic* geographic focus area with > 300 new HIV diagnoses annually
- Reliable incidence estimates from the CD4-based model
- Previous success in implementing recency assay-based HIV Incidence Surveillance
- Based on the above criteria, the following eight recipients are eligible for voluntary participation:

Alabama	Florida	Michigan	South Carolina
District of Columbia	Houston	New York City	Texas

Component C:

Only jurisdictions eligible for Component A of this NOFO, PS20-2010, can apply for Component C. Applicants must demonstrate that the proposed STD specialty clinic has the following services available onsite: STAT syphilis test, microscope for STAT Gram stain/Methylene Blue/Gentian Violet and wet mount, gonorrhea culture capacity, and medications on site including Benzathine Penicillin LA and ceftriaxone.

3. Justification for Less than Maximum Competition

The Ending the HIV Epidemic in America is a new initiative announced by the President in February 2019. The phase 1 jurisdictions represent more than 50% of new HIV diagnoses in only 48 counties, Washington, D.C., and one municipality, San Juan, Puerto Rico. In addition, 7 states have a substantial rural burden with over 75 cases and 10% or more of the diagnoses in rural areas. Thus, eligibility is limited to state, local and territorial health departments, or their Bona Fide Agents identified in Phase 1 of the Ending the HIV Epidemic Initiative and that have a current direct funding relationship with CDC.

Eligibility for funding to implement the proposed program is contingent upon the existence of a comprehensive Ending the HIV Epidemic plan and receipt of funding under *PS19-1906:*

Strategic Partnerships and Planning to Support Ending the HIV Epidemic in the United States.

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Required Registrations

Additional materials that may be helpful to applicants: http://www.cdc.gov/ od/ pgo/ funding/ docs/ Financial ReferenceGuide.pdf.

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.

a. Data Universal Numbering System: All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http:// fedgov.dnb. com/ webform/ displayHomePage.do. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS 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. 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 https://www.sam.gov/SAM/.

c. Grants.gov: The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.

All applicant organizations must register at www.grants.gov. 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	Data Universal	1. Click on http:// fedgov.dnb.com/	1-2 Business Days	To confirm that you have been

	Number System (DUNS)	webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number		issues a new DUNS number check online at (http:// fedgov.dnb.com/ webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CCR)	1. Retrieve organizations DUNS number 2. Go to https://www.sam.gov/SAM/ and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	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
3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the Account is set up the E_BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit the applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying to grants.gov)	Register early! Log into Grants.gov and check AOR status until it shows you have been approved

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 funding opportunity at www.grants.gov.

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 or postmarked by)

Due Date for Letter of Intent: **N/A**
Letters of Intent (LOI) are not requested or required as part of the application for this NOFO.

b. Application Deadline

Due Date for Applications: **03/25/2020** , 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. 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.

Date for Informational Conference Call: 02/04/2020
Component A: Tuesday, February 4, 2020 at 2:00 pm (EST)

Registration Link: https://globalmeetwebinar.webcasts.com/starthere.jsp?ei=1280904&;tp_key=90383bbac

Component B: Wednesday, February 5, 2020 at 2:00 pm (EST)

Registration Link: https://globalmeetwebinar.webcasts.com/starthere.jsp?ei=1280906&;tp_key=88f751d0ae

Component C: To Be Announced

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http:// wwwn.cdc.gov/ grantassurances/ (S(mj444mxct51lnrv1hljjjmaa)) / Homepage.aspx.
Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file "Assurances and Certifications" and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http:// wwwn.cdc.gov/ grantassurances/

(S(mj444mxct51lnrv1hljjjmaa)) / Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

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

7. Letter of Intent

Is a LOI: Not Applicable

LOI is not requested or required as part of the application for this NOFO.

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 www.grants.gov.

9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. 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 www.grants.gov.

The summary of the proposed project must include the purpose and outcomes for each of the components for which the applicant intends to apply.

10. Project Narrative

Multi-component NOFOs may have a maximum of 15 pages for the "base" (subsections of the Project Description that the components share with each other, which may include target population, inclusion, collaboration, etc.); and up to 4 additional pages per component for Project Narrative subsections that are specific to each component.

Text should be single spaced, 12 point font, 1-inch margins, and number all pages.

Page limits include work plan; content beyond specified limits may not be reviewed. Applicants should use the federal plain language guidelines and Clear Communication Index to

respond to this Notice of Funding Opportunity Announcement. 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.

Applicants should label Project Narrative subsections by component (i.e., Component A, Component B, Component C).

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 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 period of performance. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (e.g., increase, decrease, maintain). (See the logic model in the Approach section of the CDC Project Description.)

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 period of performance. (See CDC Project Description: Strategies and Activities section.)

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.

Applicants should include subheadings for each component (i.e., Component A, Component B, Component C) under the Strategies and Activities section of their application.

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.

Applicants should include subheadings for each component (i.e., Component A, Component B, Component C) under the Strategies and Activities section of their application.

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 https://www.cdc.gov/od/science/integrity/reducePublicBurden/.
- 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.

The EPMP, including the DMP, should include subheadings for each component (i.e., Component A, Component B, Component C) for which the applicant intends to apply.

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 www.grants.gov. 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 www.grants.gov.

Note: Provide a separate itemized budget if applying for DA. In addition, provide a separate 424A form.

Note: A separate itemized budget is required for each component (i.e., Component A, Component B, Component C) for which applicant intends to apply.

13. Intergovernmental Review

Executive Order 12372 does not apply to this program.

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.

14a. 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 2 CFR 200 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.

14b. 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.

14c. 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.

14d. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan. The DMP is the applicant's assurance of the quality of the public health data through the data's lifecycle and plans to deposit 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/additionalrequirements/ar-25.html

15. 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
    - 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 Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
- 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.
- In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

- 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.
- Recipients may not use funds to purchase antiretroviral therapy.
- Recipients may not use funds to purchase sterile needles or syringes for drug injection.
- Funding should not be used for construction purposes.
- Recipients may not use funds to purchase HIV Pre-exposure Prophylaxis (PrEP) medications or family planning medications.
- Recipients may not use funds to purchase medications, other than those noted in this NOFO for the treatment of STDs, unless they receive prior approval from CDC.

16. 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 www.grants.gov 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 www.grants.gov 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 www.grants.gov 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 www.grants.gov. 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 www.grants.gov, applicants should contact Customer Service at www.grants.gov. 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 support@grants.gov. 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 www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@grants.gov 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 (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

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

a. Phase I Review
All applications will be initially reviewed for eligibility and completeness by the Office of Grants Services. Complete applications will be reviewed for responsiveness by Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. 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.

Component A: Approach	Maximum Points: 45

Evaluate the extent to which the applicant:

1. Presents outcomes that are consistent with the project period outcomes described in the Project Description and logic model.
2. Describes an overall strategy consistent with the Project Description and logic model, including describing:
    a. The proposed strategy for addressing social determinants of health.
    b. The processes for ensuring community involvement in the planning and implementation of the proposed EHE activities.
3. Describes each strategy and the associated activities that are achievable, appropriate to achieve the outcomes of the project, and evidence-based (to the degree practicable).
4. Describes the rationale that explains why they believe their proposed innovative activities will successfully advance the corresponding strategy.
5. Shows that the proposed use of funds is an efficient and effective way to implement each of the required strategies and associated activities and attain the project period outcomes.
    - Including, describing the proposed funding allocated for each EHE Phase 1 counties.
6. Presents a work plan that is aligned with each of the required strategies and associated

activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC.

Component A: Evaluation and Performance Measurement Maximum Points: 30

Evaluate the extent to which the applicant:

1. Shows/affirms the ability to collect data on the process and outcome performance measures specified by CDC in the project description and presented by the applicant in their approach.
2. Describes clear monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities.
3. 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.
4. Describes how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base.
5. Describes any evaluation activities they are to undertake. Describe in sufficient detail to identify the key evaluation questions, and data sources and analysis methods.
6. Includes a preliminary Data Management Plan (DMP).

Component A: Organizational Capacity to Implement the Approach Maximum Points: 25

Evaluate the extent to which the applicant addresses the items below.

1. Demonstrates relevant experience and capacity (management, administrative, and technical) to implement each of the required strategies and associated activities and achieve the project outcomes.
2. Demonstrates experience and capacity to implement the evaluation plan.
3. Provides capacity building needs.
4. Provides a staffing plan and project management structure that will be sufficient to achieve the project outcomes and which clearly defines staff roles. Provides an organizational chart.
5. Demonstrates experience and capacity to coordinate with tribal governments and/or tribally designated organizations in their jurisdiction, if applicable.

Component A: Budget and Budget Justification Maximum Points: 0

Evaluate the extent to which the budget appears reasonable and consistent with the proposed activity and purpose of the program.

Component B: Approach Maximum Points: 35

Evaluate the extent to which the applicant provides a detailed description of the proposed HIV Incidence Surveillance and related activities to include:

1. Collaborate with CDC, laboratories, HIV testing providers, and affected communities to further develop and ensure the capability to conduct HIV Incidence Surveillance.

2. Consistent with CDC's guidance, collect results of tests from a recent infection testing algorithm (RITA) for persons with new HIV diagnoses.
3. For persons with a new diagnosis of HIV that has been reported to HIV surveillance, obtain HIV testing history (e.g., dates, tests used), antiretroviral (ARV) drug exposure history, and viral load data, consistent with CDC's guidance.
4. Ensure integration of HIV Incidence Surveillance activities with routine HIV surveillance activities.
5. Submit data, as specified by CDC, by using eHARS software and by complying with data submission standards established by CDC.
6. Conduct systematic data quality and evaluation of HIV Incidence Surveillance.
7. Calculate and disseminate annual population-based HIV incidence estimates and promote the use of HIV incidence data for prevention and health services planning.
8. Ensure that the security and confidentiality procedures of the program are consistent with the requirements of CDC's Data Security and Confidentiality Guidelines.

Component B: Evaluation and Performance Measurement Maximum Points: 25

Evaluate the extent to which the applicant:

1. Provides information on the project description and approach.
    a. Annual program goals and SMART objectives for the proposed activity, to include program performance targets.
    b. Activities that will be conducted to meet the objectives.
    c. Capacity building needs.
    d. Timeline for the project period that shows the implementation of the proposed project related activities. Timeline includes planning, implementation and evaluation phases.
2. Provides information for the monitoring and evaluation description.
    a. Describes a plan for evaluating progress and outcomes of the project and for identifying lessons learned.
    b. Proposed project should have a separate EPMP, including data management plan. Refer to EPMP and DMP sections
        i. Data collection and management, entry, submission, and data analysis
        ii. Data usage: how, by whom, and when data will be used to support program planning, resource allocation, and evaluation; measure progress toward meeting objectives; and to improve program performance, quality, and accountability
        iii. Local monitoring and evaluation activities.
        iv. A description of procedures in place for data security and confidentiality. These procedures must be in accordance with CDC's Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, STD, and TB Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action.
        v. Describes how the results will be used and shared, including data dissemination and sharing with participating healthcare/non-healthcare

facilities, CBOs or other service organizations, and key stakeholders.

Component B: Applicant's Organizational Capacity to Implement the Approach	Maximum Points: 40

Evaluate the extent to which the applicant:

1. Describes the health department's experience and capacity to implement the project.
2. Submits a staffing and management description for the proposed project that includes staff experience and background to support and carry out the activities of the program including evaluation.
3. Describes how applicant will manage, monitor, and maintain collaborations with other programs, service providers and/or stakeholders.
4. Plans to collaborate with CDC or other technical assistance providers to provide ongoing training, technical assistance, and consultation to all staff conducting the project.

Component B: Budget and Budget Justification	Maximum Points: 0

Evaluate the extent to which the budget appears reasonable and consistent with the proposed activity and purpose of the program.

Component C: Approach	Maximum Points: 35

The extent to which the applicant:

1. Describes the need for assistance to expand culturally sensitive clinical HIV prevention services to reach the populations at risk of acquiring HIV as identified in the background section of this NOFO.
    - This includes the percent of racial, ethnic and sexual minority patients receiving services in the proposed STD clinic in 2018 and the proportion of patients who are uninsured and underinsured.
2. Describes, with consistent and complete information, existing HIV prevention services available in the area and documented service gaps and need for this program within the target community as well as factors affecting the broader health care environment in the selected jurisdiction.
3. Demonstrates, with consistent and complete information, that the proposed clinic site, service delivery model(s), clinical services, and staffing plan are adequate to achieve the desired goals of this project. This includes the extent to which the proposed site meets the CDC definition of STD specialty clinic.
4. Describes in detail the process for conducting the assessment of the STD specialty clinic and proposes to address identified gaps.
5. Describes the completeness and quality of the proposed approach to ensure that the HIV prevention services, including HIV testing, STD testing at relevant anatomical sites, and provision of PrEP/nPEP will be operational, and compliant within 90 days of award with appropriate staff and providers will be in place to deliver services.
6. The quality of plans to expand the capacity of the specialty STD clinic, including plans to strengthen laboratory capacity.

7. The quality of appropriate, realistic, and achievable plans to ensure sustainability of the program, including capacity to bill Medicaid and/or private health insurance.
8. The strength of the applicant's collaboration and coordination with other HIV health care providers, HIV and STD health department staff and community organizations in the proposed service area; and plans to optimize linkage to and re-engagement with HIV medical care and treatment.

Component C: Evaluation and Performance Measurement: Maximum Points: 25

The extent to which the applicant:

1. Describes an evaluation plan that is consistent with their work plan and the CDC evaluation performance strategy, and that is feasible and likely to demonstrate grantee performance outcomes, including successes and needed improvements.
2. Demonstrates a strength of monitoring and evaluation procedures and how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities.
3. Describes the degree to which clinic and local health department staff will be engaged in the evaluation and performance measurement planning processes.
4. Describes potentially available data sources and feasibility of collecting appropriate evaluation and performance data.
5. Describes how evaluation findings will be used for continuous program and quality improvement.

Component C: Applicant's Organizational Capacity to Implement the Approach Maximum Points: 40

The extent to which the applicant:

1. Describes the degree to which the proposed STD clinic and local health department's experience and expertise working with and addressing needs of the target population(s) have positioned the applicant organization to successfully implement the proposed project in the proposed timeframe.
2. Describes the electronic health record or other data systems to monitor project impact being used in the STD clinic.
3. Outlines a feasible plan to obligate the resources within the first three months of the award.
4. Provides letters of support stating commitment of collaboration or MOU from the health officer and the medical director of the STD specialty clinic support the proposed project through detailed descriptions of collaboration and coordination.
5. Describes the quality of proposed activities to achieve desired short-term outcomes.
6. Describes their plan to effectively recruit and retain key management staff and health care providers including a medical director of the STD clinic who has experience caring for patients living with HIV and to adequately support and implement the proposed strategies.
7. Describes the quality of the staffing plan, with well-defined roles and responsibilities, including qualifications and percentage of time that each person will devote to the project.

8. Describes the quality of the plans for managing the multiple strategies, including clear procedures for ensuring all required activities are performed and all deadlines are met.
9. Describes a clear description of institutional commitment to the proposed activity at the state, local and clinic levels, including the ability to develop and maintain the necessary infrastructure and staff the project.
10. Demonstrates the capacity to bill in the proposed STD specialty clinic or includes a detailed plan for sustainability of this project through billing, partnering or leveraging resources with other partners in the community.
11. Demonstrates onsite availability of the following services in the STD specialty clinic or provides detailed plans for incorporating these services during the first 6 months of the project:
    - STAT syphilis test
    - Microscope for STAT Gram stain/Methylene Blue/Gentian Violet and wet mount
    - Gonorrhea culture capacity
    - Benzathine Penicillin LA
    - Ceftriaxone

Component C: Budget and Budget Justification	Maximum Points: 0

Evaluate the extent to which the budget appears reasonable and consistent with the proposed activity and purpose of the program.

c. Phase III Review

A technical review process will be conducted by CDC to provide feedback to all applicants on the proposed program. All eligible and technically acceptable applications submitted in response to Components A and B will be funded. For Component C, applications will be funded in order by score and rank determined by the review panel. Geographic distribution and morbidity may be considered in final funding decisions.

Funding preference will be given to applicants who can demonstrate the capacity to bill in the proposed STD specialty clinic or those who provide detailed plans to sustain this project through billing, or leveraging resources with other partners in the community; and to applicants with a functional STD specialty clinic that have the following services available onsite or provide detailed plans to have these services available onsite within 12 months:

- STAT syphilis test
- Microscope for STAT Gram stain/Methylene Blue/Gentian Violet and wet mount
- Gonorrhea culture capacity
- Benzathine Penicillin LA
- Ceftriaxone.

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

Award Announcement Date and Anticipated Award Date: June 1, 2020

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 NOFO will be subject to the DUNS, 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 or by U.S. mail.

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 http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17.

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

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

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the period of performance. 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 NOFO 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 period of performance.	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30.	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 publically 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 www.Grantsolutions.gov 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 weblinks 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)
    - SF-424A Budget Information-Non-Construction Programs.

- Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- Indirect Cost Rate Agreement.

The recipient must submit the Annual Performance Report via www.Grantsolutions.gov 120 days prior to the end of the budget period.

The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signal, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances); and
- Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

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.

In addition to the Annual Performance Report, recipients are required to submit data at the end of each budget year. Recipients will be required to complete an End of Year (EOY) Performance Report that captures the quantitative data from the last six months of the previous budget period and qualitative data for the entire 12 month budget period. The EOY Performance Report is due 90 days after the end of the budget period. Data collection has been approved by the Office of Management and Budget (OMB) under OMB Number 0920-0573, National HIV Surveillance System, Expiration Date: November 30, 2022, and OMB Number 0920-0696, National HIV Prevention Monitoring and Evaluation, Expiration Date: October 31, 2021. Changes to data collection requirements during the project period will be subject to review and approval by OMB.

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. 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, awardees 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)
This report is due 90 days after the end of the period of performance. 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 period of performance, 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).

Recipients will be required to complete a Program Closeout Report that captures the quantitative data from the last six months of the previous budget period and qualitative data for the entire project period. The Program Closeout Report is due 90 days after the end of the project period.

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, http://www.USASpending.gov. 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.

G. Agency Contacts

CDC encourages inquiries concerning this NOFO.

Program Office Contact

For programmatic technical assistance, contact:

Renata D. Ellington, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
Atlanta, GA
Email: EHENOFO@CDC.GOV

Grants Management Office Information

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

Laquenda White, Grants Management Specialist
Department of Health and Human Services
Office of Grants Services
Atlanta, GA
Telephone: (770) 488-2648
Email: hkv3@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, 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 www.grants.gov. 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
- CDC Assurances and Certifications
- 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
- Organization Charts
- Indirect Cost Rate, if applicable
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent status documentation, if applicable

PS20-2010 website: https://www.cdc.gov/hiv/funding/announcements/ps20-2010/index.html

All attachments are located at https:www.cdc.gov/hiv/funding/ps20-2010/attachments/html

- Attachment A: PS20-2010 Logic Model
- Attachment B: Sample Table of Contents
- Attachment C: Funding Range Tables
- Attachment D: PS20-2010 Evaluation and Performance Measurement Plan (EPMP) and Work Plan: Component A
- Attachment E: Sample PS20-2010 Evaluation and Performance Measurement Plan (EPMP) and Work Plan: Component
- Attachment F: Sample Letter of Agreement (LOA) for City/State pairs, if applicable
- Attachment G: CDC Assurance of Compliance (must be downloaded from www.grants.gov)

***PS20-2010 application package and CDC Assurances of Compliance must be downloaded from https://www.grants.gov/

Footnotes

a Applicants can propose activities in either or both categories; the total for both categories combined cannot exceed 10%.

b Support to provide HIV prevention services in STD specialty clinics should be proposed under component C of this NOFO.

c HRSA and CDC funded grantees are encouraged to collaborate and ensure services are complementary and not duplicative.

d STD specialty clinic is a clinic with available same–day, culturally sensitive, safety net, confidential STD evaluation and treatment services for patients and sexual contacts. Available services may include: STAT syphilis test, microscope for STAT Gram stain/Methylene Blue/Gentian Violet and wet mount, GC culture capacity and medications on site including Benzathine Penicillin LA and ceftriaxone.

e Funding from Component C can be used to screen, diagnose, or treat STDS for uninsured and underinsured people, but cannot be used to cover the costs of antiretroviral medication, including PrEP

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3. National HIV/AIDS Strategy for the United States: Updated to 2020. Published July 2015. https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update
4. CDC. Understanding the HIV Care Continuum. Published June 2018. https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf
5. CDC. Effective Interventions, behavioral interventions. https://effectiveinterventions.cdc.gov
6. US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
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Additional Resources

- National HIV Curriculum, Linkage to Care: https://www.hiv.uw.edu/pdf/screening-diagnosis/linkage-care/core-concept/all
- PositiveLinks- https://www.positivelinks4ric.com/
- Telemedicine and Telehealth: https://www.healthit.gov/topic/health-it-initiatives/telemedicine-and-telehealth
- HIV Treatment and Care: Information for Health Care Providers- https://www.cdc.gov/actagainstaids/campaigns/pic/materials/treatment-and-care.html

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 http:// www.cdc.gov/ grants/ additional requirements/ index.html. 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 (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

Assistance Listings (CFDA) 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 period of performance. 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.

CDC Assurances and Certifications: Standard government-wide grant application forms.

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. http:// www.cdc.gov /grants /additionalrequirements /index.html.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.

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 www.USAspending.gov.

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 www.grants.gov.

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.
Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-_SPOC_01_2018_OFFM.pdf
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 http://www.phaboard.org.
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 www.grants.gov 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.
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.

Cluster or outbreak: A cluster or outbreak is a group of people among whom there is suspected rapid transmission. A cluster or outbreak can be detected using various approaches, including time-space analysis to identify increases in HIV diagnoses, molecular analysis to identify groups of people with very similar HIV strains, or through notification by providers, community members, or public health staff. There is a range of concerning levels of transmission, and clusters and outbreaks exist on the same spectrum. Response to clusters and outbreaks should be guided by the local epidemiology, context, and the level of concern for ongoing transmission.

Immediate Re-Engagement: Re-engaging clients into HIV medical care as soon as possible, but less than one month.

Rapid Linkage: For persons newly diagnosed with HIV, ensuring rapid linkage to care and starting antiretroviral therapy, ideally within 7 days, is a key pillar of the national initiative, Ending the HIV Epidemic: A Plan for America.

Telemedicine: The use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration.