

Centers for Disease Control and Prevention

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

Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men (MSM) and Transgender Persons

CDC-RFA-PS15-1506

Application Due Date: 06/01/2015

Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men (MSM) and Transgender Persons

CDC-RFA-PS15-1506

TABLE OF CONTENTS

Part I. Overview Information

A. Federal Agency Name
B. Funding Opportunity Title
C. Announcement Type
D. Agency Funding Opportunity Number
E. Catalog of Federal Domestic Assistance (CFDA) Number
F. Dates
G. Executive Summary

Part II. Full Text

A. Funding Opportunity Description
B. Award Information
C. Eligibility Information
D. Required Registrations
E. Review and Selection Process
F. Award Administration Information
G. Agency Contacts
H. Other Information
I. Glossary

Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-PS15-1506. 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. Funding Opportunity Title:

Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men (MSM) and Transgender Persons

C. Announcement Type: New - Type 1

This announcement is only for non-research domestic activities supported by CDC. If research is proposed, the application will not be considered Research for this purpose is defined at http://www.cdc. gov/od/ science / integrity/ docs/cdc- policy- distinguishing- public- health- research- nonresearch. pdf.

D. Agency Funding Opportunity Number:

CDC-RFA-PS15-1506

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.940

F. Dates:

1. Due Date for Letter of Intent (LOI):	**N/A**
2. Due Date for Applications:	**06/01/2015**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.
3. Date for Informational Conference Call:	**04/22/2015**

An informational conference call will be held on April 22, 2015 from 3:30 - 4:30 pm EST.

Dial in number: 800-779-9794

Passcode: 3350866

Questions may also be directed to 1506foamailbox@cdc.gov.

G. Executive Summary:

1. Summary Paragraph:

Gay, bisexual and other men who have sex with men (MSM) remain the population most heavily affected by HIV infection in the United States (US). Transgender persons and other populations with ongoing risk behavior are also at high risk for HIV infection. [Note: In this announcement, transgender persons include individuals who identify their gender as transgender and have sex with men.] High-impact HIV prevention approaches need to be implemented by state, local and territorial health departments to reduce new HIV infections among these populations. Pre-exposure prophylaxis (PrEP) is a potent new prevention tool for HIV-negative MSM, transgender persons, and other populations with ongoing risk behavior who are at substantial risk of acquiring infection (http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf). Another potent prevention tool is the use of antiretroviral treatment to suppress HIV-1 viral load to improve health outcomes and reduce transmission risk among people living with HIV (PLWH). The importance of HIV

treatment has increased focus on interventions and public health strategies designed to link, engage and re-engagePLWH in healthcare. “Data to Care” is a strategy for identifying diagnosed PLWH who are not in HIV medical care. The purpose of this Funding Opportunity Announcement is to support health departments in the US to implement PrEP and Data to Care demonstration projects prioritizing MSM and transgender persons at high risk for HIV infection, particularly persons of color, recognizing that the population with the highest incidence of HIV in the U.S. is young Black MSM.

a. Eligible Applicants:	Limited
b. FOA Type:	Cooperative Agreement
c. Approximate Number of Awards:	24
d. Total Project Period Funding:	$125,000,000
e. Average One Year Award Amount:	$2,900,000
f. Number of Years of Award:	3
g. Estimated Award Date:	09/30/2015
h. Cost Sharing and / or Matching Requirements:	N

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

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

State, local and territorial health departments in the US are implementing high impact HIV prevention programs to reduce new HIV infections among populations of gay, bisexual, and other men who have sex with men (MSM) and transgender persons. Additional effort is needed to realize the benefits of new prevention strategies that have the potential to significantly reduce new HIV infections and increase viral suppression among MSM and transgender persons.

Pre-exposure prophylaxis (PrEP) is a potent new prevention tool for MSM without HIV but who are at substantial risk of acquiring HIV infection. The daily use of oral, antiretroviral medication (PrEP) with co-formulated tenofovir disoproxil fumarate and emtricitabine (marketed as Truvada®) is proven to significantly reduce the risk of HIV acquisition among sexually active adults. In July 2012, the US Food and Drug Administration approved an HIV prevention indication for Truvada, and in May 2014 CDC published Public Health Service clinical practice guidelines for provision of PrEP to persons at substantial risk of HIV acquisition through sexual or injection routes of transmission as part of a package of HIV prevention clinical services. It is critical for health departments to address barriers to and facilitate broader awareness, support and capacity for the scale-up of PrEP services for MSM and transgender persons at high risk for HIV infection, particularly persons of color, recognizing that the population with the highest incidence of HIV in the U.S. is young Black MSM.

Another potent prevention tool involves antiretroviral medication to suppress HIV-1 viral load, improve health outcomes and reduce transmission risk among people living with HIV (PLWH). The importance if antiretroviral treatment has increased focus on interventions and public health strategies designed to link, engage and re-engage persons living with HIV in health care, with the ultimate outcome of suppressing HIV viral load, decreasing morbidity and increasing survival. To increase viral suppression, more people who are diagnosed with HIV will need to be retained in HIV medical care and receive antiretroviral treatment. There

is a need for health departments to implement public health strategies for improving linkage, engagement and re-engagement of MSM and transgender persons who are not in care. Data to Care is a public health strategy for identifying these individuals. Data to Care is based on the use of surveillance data to intervene directly in disease control. Data to Care programs use laboratory reports received by a health department's HIV surveillance program, and a range of other data sources as markers of HIV care, and analyze these reports to confidentially identify HIV-diagnosed individuals who are not engaged in HIV medical care or have not achieved viral suppression. Several state health departments have taken steps toward initiating a Data to Care program, and a few have reported successful implementation of Data to Care activities. It is important that these efforts be expanded and that other state, local and territorial health departments scale up and implement this promising public health strategy to improve outcomes along the HIV continuum of care and prevent new HIV infections.

The purpose of this FOA is to support awards for up to 24 health departments in the United States to implement PrEP and Data to Care demonstration projects prioritizing MSM and transgender persons at high risk of HIV infection, particularly persons of color. Health departments that are funded under this FOA will be required to prioritize their services to these populations. Services may also be provided for persons at substantial risk for HIV (for PrEP) or persons who have HIV and are not virally suppressed or have ongoing risk behavior (for Data to Care) who are not MSM or transgender.

b. Statutory Authorities

This program is authorized under Section 318 of the Public Health Service Act (42 U.S.C. Sections 247b(k)(2) and 247c), as amended.

c. Healthy People 2020

This FOA addresses the "Healthy People 2020" focus area of HIV. http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=2.

d. Other National Public Health Priorities and Strategies

1. The National HIV/AIDS Strategy: http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf

2. CDC Division of HIV/AIDS Prevention (DHAP) Strategic Plan: http://www.cdc.gov/hiv/pdf/policies_DHAP-strategic-plan.pdf

3. Executive Order (July 15, 2013): http://www.whitehouse.gov/the-press-office/2013/07/15/executive-order-hiv-care-continuum-initiative

4. Minority AIDS Initiative (MAI): http://www.hhs.gov/ash/ohaidp/initiatives/

5. CDC Winnable Battles: http://www.cdc.gov/winnablebattles/hiv/index.html

6. Affordable Care Act: http://aids.gov/federal-resources/policies/health-care-reform

7. The Rehabilitation Act and the Americans with Disabilities Act (ADA): http://www.ada.gov/cguide.htm

8. Standards for Privacy of Individually Identifiable Health Information: http://privacyruleandresearch.nih.gov/

9. This FOA supports a holistic framework that enables NCHHSTP to address the broader, cross-cutting issues of health and wellness by addressing Health Equity, Program Collaboration and Service Integration (PCSI), and Advancing Public Health Approaches to Improve Sexual Health. Additional information about these imperatives is available: http://www.cdc.gov/nchhstp

e. Relevant Work

This FOA builds upon current HIV prevention programs, projects, and technical assistance efforts including:

CDC-RFA-PS-12-1201, "Comprehensive HIV Prevention Programs for Health Departments" http://www.cdc.gov/hiv/policies/funding/announcements/ps12-1201/index.html

CDC-RFA-PS10-10181, "Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS" http://www.cdc.gov/hiv/prevention/demonstration/echpp/

CDC-RFA-PS-12-1210, "Secretary's Minority AIDS Initiative Funding for Care and Prevention in the United States (CAPUS) Demonstration Project" http://www.cdc.gov/hiv/policies/funding/announcements/ps12-1210/index.html

CDC-RFA-PS13-1302, " National HIV Surveillance System (NHSS)" http://www.cdc.gov/hiv/policies/funding/announcements/ps13-1302/index.html

CDC-RFA-PS14-1403, "Capacity Building Assistance for High-Impact HIV Prevention" http://www.cdc.gov/hiv/topics/funding/PS14-1403/index.htm

CDC-RFA-PS14-1410, "Secretary's Minority AIDS Initiative Funding to Increase HIV Prevention and Care Service Delivery among Health Centers Serving High HIV Prevalence Jurisdictions" http://www.cdc.gov/hiv/policies/funding/announcements/PS14-1410/index.html
CDC–HCVJB2X2–2013-60075, "Data to Care: Providing technical assistance to state and local public health jurisdictions in their use of HIV surveillance data to support continuous, high-quality care for persons living with HIV"

CDC PrEP resources are available online:

- Centers for Disease Control and Prevention. Pre-Exposure Prophylaxis (PrEP) Fact Sheet. Available at: http://www.cdc.gov/hiv/prevention/research/prep/.
- Centers for Disease Control and Prevention: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline. Available at: http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf .

CDC Data to Care resources are available online:

- Data to Care: Using HIV Surveillance Data to Improve the HIV Care Continuum. Available at: http://www.effectiveinterventions.org/en/HighImpactPrevention/PublicHealthStrategies/DatatoCare.aspx.

Relevant citations:

Centers for Disease Control and Prevention. Estimated HIV incidence in the United States, 2007–2010. HIV Surveillance Supplemental Report 2012; 17(No. 4). http://www.cdc.gov/hiv/topics/surveillance/resources/reports/#supplemental. Published December 2012.

Centers for Disease Control and Prevention. HIV Testing at CDC-Funded Sites, United States, Puerto Rico, and the U.S. Virgin Islands, 2010. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; September 2012: 17.

Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas—2011. HIV Surveillance Supplemental Report 2013;18(No. 5). http://www.cdc.gov/hiv/library/reports/surveillance/. Published October 2013. Accessed 7 August 2014.

Centers for Disease Control and Prevention; US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States - 2014: a clinical practice guideline. 2014:1-67. http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf. Accessed 28 May 2014.

Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med, 2011;365(6)493-505.

Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. Dec 30 2010;363(27):2587-2599.

Grant, RM., Anderson PL, McMahan V, et al. "Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study." The Lancet infectious diseases. 2014. Doi: 10.1016/S1473-3099(14)70847-3.

Herbst JH, Jacobs ED, Finlayson TJ, et al. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: A systematic review. AIDS Behav. 2008;12:1-17.

Johnson AS, Hall HI, Hu X, Lansky A, Holtgrave DR, Mermin J. Trends in Diagnoses of HIV Infection in the United States, 2002-2011. JAMA. 2014; 312(4):432-434. doi:10.1001/jama.2014.8534.

Purcell D, Johnson CH, Lansky A, et al. Estimating the population size of men who have sex with men in the United States to obtain HIV and syphilis rates. The Open AIDS Journal 2012; 6:98–107.

Sevelius JM, et al. HIV/AIDS programming in the United States: Considerations affecting transgender women and girls. Women's Health Issues. 2011:21-6S; S278-S282.

Sweeney P, Gardner LI, Buchacz K, Garland PM, Mugavero MJ, Bosshart JT, et al. Shifting the paradigm: Using HIV surveillance data as a foundation for improving HIV care and preventing HIV infection. Milbank Quarterly 2013; 91: 558–603.

2. CDC Project Description

a. Approach

Category 1: Pre-exposure prophylaxis (PrEP) support demonstration projects prioritizing men who have sex with men (MSM) and transgender persons at high risk for HIV infection, particularly persons of color.

Purpose: To support Centers for Disease Control and Prevention (CDC) funded health department implementation of PrEP support demonstration projects to expand or enhance HIV prevention activities in local jurisdictions. *Note: Italics indicate the expected project period outcomes.*

Early Strategies & Activities	Later Strategies & Activities	Short-Term Outcomes	Intermediate Outcomes	Long-Term outcomes
Create new or expand existing partnerships (as needed) with community based organizations, LGBT organizations, private health care providers, clinics, and community health centers Identify and convene Community Advisory Board Develop provider buy-in and support Develop local evaluation framework for activities Assure compliance with CDC/NCHHSTP Security and Confidentiality Guidelines across all programs	Example activities include: Train clinicians and counselors Develop policies Create educational materials and online/mobile tools for providers and consumers Develop and conduct media campaigns for providers and consumers Use DIS to refer consumers to PrEP services when indicated Provide screening for indications for PrEP (i.e., level of risk for HIV acquisition) as a routine procedure in conjunction with receiving HIV-negative test results Enhance PrEP activities through integration with STD and Hepatitis screening services Refer consumers to PrEP providers Develop procedures for health department staff to help providers and consumers navigate public and private programs that provide or reimburse for PrEP	*Increased capacity of health departments to implement PrEP support activities for MSM, transgender persons, and other persons at substantial risk for HIV* *Increase knowledge and awareness of PrEP, and training in clinical management of PrEP, for HIV prevention among providers* *Increase knowledge and awareness of PrEP for HIV prevention among MSM, transgender persons, and other persons at substantial risk for HIV* *Increased capacity of health departments to integrate services and share data across HIV, STD, and Hepatitis to help identify MSM, transgender persons, and other persons at substantial risk for HV who can benefit from PrEP*	*Establishment of policies, procedures and protocols to implement PrEP support activities for MSM, transgender persons, and other persons at substantial risk for HIV* *Increased number of providers trained to offer PrEP to MSM, transgender persons, and other persons at substantial risk for HIV* *Increased number of MSM, transgender persons, and other persons at substantial risk for HIV who are prescribed PrEP* *Establishment of policies, procedures and protocols to integrate services and share data across HIV, STD, and Hepatitis to help identify MSM, transgender persons, and other persons at substantial risk for HIV who can benefit from PrEP*	Increased number of MSM and transgender persons requesting PrEP for HIV prevention Increased number of MSM and transgender persons who are prescribed PrEP Reduced number of new HIV infections among MSM and transgender persons

Category 2: Data to Care demonstration projects that use HIV surveillance data that prioritize identifying HIV-diagnosed men who have sex with men (MSM) and transgender persons who have sex with men. Purpose: To support Centers for Disease Control and Prevention (CDC) funded health department implementation of Data to Care demonstration projects to expand or enhance HIV prevention activities in local jurisdictions. *Note: Italics indicate the expected project period outcomes.*

Early Strategies & Activities	Later Strategies & Activities	Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Create new or expand existing partnerships (as needed) with community based organizations, LGBT organizations, private health care providers, clinics, and community health centers Identify and convene Community Advisory Board and other community engagement activities Develop provider buy-in and support Develop local evaluation framework for activities Assure compliance with CDC/NCHHSTP Security and Confidentiality Guidelines across all programs Review of state or local laws and regulations affecting collection and use of HIV surveillance data for Data to Care activities	Example activities include: -Develop organizational procedures, policies and protocols to use HIV surveillance data, as needed, to link and re-engage HIV-diagnosed MSM and transgender persons in HIV care and achieve viral suppression -Develop confidential list of persons not in HIV medical care from routinely collected HIV surveillance data -Develop agreements for data sharing across programs when necessary for the purposes of Data to Care -Enhance Data to Care activities through integration with STD and Hepatitis surveillance data and referrals via existing programs to help identify MSM and transgender persons who are not in HIV care -Enhance capacity to implement Data to Care activities through staff training, hiring new staff or redirecting staff activities, working with community-based organizations, or other efforts that build capacity to implement robust Data to Care activities	*-Increased capacity of health departments to implement Data to Care activities for HIV diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care, including:* *-Confidential list of persons not in HIV medical care from routinely collected HIV surveillance data* *-Processes for integrating existing STD, Hepatitis and other surveillance data with lab reporting* *-Agreements for data sharing between health departments and health care providers when necessary for the purposes of Data to Care* *-Data to Care protocols and standard operating procedures* *-Increased capacity of health departments to conduct outreach to HIV-diagnosed MSM, transgender persons, and other persons who have HIV bur are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care*	*-Increased capacity of health departments to use surveillance and other data to accurately identify HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care and reside in their jurisdiction* *-Increased capacity of health departments to contact HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in HIV medical care* *-Increased capacity of health departments to refer to HIV medical care HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, and who are not in care* *-Increased proportion of all HIV-diagnosed MSM who are virally suppressed* *-Reduced length of time between identification of and the successful engagement or re-engagement in HIV medical care of MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in care*	Increased percentage of MSM and transgender persons diagnosed with HIV who are engaged in care Increased percentage of MSM and transgender persons diagnosed with HIV who have a suppressed viral load Reduced number of new HIV diagnoses among MSM and transgender persons Increased survival of MSM and transgender persons diagnosed with HIV

i. Purpose

The purpose of this FOA is to support awards for up to 24 health departments in the United States to implement PrEP and Data to Care demonstration projects prioritizing populations of MSM and transgender persons at high risk for HIV infection, particularly persons of color. Health departments funded under this FOA will be required to prioritize their services to these populations. Services may also be provided for persons at substantial risk for HIV (for PrEP) or persons who have HIV and are not virally suppressed or have ongoing risk behavior (for Data to Care) who are not MSM or transgender.

ii. Outcomes

Key outcomes to be expected by the end of the project period are illustrated in the logic models for PrEP support projects (Category 1) and Data to Care projects (Category 2). Potential indicators that quantify these outcomes are described in Section b. Evaluation and Performance Measurement. Only the project period outcomes are listed below.

CATEGORY 1: PrEP SUPPORT DEMONSTRATION PROJECTS TARGETING MSM AND TRANSGENDER PERSONS AT SUBSTANTIAL RISK OF ACQUIRING HIV

Short-Term Outcomes

- Increased capacity of health departments to implement PrEP support activities for MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons

at substantial risk for HIV
- Increased knowledge and awareness of PrEP, and training in clinical management of PrEP for HIV prevention among providers
- Increased knowledge and awareness of PrEP for HIV prevention among MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV
- Increased capacity of health departments to integrate services and share data across HIV, STD, and Hepatitis to help identify MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV who can benefit from PrEP

Intermediate Outcomes

- Establishment of policies, procedures and protocols to implement PrEP support activities for MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV
- Increased number of providers trained to offer PrEP to MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV
- Increased number of MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV who are prescribed PrEP
- Establishment of policies, procedures and protocols to integrate services and share data across HIV, STD, and hepatitis to help identify MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV who can benefit from PrEP

CATEGORY 2: DATA TO CARE DEMONSTRATION PROJECTS THAT USE SURVEILLANCE DATA SOURCES TO IDENTIFY MSM AND TRANSGENDER PERSONS NOT IN HIV CARE

Short-Term Outcomes

- Increased capacity of health departments to implement Data to Care activities, including:
    - Confidential list of persons not in HIV medical care from routinely collected HIV surveillance data
    - Processes for integrating existing STD, hepatitis and other surveillance data with lab reporting
    - Agreements for data sharing between health department programs and health care providers when necessary for the purposes of Data to Care
    - Data to Care protocols and standard operating procedures
- Increased capacity of health departments to conduct outreach to HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care

Intermediate Outcomes

- Increased capacity of health departments to use surveillance and other data to accurately identify HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care and reside in their jurisdiction
- Increased capacity of health departments to contact HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in HIV medical care
- Increased capacity of health departments to refer to HIV medical care HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, and who are not in care
- Increased proportion of all HIV-diagnosed MSM who are virally suppressed
- Reduced length of time between identification of and the successful engagement or re-engagement in HIV medical care of MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in care

iii. Strategies and Activities

CATEGORY 1: PrEP SUPPORT DEMONSTRATION PROJECTS TARGETING MSM AND TRANSGENDER PERSONS AT SUBSTANTIAL RISK OF ACQUIRING HIV

Applicants should propose support activities to strengthen or enhance the ability to identify MSM and transgender persons who stand to benefit the most from PrEP, refer appropriate candidates to PrEP providers in the jurisdiction, and increase the number of providers knowledgeable and capable of offering PrEP to MSM and transgender persons at high risk for HIV infection, particularly persons of color. PrEP-related activities must be implemented as part of a comprehensive HIV prevention program that includes, when indicated, referral to prevention, screening and treatment services for STD, viral hepatitis, substance abuse, and mental health services.

Funds may not be used for PrEP medications (e.g., Truvada), laboratory testing related to PrEP (for example, creatinine tests, liver function tests, pregnancy tests, and other clinical tests that could result from evaluation of side effects/toxicities), or personnel costs for the provision of PrEP medication and recommended clinical care associated with PrEP. Funds may be used for HIV tests, hepatitis B screening, and STD testing. However, grantees should coordinate these services and seek payment from other sources, where available. Possible payment sources that should be explored include Medicaid, Medicare, and private health insurance.

Early activities for all proposed demonstration projects include: create new or expand existing partnerships with community-based organizations, LGBT organizations, private health care providers, clinics and community health centers including STD clinics that serve MSM and transgender persons; identify and convene Community Advisory Boards to inform program planning and implementation processes; develop provider buy-in and support; develop local evaluation framework for activities; and assure compliance with CDC/NCHHSTP Security and Confidentiality Guidelines across all programs.

Example PrEP support activities that can be implemented by health departments include:

- Training for clinicians about PrEP including its safety and efficacy, for whom it is indicated, and recommended clinical procedures either directly or in collaboration with local partners (for example, HIV/STD Prevention Training Centers, HRSA funded AIDS Education and Training Centers, PrEP Warmline)
- Training for counselors about PrEP and methods to support medication adherence and maintain sexual risk reduction practices
- The development of policies that support the use of PrEP as an HIV prevention tool in accordance with clinical guidelines
- Create or identify educational materials including online and mobile tools for providers and consumers describing the safety and effectiveness, recommended clinical practices for providing PrEP-related clinical care, and the local availability of PrEP providers
- Develop and conduct media campaigns for providers and consumers to increase awareness of PrEP availability in the local area
- Using disease intervention specialists (DIS) to refer consumers to PrEP services when indicated, consistent with PrEP Guidelines
- Provide screening for indications for PrEP (i.e., level of risk for HIV acquisition) as a routine procedure in conjunction with receiving HIV-negative test results and provision of other offers of services and screening for STDs.
- Enhance PrEP activities through integration with STD and hepatitis screening services
- Referral of consumers to PrEP providers in the local area
- Develop procedures for health department staff to help providers and consumers navigate public and private programs that provide or reimburse for PrEP

CATEGORY 2: DATA TO CARE DEMONSTRATION PROJECTS THAT USE SURVEILLANCE DATA SOURCES TO IDENTIFY MSM AND TRANSGENDER PERSONS NOT IN HIV CARE

Applicants should propose activities that support expanding or enhancing their ability to use HIV surveillance data and other data sources, as appropriate, to improve clinical outcomes along the HIV continuum of care for MSM and transgender persons. These activities use lab reports received by a health department's surveillance system as markers for HIV care. Health departments should use these data to generate lists of individuals that may not have been linked to or who may have dropped out of HIV medical care. Several strategies, including conferences with health care providers and clinic staff, can occur to determine which names on the list are likely not in HIV care and should be prioritized for outreach. To improve outcomes along the continuum of HIV care for MSM and transgender persons who have sex with men, applicants should propose activities that use available data to improve identification, linkage to care, or re-engagement in care among persons not in care. These are key antecedents to improve HIV viral suppression among persons in care.

Funds may **not** be used for clinical care or HIV medications (antiretroviral therapy).

Early activities for all proposed demonstration projects include: create new or expand existing partnerships with community-based organizations, LGBT organizations, private health care providers, clinics and community health centers; identify and convene Community Advisory Boards to inform program planning and implementation processes; develop provider buy-in and support; develop local evaluation framework for activities; assure compliance with CDC/NCHHSTP Security and Confidentiality Guidelines across all programs; and review of state and local laws and regulations affecting collection and use of HIV surveillance data (for Data to Care activities).

Example activities that can be implemented by health departments in support of Data to Care include:

- Develop organizational procedures, policies and protocols to use HIV surveillance data, as needed, to engage or re-engage HIV-diagnosed MSM, transgender persons, and other persons who have HIV and are not virally suppressed or have ongoing risk behavior in HIV medical care so they can achieve HIV viral suppression
- Develop confidential list of persons not in HIV medical care from routinely collected HIV surveillance data
- Develop agreements for data sharing across programs when necessary for the purposes of Data to Care
- Enhance Data to Care activities through integration with STD and Hepatitis surveillance data and referrals via existing programs to help identify MSM, transgender persons, and other persons not in HIV care who have HIV and are not virally suppressed or have ongoing risk behavior
- Enhance capacity to implement Data to Care activities through staff training, hiring new staff or redirecting staff activities, working with community-based organizations, or other efforts that build capacity to implement robust Data to Care activities
- Other activities can include:
    - Review state and/or local laws and regulations affecting collection and use of HIV surveillance data and other data sources as appropriate
    - Community engagement activities to share plans for Data to Care, gather input on the program from affected communities, and to enlist support for the Data to Care activities
    - Collaborate with local providers and organizations to develop and/or improve procedures to share data including across program areas when necessary
    - Use of HIV surveillance data to help identify persons not in care and prioritize them for engagement or re-engagement in care activities
    - Activities that match lists of patients not in HIV care with lists of persons with recent STD, Hepatitis or TB infections to prioritize outreach.
    - Other potential activities are discussed at http://www.effectiveinterventions.org/en/HighImpactPrevention/PublicHealthStrategies/DatatoCare.aspx

1.Collaborations

a. With CDC-funded programs:

Health department awardees are required to collaboratively partner with CDC. In addition, awardees should collaborate with other CDC-funded programs, where appropriate, to apply programmatic successes and lessons learned.

b. With organizations external to CDC:

For PrEP support projects, health departments should partner with HIV and other health care providers and organizations with experience providing medical care, reaching and engaging the target populations in the jurisdiction.

For Data to Care projects, health departments should partner with key HIV and other health care providers, and other engagement and re-engagement programs in the jurisdiction.

For all projects, health departments should create new or expand existing partnerships (as needed) with community-based organizations, LBGT organizations, private providers, clinics, and community health centers. Health departments should also identify and convene Community Advisory Boards.

2. Target Populations

Health departments should focus their activities on gay, bisexual, and other men who have sex with men (collectively referred to as MSM), and transgender persons at high risk for HIV infection, particularly persons of color. Applicants should describe how the work plan will impact the local HIV epidemic among these populations.

a. Inclusion

All applicants should design their program so that it is accessible and available to participants regardless of age, race/ethnicity, sexual orientation, gender identity, or socio-economic status. Additionally, all grantees should provide programs and services to multiple underserved populations including but not limited to racial/ethnic minorities, individuals with disabilities, and individuals with limited English proficiency. All applicants' activities should result in measurable improvements among target populations.

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

N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Evaluation and performance measurement will demonstrate achievement of the work plan outcomes and show effective implementation of the program activities implemented by the health departments. Evaluation findings can be used by awardees and CDC to ensure continuous program and system improvement, help create an evidence-base for program activities to expand or enhance HIV prevention activities for MSM and transgender persons, and assess which activities are scalable and effective in various contexts.

The CDC strategy for monitoring and evaluating program and awardee performance will involve process and outcome data and will be consistent with the logic models (Categories 1 and 2) and approach presented above. Awardees will be responsible for monitoring and evaluation of their own programs for continuing quality improvement. The CDC strategy will require the following from awardees: use approximately 10% of the overall budget to support local program evaluation of funded activities; collaborate with CDC in development of evaluation plans and data collection activities as appropriate; participate in data collection activities as appropriate; submit progress reports; conduct real-time documentation and tracking of program activities using existing health department and partnering agency IT applications; and periodic data entry and electronic submission of data and reporting information.

When possible, program effectiveness will primarily be assessed using short-term and intermediate outcome measures. Where appropriate, outcomes can be calculated using existing HHS-supported data sources (e.g., HIV case surveillance and HIV testing). CDC will also require the collection and reporting of data from health department staffs, and staff from partnering agencies (as appropriate) to measure additional program processes and outcomes. Guidance on program monitoring and evaluation and performance measures will be provided by CDC on an ongoing basis throughout the project period.

As stated above, the CDC evaluation strategy will assess grantees' achievement of program goals in terms of process, organizational change, and short-term and intermediate outcomes. Cost indicators will also be collected. Indicators aligning with short-term and intermediate project outcomes are listed for each activity.

CATEGORY 1: PrEP SUPPORT DEMONSTRATION PROJECTS TARGETING MSM AND TRANSGENDER PERSONS AT SUBSTANTIAL RISK OF ACQUIRING HIV

SHORT-TERM OUTCOMES:

- Outcome: Increased capacity of health departments to implement PrEP support activities for MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV
    - Indicator: Developing draft policies, protocols and procedures, memoranda of agreement, and establish partnerships with key stakeholders to support PrEP activities
- Outcome: Increase knowledge and awareness of PrEP, and training in clinical management of PrEP for HIV prevention among providers
    - Indicator: Creation or identification of educational materials and tools for providers, provision of clinical training to providers, and media campaigns as indicated by counts of materials/tools, trainings, media events
- Outcome: Increase knowledge and awareness of PrEP for HIV prevention among MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV
    - Indicator: Creation or identification of educational materials and tools for consumers and media campaigns as indicated by counts of materials/tools and media events
    - Indicator: Dissemination of educational materials and tools for consumers and media campaigns as indicated by counts of media events and dissemination activities
- Outcome: Increased capacity of health departments to integrate services and share data across HIV, STD, and Hepatitis to help identify MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV who can benefit from PrEP
    - Indicator: Developing draft policies, protocols and procedures for integrating and sharing data across HIV, STD and Hepatitis for referring MSM, transgender persons, and other persons at substantial risk for acquiring HIV

INTERMEDIATE OUTCOMES:

- Outcome: Establishment of policies, procedures and protocols to implement PrEP support activities for MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV
    - Indicator: Final written policies, procedures and protocols (e.g., health departments, clinics, health care providers) to support provision of PrEP to MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV
- Outcome: Increased number of providers trained to offer PrEP to MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV

- Indicator: Number of providers trained by the health departments or their agents to offer PrEP to MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV

- Outcome: Increased number of MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV who are prescribed PrEP
  - Indicator: Number of MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV who are prescribed PREP
- Outcome: Establishment of policies, procedures and protocols to integrate services and share data across HIV, STD and Hepatitis to help identify MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other persons at substantial risk for HIV who can benefit from PrEP
  - Indicator: Final written policies, procedures and protocols (e.g., health departments, clinics, health care providers) to support integrating services and data sharing across HIV, STD and Hepatitis

CATEGORY 2: DATA TO CARE DEMONSTRATION PROJECTS THAT USE SURVEILLANCE DATA SOURCES TO IDENTIFY NEWLY-DIAGNOSED MSM AND TRANSGENDER PERSONS NOT IN HIV CARE

SHORT-TERM OUTCOMES:

- Outcome: Increased capacity of health departments to implement Data to Care activities for HIV diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care
  - Indicator: Development of procedures to create confidential list of persons not in HIV medical care from routinely collected HIV surveillance data; processes for integrating existing STD, Hepatitis and other surveillance data with lab reporting; agreements for data sharing between health departments and health care providers when necessary for the purposes of Data to Care; and Data to Care protocols and standard operating procedures
- Outcome: Increased capacity of health departments to conduct outreach to HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care
  - Indicator: Number of staff trained to conduct outreach to HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care

INTERMEDIATE OUTCOMES:

- Outcome: Increased capacity of health departments to use surveillance and other data to accurately identify HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who currently are not in HIV medical care and reside in their jurisdiction
  - Indicator: Prioritized list of HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are accurately identified as not in HIV medical care
- Outcome: Increased capacity of health departments to contact HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in HIV medical care

- Indicator: Proportion of identified HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in HIV medical care successfully contacted by health department

- Outcome: Increased capacity of health departments to refer to HIV medical care HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in care
  - Indicator: Proportion of identified HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in care that are referred to HIV medical care
- Outcome: Increased proportion of all HIV-diagnosed MSM who are virally suppressed
  - Indicator: Proportion of HIV-diagnosed MSM who are virally suppressed
- Outcome: Reduced length of time between identification of and the successful engagement or re-engagement in HIV medical care of HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in care
  - Indicator: Proportion of identified HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in care successfully engaged or re-engaged in HIV medical care within 90 days of being identified as not in care
  - Indicator: Number of days between identification of HIV-diagnosed MSM, transgender persons, and other persons who have HIV but are not virally suppressed or have ongoing risk behavior, who are not in care and their successful engagement or re-engagement in HIV medical care

ii. Applicant Evaluation and Performance Measurement Plan

The health department awardee will collaborate with CDC to further develop and implement performance measurement standards that are based on its specific programmatic objectives.

The health department awardee will be required to provide descriptions of the development and implementation of program activities in annual progress reports and other formats as required by CDC. The CDC will provide the template and guidance for these reports.

Post-award, a more detailed evaluation and performance measurement plan for the entire project will be developed by awardees in collaboration with CDC. This more detailed evaluation plan will build on elements stated in the initial plan. In addition to the items in the initial plan, awardees will:

- Describe baseline and target performance for each reporting year. Targets should demonstrate adequate progress toward meeting or exceeding national goals identified in the NHAS as well as CDC goals;
- Describe the frequency that monitoring and evaluation and performance data are to be collected, keeping in mind CDC data submission requirements and local data use for routine project oversight;
- Describe the data system to be used for local data management and use; CDC will specify the system to be used for submission of required data;
- Describe how program monitoring data will be used for continuous quality improvement;
- Describe dissemination channels and populations (including public dissemination) of local evaluation findings; and
- Describe other information requested, as determined by the CDC program.

Paperwork Reduction Act (PRA) applicability will depend upon the evaluation and reporting methods to be used for each activity.

c. Organizational Capacity of Awardees to Execute the Approach

All applicants must demonstrate their existing or forthcoming capacity to successfully execute all proposed strategies and activities to meet program requirements. Applicants should address infrastructure (the applicant organization's physical space and equipment), workforce capacity and competence, expertise and experience related to all program focus areas, information and data systems, and electronic information and communication systems to implement the award. Applicants must provide evidence of program management/staffing plans, performance measurement, evaluation, financial reporting, management of travel requirements, and workforce development and training. Applicants are encouraged to provide additional information that demonstrates their capacity to efficiently manage fiscal mechanisms (e.g., subcontracts and hiring new staff) in support of the project.

For PrEP support projects, applicants must have demonstrable capacity to coordinate and facilitate development of trainings, policies, educational materials, social media campaigns, integration with other screening services, and referral of eligible clients to PrEP providers.

For Data to Care projects, applicants must have demonstrable capacity to coordinate and facilitate project activities that support the use of HIV surveillance data to identify patients who may have never linked to care or who have fallen out of HIV care as indicated by missing lab data.

Applicants must have complete HIV laboratory reporting of CD4 and viral load test results, defined as follows:

i. The jurisdiction's laws or regulations require the reporting of all CD4 and viral load results to the state or city health department.
ii. A minimum of 95% of HIV-related test results from laboratories that perform HIV-related testing for each area are being reported to the state or city health department.
iii. The jurisdiction is reporting at least 95% of all CD4 and viral load test results to CDC as of December 31, 2013 (as outlined in the 2012 Monitoring Report, published in November 2014).

Note: Complete HIV laboratory reporting should be consistent with the definition as defined in CDC's HIV Surveillance Supplemental Report, Volume 18, Number 2 entitled "Monitoring Selected National HIV Prevention and Care" Objectives by Using HIV Surveillance Data—United States and 6 U.S. Dependent Areas—2010 (pages 9 -10). Available at: http://www.cdc.gov/hiv/library/reports/surveillance/2010/surveillance_Report_vol_18_no_2.html

In addition, the applicant must demonstrate capacity to safeguard data. In accordance with H.19 308(d) Contract Clause for Safeguards for Individuals and Establishments against Invasions of Privacy and with Subsection (m) of the Privacy Act of 1974 (5 U.S.C. 552a) and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the applicant is required to comply with the applicable provisions of the Privacy Act and to undertake other safeguards to protect individuals and establishments against invasions of their privacy. To successfully meet these requirements over the course of this cooperative agreement, the grantee must:

1. Comply with all federal (i.e., HHS, and/or CDC) information systems and information processing security policies. For example, local policies and procedures should clearly describe required physical security attributes of all facilities; procedures for protecting, controlling, and handling data during performance of the project, including any development and testing activities; required limitations on employees with respect to the reproduction, transmission, or disclosure of data; physical storage procedures to protect data; procedures for the destruction of source documents and other contract-related waste material; and personnel security procedures.

2. Ensure that data collection, entry, management, submission, analysis, use, and dissemination procedures are consistent with CDC security and confidentiality guidelines, as outlined above.

3. Ensure data security and confidentiality policies are in place and conform with NCHHSTP Data Security and Confidentiality Guidelines. MOAs should include a certification statement agreeing that these policies will be in place before project activities are implemented.

4. Procedures for electronic and physical data security and data sharing must be reviewed and approved by the applicable Overall Responsible Party(s) (ORPs). If more than one ORP is at the health department, the HIV Surveillance Program's ORP should review and approve all procedures for data sharing.

5. Develop and maintain 'Rules of Behavior' for persons who have access to data systems under the agency's responsibility. State and local data system rules of behavior need to be responsive to CDC data security policies.

6. The applicant should sign and submit to CDC an interagency MOU regarding protection of sensitive data collected for this program. This MOU will be provided to grantees on receipt of award or shortly thereafter. http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf

7. Ensure all agency personnel having access to identifiable and confidential information receive appropriate annual training and sign confidentiality pledges (Non-Disclosure Agreement). CDC will provide on-line training materials.

8. Conduct a privacy impact assessment (PIA) on all information systems acquired, developed, or used in conjunction with data collected for this project.

9. Annually review and validate system user accounts to ensure continued need for access to system.

10. Work with CDC on an ongoing basis to review security controls and measures and ensure continued compliance with federal information security regulations.

d. Work Plan

In order to better integrate new HIV prevention strategies for MSM, transgender persons who have sex with men, and other persons at substantial risk for HIV, applicants must develop a work plan for PrEP support and Data to Care activities, as appropriate. Applicants must describe how the work plan will address unmet needs and impact the local HIV epidemic among MSM, transgender persons, and other persons at substantial risk for HIV. Proposed work plans should be consistent with and support long-term goals of the National HIV/AIDS Strategy (NHAS) including reducing HIV incidence, increasing access to HIV care and optimizing health outcomes, and reducing HIV-related health disparities (http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf).

Proposed approaches should be able to demonstrate an impact on the short and intermediate outcomes outlined in the accompanying logic models (see Categories 1 and 2). Applicants should cite available local epidemiologic data, cost data or other sources for articulating how the proposed approach will have the greatest impact for their jurisdiction. Proposed work plan activities should address high priority unmet needs and not be duplicative with other funded activities.

Activities in this Funding Opportunity Announcement should expand or enhance current activities or in other ways increase their impact in their jurisdiction in improving HIV outcomes for MSM and transgender persons who have sex with men. To this end, applicants should articulate how the proposed work plan will further extend or leverage other funded activities. Applicants must plan for how they will incorporate structural-level changes (e.g., policies, procedures, etc.) which are likely to have enduring influence after the demonstration project ends.

Applicants are required to provide a work plan that provides both a high-level overview of the entire three-year project period and a detailed description of the first year of the award. The work plan should incorporate all FOA-related program strategies and activities. Applicants should describe how they plan to monitor each activity. Note: Post-award, proposed work plan activities may be adjusted in consultation with CDC and other federal partners to better address the overarching goals of the project.

The applicant should address the following outline in their work plan for each activity (PrEP support and Data to Care projects):

Three-Year Overview of Project Work Plan:

- Intended outcomes for the entire three-year project period
- A logic model with the conditions, inputs, activities, outputs, and outcomes to be achieved by the end of the two-year project period (include graphic and narrative)

Year 1 Detailed Work Plan:

- Program strategies and activities
- Outcomes aligned with program strategies and activities
- Timeline
- Budget and budget narrative

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee 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 awardee progress in achieving the desired outcomes.
- Ensuring the adequacy of awardee 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:

- Ensuring that work plans are feasible based on the budget and consistent with the
- intent of the award.
- Ensuring that awardees are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with awardees 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.

Other activities deemed necessary to monitor the award, if applicable.

These activities may include 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 grantees.

No additional activities are applicable.

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

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

A. Provide consultation and technical assistance to grantees on all aspects of the implementation of the funding program as well as all protocols, procedures, and instruments related to the plan, both directly and through CDC's network of grantees and partners.
B. Work with grantees to address training, capacity building and technical assistance needs that are crucial to the successful execution of the plan, and that are not addressed by other funding sources.
C. Facilitate coordination, collaboration, and, where feasible, service integration among other CDC programs, health departments and their programmatic divisions, local planning groups, directly-funded CBOs, national capacity building assistance providers, care providers, and other critical partners. working with at risk

populations and towards common goals of risk reduction, disease detection, and a continuum of HIV prevention, care, and treatment.
D. Monitor grantee progress in implementing the program and work with grantees through consultation via site visits, email, telephone, and review of progress reports to support implementation of the project.
E. Monitor grantee progress in developing and conducting monitoring and evaluation activities through consultation via site visits, email, telephone, and review of progress reports and other data reports to support progress, program improvement, and reductions in HIV incidence.
F. Provide requirements and expectations for standardized and other data reporting and support monitoring and evaluation activities with technical assistance, web-based training on M&E, M&E-related materials such as data collection tools, and on-line TA via the National HIV Monitoring and Evaluation Service Center as appropriate.
G. Facilitate necessary CDC and other clearances.
H. Plan, convene, and facilitate joint grantee meetings during the project period.

B. Award Information

1. Funding Instrument Type: Cooperative Agreement

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

2. Award Mechanism: U62

U62 - Prevention/Surveillance Activities/Studies of AIDS

3. Fiscal Year: 2015

Estimated Total Funding: $50,000,000

4. Approximate Total Fiscal Year Funding: $50,000,000

5. Approximate Project Period Funding: $125,000,000

6. Total Project Period Length: 3 year(s)

7. Expected Number of Awards: 24

8. Approximate Average Award: $2,900,000 Per Budget Period

9. Award Ceiling: $7,000,000 Per Budget Period

10. Award Floor: $500,000 Per Budget Period

For those applicants eligible for both Category 1 (PrEP) and Category 2 (Data to Care), it is strongly recommended that the applicants apply for both. When proposing activities under both Category 1 and Category 2, no less than 25% of the overall proposed budget should be allocated to either Category.

For applicants that are eligible for Category 1 only and applicants that are eligible for both Categories but applying for only one Category, the available funding will be 75% of the available funding levels for proposals addressing both Categories (approximate average award = $2,175,000; award ceiling = $5,250,000; award floor = $375,000)

11. Estimated Award Date: 09/30/2015

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).

12. Budget Period Length: 12 month(s)

13. Direct Assistance

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

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments

Government Organizations:

State (includes the District of Columbia)
Local governments or their bona fide agents
Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

2. Additional Information on Eligibility

Eligibility for Category 1 (PrEP Support Demonstration Projects Targeting MSM and Transgender Persons at Substantial Risk of Acquiring HIV) is limited to health departments whose jurisdiction includes one or more of the thirty two (32) MSAs/MDs in which there are greater than 3,000 MSM living with diagnosed HIV by year-end 2010 (2011 MSA report, table 6b, published Oct 2013).

Eligibility for Category 2 (Data to Care Demonstration Projects That Use Surveillance Data Sources to Identify MSM and Transgender Persons Not in HIV Care) is limited to health departments that are eligible to apply for Category 1 and have complete reporting of all CD4 cell count and HIV viral load results.

Complete laboratory reporting of CD4 and HIV viral load test results is defined as follows:

i. The jurisdiction's laws/regulations require the reporting of all CD4 and viral load results to the state/city health department
ii. A minimum of 95% of HIV-related test results from laboratories that perform HIV-related testing for each area are being reported to the state/city health department
iii. The jurisdiction is reporting at least 95% of all CD4 and viral load test results to CDC as of December 31, 2013 (as outlined in the 2012 Monitoring Report, published in November 2014).

States that have local health departments directly funded by CDC are not eligible to apply for the MSAs/MDs that contain locally funded health departments within the state.

State health departments with one eligible MSA/MD are required to work in the specified eligible MSA/MD. States that have more than one eligible MSA/MD may elect to work in all or a reduced number of eligible MSAs or MDs, in order of prevalence.

The award ceiling for this FOA is $7,000,000. CDC will consider any application requesting an award higher than this amount as non- responsive and it will receive no further review. If a pre-application is required, then specify here and include it in the special eligibility requirements section. (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf)

3. Justification for Less than Maximum Competition

As both NHAS and DHAP's Strategic Plan (2011-2015) note, in the face of increasingly constrained resources and a concentrated, inequitably distributed epidemic, HIV prevention funding must be allocated to those communities and regions that shoulder the greatest share of the national burden. In addition, reducing HIV-related health disparities is one of the 3 primary goals of NHAS.

Health departments are in a unique position and have the authority to consider the local epidemic at a jurisdiction level and to make decisions about allocating HIV prevention resources accordingly to have the most impact. Other types of organizations do not have the legal authority to collect and report HIV surveillance data describing the local epidemic (which is critical for Category 2 activities in this FOA) nor do they have the infrastructure that health departments have regarding implementation of programs such as PrEP (Category 1 of this FOA) across an entire jurisdiction. Additionally, health departments are able to coordinate and align any new activities with the current jurisdictional HIV prevention plan that they are responsible for developing and administering. For these reasons, eligible applicants are limited to state, local, and territorial health departments.

Gay, bisexual and other men who have sex with men (MSM) remain the population most heavily affected by HIV infection in the US. Transgender persons who have sex with men are also at high risk for HIV infection. Thus the activities in this FOA are directed toward potent HIV prevention tools for MSM and transgender persons.

PrEP is one new potent prevention tool for MSM, transgender persons, and other persons who are at substantial risk of acquiring infection (http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf). Health departments are uniquely positioned to work across public and private-funded HIV care providers to facilitate increased uptake of PrEP as a prevention tool. However, to have the greatest impact on preventing new HIV infections among these populations, resources should be allocated to health departments in the geographic areas of the United States where the largest populations of MSM living with HIV reside. Thus applicants eligible to apply for Category 1 of this cooperative agreement (PrEP Support Demonstration Projects Targeting MSM and Transgender Persons at Substantial Risk of Acquiring HIV) are limited to state, local or territorial health departments in Metropolitan Statistical Areas (MSAs) or specified Metropolitan Divisions (MDs) in which there are greater than 3,000 MSM living with diagnosed HIV by year-end 2010 (2011 MSA report, table 6b, published Oct 2013). This includes 24 health departments.

Rank	MSA/MD	Estimated MSM Living with Diagnosed HIV	Health Department
1	New York–White Plains–Wayne Division	48,141	New York City Department of Health and Mental Hygiene
2	Los Angeles Division	31,392	Los Angeles County Public Health Department
3	Chicago Division	15,162	Chicago Department of Public Health
4	Atlanta-Sandy Springs-Marietta, GA	13,527	Fulton County Department of Health and Wellness
5	Washington Division	12,832	District of Columbia Department of Health
6	San Francisco Division	12,204	San Francisco Department of Public Health
7	Miami Division	12,033	Florida State Department of Health

7	Miami Division	12,033	Florida State Department of Health
8	Houston-Baytown-Sugar Land, TX	11,211	Houston Department of Health and Human Services
9	Dallas Division	10,898	Texas State Department of Health Services
10	San Diego-Carlsbad-San Marcos, CA	8,667	California Department of Public Health (Office on AIDS)
11	Fort Lauderdale Division	7,450	Florida State Department of Health
12	Philadelphia Division	6,890	City of Philadelphia Public Health Department
13	Phoenix-Mesa-Scottsdale, AZ	6,350	Arizona Department of Health
14	Denver-Aurora, CO	6,120	Colorado Department of Health
15	Seattle Division	5,236	Washington State Department of Health

16	Riverside-San Bernardino-Ontario, CA	5,235	California Department of Public Health (Office on AIDS)
17	Tampa-St. Petersburg-Clearwater, FL	5,224	Florida State Department of Health
18	Orlando, FL	5,195	Florida State Department of Health
19	Baltimore-Towson, MD	4,963	Baltimore Department of Health
20	Santa Ana Division	4,785	California Department of Public Health (Office on AIDS)
21	St. Louis, MO-IL	4,211	Missouri Department of Health and Senior Services
22	Oakland Division	4,188	California Department of Public Health (Office on AIDS)
23	Las Vegas-Paradise, NV	3,789	Nevada Department of Health
24	Detroit Division	3,728	Michigan Department of Community Health
25	New Orleans-Metairie-Kenner, LA	3,653	Louisiana Department of Health
26	Newark Division	3,627	New Jersey Department of Health and Senior Services
27	Minneapolis-St. Paul-Bloomington, MN-WI	3,615	Minnesota Department of Health
28	Memphis, TN-MS-AR	3,538	Tennessee Department of Health
29	Boston Division	3,435	Massachusetts Department of Public Health
30	Virginia Beach-Norfolk-Newport News, VA-NC	3,197	Virginia State Department of Health
31	Kansas City, MO-KS	3,078	Missouri Department of Health and Senior Services
32	San Antonio, TX	3,053	Texas State Department of Health Services
Total		**276,627**	

Another potent prevention tool is the use of antiretroviral treatment to suppress HIV-1 viral load to improve health outcomes and reduce transmission risk among PLWH. The importance of HIV treatment has increased focus on interventions and public health strategies designed to link, engage and re-engage PLWH in health care. “Data to Care” is a strategy for identifying diagnosed PLWH who are not in HIV medical care. This public health strategy uses HIV surveillance data, collected and managed by health departments, to identify HIV infected persons who are not in care, link them to care, and achieve a suppressed viral load. By using information from HIV surveillance systems to trigger linkage and re-engagement to care, health departments will be able to work with health centers to ensure that individual patients remain or are re-engaged back into care. State, local, and territorial health departments are uniquely positioned for this activity as they are responsible for and have authority to conduct HIV surveillance and to provide linkage to HIV medical care for HIV-infected individuals within their jurisdiction.

Applicants eligible for Category 2 (Data to Care Demonstration Projects That Use Surveillance Data Sources to Identify MSM and Transgender Persons Not in HIV Care) must also be eligible for Category 1. Limiting competition to the health departments in the geographic areas of the United States where the

largest populations of MSM living with HIV reside will ensure that the project can have the most impact on the HIV epidemic. In addition, eligibility is limited to 12 health departments in 16 MSAs/MDs who have complete reporting of all CD4 cell count and HIV viral load results, defined as: i) the jurisdiction's laws/regulations require the reporting of all CD4 and viral load results to the state/city health department; ii) a minimum of 95% of HIV-related test results from laboratories that perform HIV-related testing for each area are being reported to the state/city health department; and iii) the jurisdiction is reporting at least 95% of all CD4 and viral load test results to CDC as of December 31, 2013 (as outlined in the 2012 Monitoring Report, published in November 2014).

MS/MD	Health Department
New York–White Plains–Wayne Division	New York City Department of Health and Mental Hygiene
Los Angeles Division	Los Angeles County Public Health Department
Chicago Division	Chicago Department of Public Health
Washington Division	District of Columbia Department of Health
San Francisco Division	San Francisco Department of Public Health
Houston-Baytown-Sugar Land, TX	Houston Department of Health and Human Services
Dallas Division	Texas State Department of Health Services
San Diego-Carlsbad-San Marcos, CA	California Department of Public Health (Office on AIDS)
Riverside-San Bernardino-Ontario, CA	California Department of Public Health (Office on AIDS)
Baltimore-Towson, MD	Baltimore Department of Health
Santa Ana Division	California Department of Public Health (Office on AIDS)
St. Louis, MO-IL	Missouri Department of Health and Senior Services
Oakland Division	California Department of Public Health (Office on AIDS)
Detroit Division	Michigan Department of Community Health
New Orleans-Metairie-Kenner, LA	Louisiana Department of Health
San Antonio, TX	Texas State Department of Health Services

An important on-going HIV surveillance activity of state and local health departments is to collect the results of all CD4 cell count and HIV viral load tests performed in their jurisdiction. Laws and regulations require the reporting of these CD4 cell count and viral load results to the appropriate state or local health department and that the health departments maintain security and confidentiality of these data. A critical component of this FOA is the use of accurate and complete CD4 cell count and HIV viral load test results to determine which patients are not in care. For this reason, health departments must have this capability and must have complete reporting of all CD4 cell count and HIV viral load results.

States that have local health departments directly funded by CDC are not eligible to apply for the MSAs or MDs that contain locally funded health departments within the state.

State health departments with one eligible MSA or MD are required to work in the specified eligible MSA or MD. States that have more than one eligible MSA or MD may elect to work in all or a reduced number of eligible MSAs or MDs, in order of prevalence.

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

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

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Required Registrations

Additional materials that may be helpful to applicants: http://www.cdc.gov/od/pgo/funding/docs/FinancialReferenceGuide.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 athttp:// 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-awardees, those sub-awardees 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 an awardee. 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 usually requires not more than five business days, and registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.

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

All applicant organizations must register with www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants must start the registration process as early as possible.

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. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC PGO staff at 770-488-2700 or e-mail PGO PGOTIM@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the FOA, it will not be processed. PGO 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 PGO.

a. Letter of Intent Deadline (must be emailed or postmarked by)

N/A

b. Application Deadline

Due Date for Applications: **06/01/2015**, 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: 04/22/2015

An informational conference call will be held on April 22, 2015 from 3:30 - 4:30 pm EST.

Dial in number: 800-779-9794

Passcode: 3350866

Questions may also be directed to 1506foamailbox@cdc.gov.

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://www.cdc.gov/grants/interestedinapplying/applicationprocess.html.

- Complete the applicable assurances and certifications on an annual basis, name the file "Assurances and Certifications" and upload it as a PDF file 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.

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

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

8. Table of Contents

(No page limit and not included in Project Narrative 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

(Maximum 1 page)

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.

10. Project Narrative

(Maximum of 20 pages, single spaced, Calibri 12 point, 1-inch margins, number all pages. Content beyond 20 pages will not be considered. The 20 page limit includes the work plan. For a multi-component FOA, maximum page limit is 25.)

The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in the CDC Project Description section. Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov.

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 project period. 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 project period outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan, how these strategies will be evaluated over the course of the project period. (See 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.

2. Target Populations

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. Refer back to the CDC Project Description section – Approach: Target Population.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an overall evaluation and performance measurement plan that is consistent with the CDC Evaluation and Performance Measurement Strategy section of the CDC Project Description of this FOA. Data collected must be used for ongoing monitoring of the award to evaluate its effectiveness, and for continuous program improvement.

The plan must:

- Affirm the ability to collect the performance measures and respond to the evaluation questions specified in the CDC strategy. (For guidance regarding the Paperwork Reduction Act, please visit http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html)
- Describe how key program partners will participate in the evaluation and performance measurement planning processes.
- Describe how evaluation findings will be used for continuous program quality improvement.

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

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

- Describe potentially available data sources and feasibility of collecting appropriate evaluation and performance data.
- Describe how evaluation and performance measurement will contribute to development of that evidence base, where program strategies are being employed that lack a strong evidence base of effectiveness.

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

d. Organizational Capacity of Applicants to Implement the Approach

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

Applicants must name this file "CV/Resumes" or "Organizational Charts and upload it at www.grants.gov.

11. Work Plan

(Included in the Project Narrative's 20 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 awardee plans to carry out achieving the project period outcomes, strategies and activities, evaluation and performance measurement.

Applicants must name this file "Work Plan" and upload it as a PDF file at www.grants.gov.

12. Budget Narrative

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Execute the Approach. 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 will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities). The CDC will not reimburse indirect costs unless the recipient has an indirect cost rate covering the applicable activities and period.

For guidance on completing a detailed budget, see Budget Preparation Guidelines at:http://www.cdc.gov/grants/interestedinapplying/applicationresources.html .

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 FOA 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 FOA. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

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 Grantees under such a plan. Applicants must name this file “Indirect Cost Rate” and upload it at www.grants.gov.

There are no additional budget narrative requirements for this FOA.

13. Tobacco and Nutrition Policies

Awardees are encouraged to implement tobacco and nutrition policies.

Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.

CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically The Pro-Children Act, 20 U.S.C. 7181-7184, that prohibits smoking in certain facilities that

receive federal funds in which education, library, day care, health care,or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.
3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: http://www.gsa.gov/ graphics/pbs/Guidelines_for_ Federal_ Concessions_and_Vending_ _Operations.pdf).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:

http://www.cdc.gov/ nccdphp/dnpao/hwi/ toolkits/ tobacco/index.htm

http://www. thecommunityguide.org/ tobacco/index.html

http:// www.cdc.gov /obesity /strategies /food-serv-guide.html

14. Health Insurance Marketplaces

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible. For more information on the Marketplaces and the health care law, visit: www.HealthCare.gov.

15. Intergovernmental Review

Executive Order 12372 does not apply to this program.

16. 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 CFR section 3.908 to the award and requires that grantees 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.

17. Funding Restrictions

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

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care.
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.

- Generally, awardees 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 is not allowed.
- 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 http:// www.cdc.gov /grants /additional requirements /index.htm l#ar12 for detailed guidance on this prohibition and http://www. cdc.gov/ grants /documents/Anti- Lobbying _ Restrictions _ for_CDC _ Grantees_July _2012.pdf

- 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.

- Funds may **not** be used for PrEP medications (e.g., Truvada), laboratory testing related to PrEP (for example, creatinine tests, liver function tests, pregnancy tests, and other clinical tests that could result from evaluation of side effects/toxicities) or personnel costs for the provision of PrEP medication and recommended clinical care associated with PrEP.
- Project activities that involve the collection of information from 10 or more individuals/entities and are funded by a grant/cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

18. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by PGO Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the PGO TIMS staff at 770- 488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to PGO TIMS staff for processing from www.grants.gov on the deadline date.

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 FOA. 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 Applicant User Guide, Version 1.1, page 102.

http:// www.grants.gov /documents /19/18243 /Grantsgov ApplicantUserGuide .pdf /ce754626 -c2aa-44bc- b701 -30a75bf428c8

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@www.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@www.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 or call 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 postmarked 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, PGO 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 reviewed initially for completeness by CDC PGO staff and will be reviewed jointly for eligibility by the CDC NCHHSTP and PGO. Incomplete applications and applications that do not meet the eligibility criteria will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility 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

CATEGORY 1: Approach	**Maximum Points: 30**

A. Does the applicant adequately describe how the PrEP support demonstration project addresses the NHAS goals of reducing new HIV infections, and reducing HIV-related disparities and health inequities and expected outcomes for the jurisdiction?

B. Does the applicant clearly demonstrate how the use of oral daily antiretrovirals for pre-exposure prophylaxis (PrEP) to reduce HIV infections among persons at substantial risk of acquiring HIV can be used as an important prevention tool in the applicant's jurisdiction?

C. Does the applicant adequately describe how the proposed approach will expand or enhance current HIV prevention activities and address critical gaps in the jurisdiction for MSM and transgender persons at high risk for HIV infection, particularly persons of color? If the applicant proposes to also include other persons at substantial risk for HIV, does the applicant provide sufficient information on how the proposed approach will expand or enhance current HIV prevention activities for these populations and address related critical gaps in the jurisdiction? Does the proposed approach include the leveraging of other resources (i.e., other federal or non-federal funding sources)?

D. Does the applicant describe plans to identify, engage, and coordinate the development of the demonstration project with key stakeholders and partners, including but not limited to prevention and care providers from the public and private sector, clinics, community health centers, mental health and substance abuse services, social services, local communities, governmental and non-governmental entities, local planning groups, LGBT organizations, and other community-based organizations? Does the applicant describe how proposed activities with stakeholders and partners will be coordinated to reach and engage MSM and transgender persons in their jurisdiction to build support for PrEP?

E. Does the applicant describe plans to increase PrEP awareness among the target population and providers and clinical training of providers? Does the applicant describe plans to increase access to PrEP by assisting with locating providers willing to prescribe PrEP in the local jurisdiction? Does the applicant describe plans to help providers and consumers navigate public and private programs that provide or reimburse for PrEP?

F. Does the applicant describe plans to address capacity building needs related to the overarching project goal of supporting PrEP-related activities for MSM and transgender persons at high risk for HIV infection, particularly persons of color, and other populations targeted in their plan?

G. Does the applicant describe how PrEP support activities can be integrated with STD and hepatitis screening services?

H. Does the applicant describe plans to continue to identify ways to expand and enhance implementation of the demonstration project supporting PrEP-related activities by leveraging other resources to support the goals of the demonstration project?

CATEGORY 1: Evaluation and Performance Management	**Maximum Points: 30**

A. Does the applicant provide a detailed work plan that describes demonstration project activities as well as program monitoring and evaluation, and quality assurance activities?

B. Does the applicant describe plans to begin implementation of the CDC-approved demonstration project work plan for support of PrEP-related activities for MSM, transgender persons, and other populations targeted in their plan within 6 months of funding?

C. Does the applicant present a feasible evaluation and performance management plan that includes project goals and objectives that are specific, measurable, achievable, realistic and time-phased (SMART)?

- Does the plan identify evaluation questions for program plan objectives, describes when and how data will be collected and analyzed, indicates who will be responsible, and describes how the results will be utilized and shared?
- Does the evaluation and performance management plan include activities to identify lessons learned?

D. Does the applicant describe plans to revise and update the logic model, detailed work plan, and monitoring and evaluation, and quality assurance activities as needed during the course of the demonstration project?

E. Does the applicant agree to participate in efforts to disseminate project findings and lessons learned within the jurisdiction, and contribute to dissemination efforts at the local, regional, and national level?

CATEGORY 1: Applicants Organizational Capacity to Implement the Approach	**Maximum Points: 40**

A. Does the applicant describe the quality of the health department's experience and capacity to implement the PrEP support demonstration project?

B. Does the applicant include a letter of support from the health department Executive Director in support of a PrEP support demonstration project and affirming the health department's ability to hire staff and implement the project as proposed?

C. Does the applicant include a letter of support from the local HIV Planning Group in support of the proposed PrEP support demonstration project?

D. Does the applicant provide a description of duties, percentage-of-time commitments, and responsibilities of project personnel including clear lines of authority and supervisory capacity to successfully conduct the proposed activities? Is an organizational chart included?

E. Does the applicant propose a staffing plan that includes:

- Experienced staff member to direct demonstration project activities? It is recommended that this person contributes a minimum of 20 percent of his/her time to this project
- Are resumes/curriculum vitae included for staff listed in the application? For staff to be hired, are position descriptions, timelines for staffing, qualifications for each position, and methods for recruiting qualified applicants described in the application?
- Does the applicant demonstrate proposed staff members have experience working with or a positive relationship with the LGBT communities in their jurisdiction?

F. Does the applicant describe plans to ensure that current and new staff members have adequate training to implement activities of the demonstration project?

CATEGORY 1: Budget and Budget Narrative (Reviewed but not scored)	**Maximum Points: 0**

A. Is the budget reasonable, itemized, clearly justified, and consistent with the intended use of the funds?

B. Does the budget include itemizations, justifications, scope, and deliverables for consultants or contractors?

C. Does the applicant's budget include approximately 10% of the overall budget to support local program evaluation of funded activities?

D. Does the applicant's budget include funds for key project staff to attend a Year 1 orientation meeting; and annual meetings in Atlanta?

CATEGORY 2: Approach	**Maximum Points: 30**

A. Does the applicant adequately describe how the Data to Care demonstration project addresses the NHAS goals of reducing new HIV infections, increasing access to care and reducing HIV-related disparities and health inequities and expected outcomes for the jurisdiction?

B. Does the applicant clearly demonstrate how the use of HIV surveillance data to support continuous, high-quality HIV care (including linkage and re-engagement to care and support for providers and persons living with HIV to achieve viral suppression) can be used as an important prevention tool in the applicant's jurisdiction?

C. Does the applicant adequately describe how the proposed approach will expand or enhance current HIV prevention activities and address critical gaps in their jurisdiction for use of surveillance data to improve clinical outcomes, including HIV viral suppression, for MSM and transgender persons who have sex with men? These include both CDC-funded activities as well as those funded by other federal and non-federal agencies.

- Does the applicant describe having procedures to use HIV surveillance data to identify MSM and transgender persons who are not in care, having information technology support to create lists of patients who are potentially not in care, and having procedures to ensure confidentiality of data when locating persons not in care?
- Does the applicant describe an approach to use HIV surveillance data to enhance or expand services that ensure linkage of HIV-diagnosed MSM, transgender persons, and other persons not in HIV care who have HIV and are not virally suppressed or have ongoing risk behavior into HIV medical care? Does the applicant describe an approach that addresses the barriers to effective engagement and retention in HIV care?

D. Does the applicant describe plans to identify, engage, and coordinate the development of the demonstration project with key stakeholders and partners, including but not limited to prevention and care providers from the public and private sector, clinics, community health centers, mental health and substance abuse services, social services, local communities, governmental and non-governmental entities, local planning groups, LGBT organizations, and other community-based organizations?

E. Does the applicant describe plans to address capacity building needs related to the overarching project goal of Data to Care activities?

F. Does the applicant describe how Data to Care activities can be integrated with STD and Hepatitis screening services to aid in prioritizing the not-in-care list?

G. Does the applicant describe plans to continue to identify ways to expand and enhance implementation of the demonstration project supporting Data to Care activities by leveraging other resources to support the goals of the demonstration project?

CATEGORY 2: Evaluation and Performance Management	**Maximum Points: 30**

A. Does the applicant provide a detailed work plan that describes demonstration project activities as well as program monitoring and evaluation, and quality assurance activities?

B. Does the applicant describe plans to begin implementation of the CDC-approved demonstration project work plan for Data to Care activities within 6 months of funding?

C. Does the applicant present a viable and feasible evaluation and performance management plan that includes project goals and objectives that are specific, measurable, achievable, realistic and time-phased (SMART)?

- Does the plan identify evaluation questions for program plan objectives, describes when and how data will be collected and analyzed, indicates who will be responsible, and describes how the results will be utilized and shared?
- Does the evaluation and performance management plan include activities to identify lessons learned?

D. Does the applicant describe plans to revise and update the logic model, detailed work plan, and monitoring and evaluation, and quality assurance activities as needed during the course of the demonstration project?

E. Does the applicant agree to participate in efforts to disseminate project findings and lessons learned within the jurisdiction, and contribute to dissemination efforts at the local, regional, and national level?

CATEGORY 2: Applicants Organizational Capacity to Implement the Approach	**Maximum Points: 40**

A. Does the applicant describe the quality of the health department's experience and capacity to implement the Data to Care demonstration project?

B. Does the applicant include a letter of support from the Health Department Director in support of a Data to Care demonstration project , and affirming the health department's ability to hire staff and implement the project as proposed?

C. Does the applicant include a letter of support from the local HIV Planning Group and Ryan White Planning Council in support of the proposed Data to Care demonstration project?

D. Does the applicant provide a description of duties, percentage-of-time commitments, and responsibilities of project personnel including clear lines of authority and supervisory capacity to successfully conduct the proposed activities? Is an organizational chart included?

- Does the applicant propose a staffing plan that includes an experienced staff member to direct demonstration project activities? It is recommended that this person contributes a minimum of 20 percent of his/her time to this project.

E. Are resumes/curriculum vitas included for staff listed in the application? For staff to be hired, are position descriptions, timelines for staffing, qualifications for each position, and methods for recruiting qualified applicants described in the application?

F. Does the applicant propose a staffing plan with a sufficient number of staff hours or percent time in support of identifying HIV-diagnosed persons not in care in the community?

G. Do proposed staff have experience using health department HIV surveillance data and HIV surveillance laboratory data (CD4 cell count and HIV-1 viral load results) to improve linkage and engagement in HIV care?

H. Do proposed project staff have experience working with or have a positive relationship with the LGBT communities in their jurisdiction?

CATEGORY 2: Budget and Budget Narrative (Reviewed but not scored)	Maximum Points: 0

A. Is the budget reasonable, itemized, clearly justified, and consistent with the intended use of the funds?

B. Does the budget include itemizations, justifications, scope, and deliverables for consultants or contractors?

C. Does the applicant's budget include approximately 10% of the overall budget to support local program evaluation of funded activities?

D. Does the applicant's budget include funds for key project staff to attend a Year 1 orientation meeting; and annual meetings in Atlanta?

Not more than 30 days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

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.

c. Phase III Review

The following factors may also affect the funding decision: Funded applicants are balanced in terms of geographic diversity and distribution.

2. Announcement and Anticipated Award Dates

The anticipated award date is September 30, 2015.

F. Award Administration Information

1. Award Notices

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

Any applicant awarded funds in response to this FOA 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

Awardees must comply with the administrative and public policy requirements outlined in 45 C.F.R. Part 74 or Part 92 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html

The HHS Grants Policy Statement is available at http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

*Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

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

- AR-4: HIV/AIDS Confidentiality Provisions
- AR-5: HIV Program Review Panel
- AR-6: Patient Care
- AR-7: Executive Order 12372
- AR-9: Paperwork Reduction Act http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html
- AR-10: Smoke-Free Workplace
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14: Accounting System Requirements
- AR-16: Security Clearance Requirement
- AR-21: Small, Minority, And Women-owned Business
- AR-24: Health Insurance Portability and Accountability Act
- AR-25: Release and Sharing of Data
- AR-26: National Historic Preservation Act of 1966
- AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving," October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-33: Plain Writing Act of 2010
- AR-34: Patient Protection and Affordable Care Act (e.g., a tobacco-free campus policy and a lactation policy consistent with S4207)
- AR-35: Nutrition Policies

For more information on the C.F.R. visit http://www.ecfr.gov/cgi-bin/ECFR?page=browse.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that awardees encounter throughout the project period. Also, reporting is a requirement for awardees who want to apply for yearly continuation of funding. Reporting helps CDC and awardees because it:

- Helps target support to awardees;
- Provides CDC with periodic data to monitor awardee progress toward meeting the FOA outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the project period 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 FOA.

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 FOA copying the CDC Project Officer.

Report	When?	Required?
Awardee Evaluation and Performance Measurement Plan	6 months into award	Yes
Annual Performance Report (APR)	120 days before end of budget period. Serves as yearly continuation application.	Yes

Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	No
Federal Financial Reporting Forms	90 days after end of calendar quarter in which budget period ends	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes

a. Awardee Evaluation and Performance Measurement Plan (required)
With support from CDC, awardees must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; awardees must submit the plan 6 months into the award.

This plan should provide additional detail on the following:

- The frequency that evaluation and performance data are to be collected.
- How data will be reported.
- How evaluation findings will be used for continuous quality and program improvement.
- How evaluation and performance measurement will yield findings to demonstrate the value of the FOA (e.g., improved public health outcomes, effectiveness of FOA, cost-effectiveness or cost benefit).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

b. Annual Performance Report (APR) (required)
The awardee must submit the APR via www.grants.gov 120 days before 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:** Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Awardees must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Awardees must update work plan each budget period to reflect any changes in project period outcomes, activities, timeline, etc.
- **Successes**
    - Awardees must report progress on completing activities and progress towards achieving the project period outcomes described in the logic model and work plan.
    - Awardees must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Awardees must describe success stories.
- **Challenges**
    - Awardees must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the project period outcomes.

- Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.

- **CDC Program Support to Awardees**
  - Awardees must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving project period 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 carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, 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.

The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period.

c. Performance Measure Reporting (optional)
CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for awardees at the beginning of the award period.

CDC will work w/ grantees closely to determine specific reporting requirements over the life of the project.

d. Federal Financial Reporting (FFR) (required)
The annual FFR form (SF-425) is required and must be submitted through eRA Commons 90 days after the end of the calendar quarter in which the budget period ends. 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 PGO 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 project period. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire project period and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Awardees must report final performance data for all process and outcome performance measures.
- Evaluation Results – Awardees must report final evaluation results for the project period for any evaluations conducted.

- Impact/Results/Success Stories – Awardees must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

There are no additional report requirements for this FOA.

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

The FFATA and Public Law 109-282, which amends the FFATA, require full disclosure of all entities and organizations that receive federal funds including awards, contracts, loans, other assistance, and payments. This information must be submitted through the single, publicly accessible website, www.USASpending.gov.

Compliance with these mandates is primarily the responsibility of the federal agency. However, two elements of these mandates require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through SAM; and 2) similar information on all sub-awards, subcontracts, or consortiums for greater than $25,000. For the full text of these requirements, see: http://www.gpo.gov /fdsys/browse/ collection.action?collectionCode= BILLS.

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

Program Office Contact

For programmatic technical assistance, contact:

Carolyn Leighton, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Mailstop E-37
Atlanta, , GA 30329
Telephone: (404) 639-1908
Email: 1506foamailbox@cdc.gov

Grants Staff Contact

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

Shirley K. Byrd, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road
MS K-75
Atlanta, GA 30341-4146
Telephone: (770) 488-2591
Email: yuo6@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.

For all other **submission** questions, contact:
Technical Information Management Section
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
E-mail: pgotim@cdc.gov

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
- Table of Contents for Entire Submission

Optional attachments, as determined by CDC programs

- Resumes/CVs
- Position descriptions
- Letters of Support
- Organizational Charts
- Non-profit organization IRS status forms, if applicable
- Indirect Cost Rate , if applicable
- Memorandum of Agreement (MOA)
- Memorandum of Understanding (MOU)
- Bona Fide Agent status documentation, if applicable

Additional acceptable attachments:

- Work Plan
- Programmatic Logic Model

Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases and Tuberculosis Prevention, Centers for Disease Control and Prevention http://www.cdc.gov/hiv/

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 74 and Part 92 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 FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additionalrequirements/index.html

. Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

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

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

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

Catalog of Federal Domestic Assistance (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.

CFDA Number: A unique number assigned to each program and FOA throughout its lifecycle that enables data and funding tracking and transparency.

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 project period (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 awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

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 FOA evaluation plan is used to describe how the awardee 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.

Healthy People 2020: 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: http://www.whitehouse.gov/omb/ grants_spoc/.

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 activites; 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.

Plain Writing Act of 2010: Requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.

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 FOA; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Project Period Outcome: An outcome that will occur by the end of the FOA's funding period.

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.

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 project period 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.

Additional glossary terms applicable to this FOA:

Basic HIV Care: Management of stable HIV-positive patients who are ART naïve or on 1st line ART therapy, management of common complaints, and referrals to more complex HIV care.

Data to Care for HIV Prevention: *Data to Care* programs use laboratory reports received by a health department's HIV surveillance program as markers of HIV care and analyze them to identify individuals who either never linked to care after diagnosis or who did not continue to receive care. The program then offers individuals on this list for outreach by health departments, providers, or both to assist them with getting into HIV care. CDC promotes HIV prevention strategies, such as Data to Care, that are consistent with the National HIV/AIDS Strategy goals of decreasing HIV transmission and increasing the number of HIV-diagnosed persons linked to care. Jurisdictions should include use of HIV surveillance data for prevention programming as one part of their comprehensive strategy for linkage and re-engagement in care activities. Such a strategy might include multiple approaches for identifying HIV-diagnosed individuals not in care and linking them to or re-engaging them in care, including expanded HIV screening services, linkage to care interventions such as ARTAS, and other case management and peer-based interventions. See more at:

http://www.effectiveinterventions.org/en/HighImpactPrevention/PublicHealthStrategies/DatatoCare/ProgramIntroductionandGoals.aspx#sthash.iZsGqHGm.dpuf

Pre-Exposure Prophylaxis for HIV Prevention: Pre-exposure prophylaxis, or PrEP, is a way for people who do not have HIV but who are at substantial risk of getting it to prevent HIV infection by taking a pill every day. The pill (brand name Truvada) contains two medicines (tenofovir and emtricitabine) that are also used in combination with other medicines to treat HIV. When someone is exposed to HIV through sex or injection drug use, these two medicines can work to keep the virus from establishing a permanent infection.

When taken consistently, PrEP has been shown to reduce the risk of HIV infection in people who are at high risk by up to 92%. PrEP is much less effective if it is not taken consistently. PrEP is a powerful HIV prevention tool and can be combined with condoms and other prevention methods to provide even greater protection than when used alone. But people who use PrEP must commit to taking the drug every day and seeing their health care provider for follow-up every 3 months. Additional information is provided at: http://www.cdc.gov/hiv/prevention/research/prep/

Seroprevalence: The number of people in a population who test HIV positive based on serology (blood serum) specimens. Seroprevalence is often presented as a percent of the total specimens tested or as a rate per 1,000 persons tested.