

Image Description: Centers for Disease Control

Centers for Disease Control

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

Data to Care Rx: Using Real-time Prescription Claims Data to Support the HIV Care Continuum

CDC-RFA-PS17-1709

Application Due Date: 06/05/2017

Data to Care Rx: Using Real-time Prescription Claims Data to Support the HIV Care Continuum

CDC-RFA-PS17-1709

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-PS17-1709. 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) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Funding Opportunity Title:

Data to Care Rx: Using Real-time Prescription Claims Data to Support the HIV Care Continuum

C. Announcement Type: New - Type 1

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at <https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf>. Guidance on how CDC interprets the definition of research in the context of public health can be found at <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>.

New-Type 1

D. Agency Funding Opportunity Number:

CDC-RFA-PS17-1709

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

93.941

F. Dates:

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

05/05/2017

2. Due Date for Applications:

06/05/2017, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

LOIs will be accepted but not required for this FOA. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

3. Date for Informational Conference Call:

N/A

G. Executive Summary:

1. Summary Paragraph:

The purpose of this cooperative agreement is to develop and implement a "Data-to-Care Rx" model which uses pharmacy claims data to identify persons with HIV who fail to pick up prescribed ARV medications by 30, 60 and 90 days, and to target these individuals for adherence, retention and re-linkage interventions. The awardee must use pharmacy claims data to identify persons who fail to pick up prescribed ARVs after 30 days and conduct a low intensity 1st line adherence intervention that may be conducted by a Pharmacy Benefits Manager, insurer, filling pharmacy or other source. Persons identified as 60 days late will receive 2nd line adherence and retention interventions at the prescribing project clinics and/or filling pharmacies. Persons identified as 90 days late will receive a 3rd line intervention where the health department uses Disease Intervention Specialists or similar staff to locate and re-link the individuals to the

prescribing clinic.

Specific activities of the cooperative agreement are broadly categorized into three areas: 1) develop the Data-to-Care Rx model 2) implement the model and 3) evaluate project outcomes and disseminate results. After implementation and final adjustments to the model the model will be finalized. Key expected outcomes are: increased re-linkage to care; increased adherence to HIV medication therapy; increased retention in HIV care; and increased HIV viral load suppression.

a. Eligible Applicants:	Open Competition
b. FOA Type:	Cooperative Agreement
c. Approximate Number of Awards:	1
d. Total Project Period Funding: <i>\$250,000 first year, \$875,000 year 2 and year 3</i>	\$2,000,000
e. Average One Year Award Amount: <i>\$250,000 first year, \$875,000 year 2 and year 3</i>	\$250,000
f. Total Project Period Length:	3
g. Estimated Award Date:	09/29/2017
h. Cost Sharing and / or Matching Requirements:	N

Part II. Full Text

A. Funding Opportunity Description

Part II. Full Text

1. Background

a. Overview

Re-engaging out-of-care persons with HIV back into care, confers important individual-level health benefits and population-level prevention benefits. Use of HIV surveillance data to identify out-of-care persons, is one strategy for identifying and re-engaging out-of-care persons in care and is called Data-to-Care or D2C. Data-to-Care uses laboratory reports (i.e., CD4 and HIV viral load tests) received by a health department's HIV surveillance program as markers of HIV care. The laboratory reports are used to identify individuals who either never linked to care, after diagnosis, or who did not continue to receive care and to offer these individuals outreach by health departments, providers, or both to assist them with getting into or back into HIV care.

In the current D2C model, there is a delay in identification of out-of-care persons due to the time interval between recommended monitoring tests and the subsequent reporting of these tests to surveillance. Thus, the current D2C model identifies persons already out of care rather than identifying persons at risk for dropping out of care; the current model cannot intervene in the short time interval between the start of a gap in care (typically 6 months from the last visit) and the point at which a person is declared out of care. More real-time data is needed to identify persons at risk of dropping out of care and to intervene prior to a gap in care or loss to care.

Pharmacy prescription (claims) data are a source to identify HIV-infected persons who have stopped filling antiretroviral (ARV) medications, and who are at risk for becoming out of care. Patients may fill prescriptions at one of potentially many pharmacies. Within one pharmacy network, prescriptions can be tracked across partnered pharmacies (e.g. chain drug stores). However, if a patient switches pharmacies (to

another chain or independent pharmacy) the prior refill history remains with the first pharmacy. Pharmacy claims are adjudicated for an insurance company by a third-party claims processor or a pharmacy-benefit management (PBM) company. All pharmacy claims that are billed to an insurance company for an individual patient, can be tracked through the PBM regardless of where a patient filled the prescription. Because most ARVs are prescribed as a 30-day supply of medication, data from PBMs and other like sources can be used to identify persons who are not filling their medications on a monthly basis. Tracking ARV refill data can, therefore, be a more real-time indicator of poor adherence and can act as a harbinger of potential poor retention in care. Using real time pharmacy claims data to identify persons who fail to fill ARV prescriptions and to intervene could have a significant impact on adherence and potentially on retention in care.

The purpose of the cooperative-agreement is to develop and implement a model using real-time pharmacy data to identify persons who fail to pick up prescribed medications by 30, 60 and 90 days, and target these individuals for adherence, retention and re-linkage interventions. The intent is to identify and control a health problem with the intended benefits directed primarily towards the participants. Specific activities of the cooperative agreement are broadly categorized into three areas: (1) develop a “Data-to-Care Rx” model (2) implement the model (3) evaluate project outcomes and disseminate results. The expected outcomes of the project are: increased re-linkage in care; increased ARV adherence; increased retention in care; and increased HIV viral suppression.

b. Statutory Authorities

This program is authorized under Section 301(a) of the Public Health Service Act (42 U.S.C. section 241(a)

c. Healthy People 2020

This FOA supports the following Healthy People 2020 objectives:

HIV-2: Reduce number of new HIV infections among adolescents and adults

HIV-3: Reduce the rate of HIV transmission among adolescents and adults

HIV-4: Reduce new AIDS cases among adolescents and adults

HIV-21: (Developmental) Increase the proportion of persons with an HIV diagnosis who had at least one HIV medical care visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits

HIV-22: (Developmental) Increase the proportion of persons with an HIV diagnosis in medical care with a viral load <200 copies/mL at the last test during the 12-month measurement period

d. Other National Public Health Priorities and Strategies

This FOA supports the following goals within the National HIV/AIDS Strategy (NHAS) available at: <https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf>

- Goal 1, Step 1.B: Expand efforts to prevent HIV infection using a combination of effective, evidence-based approaches
- Goal 1, Step 1.B.4: Expand prevention with persons living with HIV
- Goal 2, Step 2.A.2: Ensure linkage to HIV medical care and improve retention in care for people living with HIV

This FOA also supports the following goals with the CDC National Center for HIV, Hepatitis, STD and TB Prevention available at: <https://www.cdc.gov/nchhstp/strategicpriorities/>

- Goal 1: Decrease incidence of infection with HIV, viral hepatitis, STDs, and TB
- Goal 2: Decrease morbidity and mortality from HIV, viral hepatitis, STDs, and TB

e. Relevant Work

This FOA is informed by current Data-to-Care models where health departments have demonstrated success in using HIV surveillance data to identify persons living with HIV who are out-of-care and re-engaging these individuals in care. Successful Data-to-Care models have been implemented in both local and state health departments and in healthcare systems. More information about the current Data-to-Care model can be found at:

<https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/PublicHealthStrategies/DatatoCare.aspx>

2. CDC Project Description

a. Approach

Bold indicates project period outcome.

CDC-RFA-PS17-1709 Logic Model: Data to Care Rx: Using Real-time Prescription Claims Data to Support the HIV Care Continuum

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
<p>Develop model to use pharmacy claims data to identify persons who fail to pick up prescribed antiretroviral medications (ARVs) and to intervene</p> <ul style="list-style-type: none"> - Develop procedures for using pharmacy claims data to identify persons with HIV who failed to pick up prescribed ARVs by 30, 60 and 90 days - Develop procedures and 1st, 2nd and 3rd line interventions for persons who failed to pick up prescribed ARVs 	<p>Among persons living with HIV in the project:</p> <ul style="list-style-type: none"> • Increased re-linkage in care 	<p>Among persons living with HIV in the project:</p> <ul style="list-style-type: none"> • Increased ARV adherence • Increased retention in care • Increased HIV viral suppression 	<ul style="list-style-type: none"> • Decreased HIV transmission • Decreased HIV morbidity
<p>Implement model</p> <ul style="list-style-type: none"> - Obtain access to pharmacy claims data - Partner with project clinics and/or pharmacies to 			

<p>implement 2nd line interventions</p> <ul style="list-style-type: none"> – Operationalize process at health department to implement the 3rd line intervention – Arrange for and finalize agreements/contracts and necessary organization approvals with project partners – Using the pharmacy claims data, identify persons who failed to pick up prescribed ARVs and conduct 1st, 2nd and 3rd line interventions – Finalize model 			
<p>Evaluate project outcomes and disseminate results</p> <ul style="list-style-type: none"> – Collect and clean project data – Analyze project data – Disseminate results 			

i. Purpose

This FOA requires the awardee to develop and implement a model to use pharmacy claims data to identify persons with HIV who fail to pick up prescribed antiretroviral (ARV) medications and target these individuals for adherence and retention interventions and to re-link these individuals to care. The goal of the model is to improve re-linkage to care, ARV adherence, retention in care and HIV viral suppression.

ii. Outcomes

- 1) Increased re-linkage in care among persons living with HIV in the project
- 2) Increased ARV adherence among persons living with HIV in the project
- 3) Increased retention in care among persons living with HIV in the project
- 4) Increased viral suppression among persons living with HIV in the project

iii. Strategies and Activities

Specific activities, of the cooperative agreement, are broadly categorized into three strategies: 1) develop the Data-to-Care Rx model 2) implement the model and 3) evaluate project outcomes and disseminate results.

The project model requires: 1) a pharmacy claims data source; 2) project clinics and/or pharmacies and 3) a health department and Disease Intervention Specialists.

A pharmacy claims data source must be used to identify persons who have not picked up prescribed ARVs by 30, 60 and 90 days. For persons who failed to pick up prescribed ARVs by 30 days, a 1st line intervention will be conducted. The 1st line intervention should be a low intensity intervention and can be an intervention conducted by a PBM or insurer, filling pharmacy or other intervention. The 1st line intervention should be designed to reach as many people as possible. For persons who failed to pick up prescribed ARVs by 60 days, a 2nd line intervention will be conducted. The 2nd line intervention will be conducted at project clinics and/or pharmacies. The 2nd line intervention must be conducted at a sufficient number of prescribing clinics and/or filling pharmacies to enroll a total of 400 patients. Lastly, the partnered health department will be informed of persons who failed to pick up prescribed ARVs by 90 days and will use Disease Intervention Specialists (or similar personnel) to locate these individuals and then re-link them to the prescribing clinic and provide follow-up. The 3rd line intervention should be designed to reach as many people as possible.

The Data-to-Care Rx model will be developed in collaboration with CDC. The Project Team which will be composed of the awardee, CDC, and other partners including the health department. The applicant may suggest additional members for the Project Team. CDC and the Project Team will have substantial involvement in the development of the Data-to-Care Rx model. Data will be collected throughout the implementation phase of the project in order to determine project outcomes. First year of the project period will involve project planning and obtaining IRB approval (if required) and OMB approval. Second and third year will be implementation of the project model and analysis of project outcomes.

This 3-year project includes the following activities:

The applicant shall work with CDC and the Project Team to conduct the following activities:

Strategy #1: Develop model to use pharmacy claims data to identify persons who fail to pick up prescribed ARVs and to intervene

Activities:

-Develop procedures for using pharmacy claims data from Pharmacy Benefit Manager (PBM), insurer(s) or other source(s) to identify persons with HIV who failed to pick up prescribed ARVs by 30, 60 and 90 days.

-Develop procedures and 1st, 2nd and 3rd line interventions for persons who failed to pick up prescribed ARVs.

– 1st line intervention

- 1st line intervention should be a low intensity intervention (e.g., contacting the patient to remind them to pick up the prescribed ARV).

- The applicant must describe a process for the 1st line intervention that will be implemented for a very broad portion of the population who failed to pick up prescribed ARVs by 30 days (ideally, offered to all) that may be an 1) intervention from an insurer or PBM; 2) an intervention from the pharmacy where the prescription was last filled or 3) other intervention.

- The 1st line intervention must be designed such that it is easily integrated into the current business practice and workflow. For instance, if the intervention comes from the insurer or PBM, the model should use existing processes and staff that can be assigned to implement it.

- If the intervention comes from the pharmacy, it should be designed such that it can be integrated into the pharmacy's usual daily workflow. The pharmacy intervention may include using a Medication Therapy Management intervention.

- The applicant must describe how relationships will be established with pharmacies to implement interventions. For example, if a partnered insurer(s) has contracted pharmacies in a network, they may establish a process whereby the pharmacy is paid to contact the patient(s) as the 1st line intervention. The funds for such an arrangement are expected to be in the course of typical business that the insurer would provide. The funds from this FOA are not intended to be used to provide this type of service fee.

- *2nd line intervention*

- Develop process for sharing the pharmacy claims data from the PBM, insurer or other data source with the project clinics and/or pharmacies including data sharing agreements if required.

- Develop procedures for using the list of persons who failed to pick up prescribed ARVs by 60 days.

- Develop process to inform prescribing clinics of patients who fail to pick up prescribed ARVs by 60 days, for both project clinics and non-project clinics.

- Develop a new intervention, or implement an existing evidence-based intervention (such as interventions found at: <https://www.cdc.gov/hiv/research/interventionresearch/compendium/lrc/index.html>), to address adherence barriers and potential retention in care barriers.

- *3rd line interventions*

- Develop process for sharing the pharmacy claims data from the PBM, insurer or other data source with the health department including data sharing agreements, if required.

- Develop procedures for using the list of persons who failed to pick up prescribed ARVs by 90 days.

- Develop process for locating patients who failed to pick up prescribed ARVs by 90 days, including the use of Disease Intervention Specialists.

- Develop process to inform prescribing clinics of patients who fail to pick up prescribed ARVs by 90 days, for both project clinics and non-project clinics.

- Develop process for re-linking patients to prescribing clinic.

- Develop follow-up procedures.

Strategy #2: Implement model

Activities:

- Obtain access to pharmacy claims data from a PBM, insurer or other source.

- Partner with project clinics and/or pharmacies to implement 2nd line intervention

- Applicants are required to collaborate with a sufficient number of clinics and/or pharmacies to achieve 400 enrolled patients.

- Applicants are encouraged to collaborate with large HIV clinics in their jurisdiction and with a diversity of clinic types (e.g., Ryan White-funded, academic-affiliated, health maintenance organization, private, or veterans administration clinics).

- If applicant intends to use pharmacies as project sites, the applicant should describe how relationships will be established with pharmacies to implement interventions.
- Develop and conduct project site training including patient consent if required, data collection and project communications with each project clinic and/or pharmacy site.
- Monitor project recruitment and enrollment and address recruitment and enrollment problems as they occur.
- Manage project clinic and/or pharmacy sites, coordinate project site activities, and provide technical assistance to project sites (e.g., data collection and management).
- Operationalize process at health department to implement the 3rd line intervention
- Arrange for and finalize agreements/contracts with project partners including project clinics and/or pharmacies, health department and potentially the PBM or insurer(s),
 - Establish necessary agreements with the clinic and/or pharmacy project sites and health department (e.g. Memorandum of Understandings, financial agreements [i.e. contracts] and clinic and/or pharmacy project sites work plans) and make necessary arrangements for clinic and/or pharmacy site and health department participation.
 - Establish data sharing agreements between project partners if necessary.
- Using the pharmacy claims data, develop list of persons who failed to pick up prescribed ARVs by 30, 60 and 90 days and conduct 1st, 2nd and 3rd line interventions.
 - Persons may receive 1, 2 or 3 interventions depending on whether the prior intervention was successful. The lines of interventions differ in approach, delivery and intensity.
 - 1st and 3rd line interventions should aim to reach as many persons as possible who were identified as failing to pick up prescribed ARVs by 30 and 90 days, respectively.
 - 2nd line interventions will be limited to the project clinic and/or pharmacy population unless otherwise decided by the Project Team. However, prescribing clinics (regardless of whether they are project clinics) should be informed of patients who fail to pick up prescribed ARVs by 60 days and 90 days.
 - Because the 2nd line intervention is a clinic-based (or pharmacy-based) intervention that only includes the project clinics and/or pharmacies populations, while the 1st and 3rd line interventions aim to reach as many persons as possible, some individuals may receive 1st and 3rd line interventions without receiving the 2nd line intervention.
 - Obtain ethical approval(s) including project IRB approval if required and assist project clinic and/or pharmacy sites and health department in obtaining local IRB approval, if required.
 - Obtain participant consent, if required.
- Finalize the service model
 - Document a comprehensive Data-to-Care Rx implementation model that includes a report to CDC with a detailed description of the implementation model and processes

Strategy #3: Evaluate project outcomes and disseminate results

Activities:

- Collect and clean project data
 - Develop a data collection system which includes, but is not limited to:
 - Development of appropriate clinical, pharmacy, medical, laboratory, sociodemographic, process, outcome and other variables to be collected.
 - Development of data collection tools.

- Development of database(s).
- Standardized definitions.
- Quality control procedures.
- Procedures for secure reporting and storage of data.
- Development of a system for secure data sharing between project partners (PBM or insurer or other pharmacy claims data source, project clinic and pharmacy sites and health department).
 - Manage data from the PBM, insurer or other source, project clinic and/or pharmacy sites and health department.
 - Ensure that all required project data elements are collected including baseline data.
 - Conduct process and outcome monitoring of the project sites and provide project progress reports of specified outcomes to CDC on a quarterly (at minimum) basis.
 - Provide CDC with cleaned, analytic datasets of the required data elements, quarterly (at minimum).
- Analyze project data
 - Work collaboratively with CDC and Project Team to develop analysis plans.
 - Work collaboratively with CDC and Project Team to analyze project data and to determine project outcomes.
- Disseminate results
 - Disseminate project results through publications, abstracts and presentations.

1. Collaborations

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

N/A

b. With organizations not funded by CDC:

In addition to CDC, the awardee will work with the project partners including the project clinics and/or pharmacies, the health department and potentially the source of the pharmacy claims data.

Letters of Support

If the applicant is other than a health department the applicant must include in the application, a Letter of Support, from the proposed partnered health department. The Letter of Support should include the health department staff that will be responsible for health department program activities and the number of Disease Intervention Specialists that will be assigned to the project. The applicant should also include Letters of Support from the proposed project clinics and/or pharmacies.

If the applicant intends to partner with a PBM, insurer or other source of pharmacy claims data (i.e., make the PBM, insurer or other organization with the pharmacy claims data part of the Project Team) they must include a Letter of Support, from the organization, with the application. If the applicant intends to use consultants to assist with project activities the applicant must include, in the application, Letters of Support from the proposed consultant(s).

Memorandum of Understanding and Contracts

Post-award, the applicant will be expected to formalize collaborations with all project partners in the form of a Memorandum of Understanding (MOU) and/or contracts.

If the applicant is other than a health department, the applicant will formalize collaboration with the partnered health department in the form of a Memorandum of Understanding (MOU) and/or contract. The MOU and/or contract must clearly convey the objectives of the project, how the project objectives will be accomplished, interventions to be conducted, data that will be collected and who will collect the data, frequency of data collection, data collection method, reporting requirements and necessary permissions to collect the data (e.g. IRB approval and patient consent, if required). The applicant must include in the MOU the timeline of the collaboration, frequency of project communications, and methods of communication. The awardee must explain, in the MOU, what resources (e.g., project training, technical assistance and data collection assistance) the awardee plans to provide the health department in order to accomplish the program objectives. The MOU must state the health department's agreement to participate in all required project activities and the roles and responsibilities of the health department and the awardee. Additional components for inclusion in the MOU may be decided upon by the Project Team.

If the awardee intends to use pharmacies as project sites, the awardee is expected to formalize collaborations in the form of a MOU or contract. The MOU with project pharmacies should have components similar to those for the health department as listed in the above paragraph. In the application, the awardee should explain how the pharmacies will be reimbursed for services, such as through the insurer.

The awardee must make arrangements (i.e. contracts) for funding the project clinic sites. Individual project clinic funding should depend on site capacity, intended number of patients to be enrolled within the site and other factors such as potential recruitment difficulties. Contracts should clearly state the project sites' responsibilities including conducting interventions, data that will be collected and who will collect the data, frequency of data collection, data collection method, reporting requirements and necessary permissions to collect the data (e.g. IRB approval and patient consent if required). Each project clinic site should have a contract and all project clinic sites MOUs or contracts should have the same content unless decided otherwise by the Project Team. Additional components for inclusion in the contracts may be decided upon by the Project Team.

If the applicant intends to partner with pharmacies, the applicant should describe how relationships will be established with pharmacies to implement interventions. The funds for such an arrangement are expected to be in the course of typical business that the insurer would provide. The funds from this FOA are not intended to be used to provide service fees such as these.

Applicants must file the Letters of Support, name the file "MOUs/MOAs", and upload it as a PDF file at www.grants.gov

2. Target Populations

Persons with HIV who are prescribed ARV therapy.

a. Health Disparities

N/A

iv. Funding Strategy

N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

In collaboration with the Project Team, the awardee will design a program performance monitoring plan that includes both outcomes and processes. Key evaluation questions, required performance measures, and potential data sources are listed below. The Project Team may suggest additional performance measures. The CDC and the awardee will monitor program performance throughout the project period.

Program outcome and process data will be reviewed at least quarterly to monitor program performance. The data will be used to make adjustments to the Data-to-Care Rx model, as needed, throughout the project period. For example, if upon review of the data, it is determined that external factors are adversely affecting the conduct of the program, the awardee and Project Team will decide upon a corrective course of action.

The outcome and process monitoring will also be used to demonstrate the effectiveness of the Data-to-Care Rx model in increasing adherence to ARV therapy, HIV viral load suppression, retention in HIV care and re-linkage to care among the program cohort.

Dissemination channels for the program results will be decided upon by the Project Team. However, potential targeted audiences include professional public health associations (e.g. American Public Health Association), professional HIV organizations (e.g. American Academy of HIV Medicine), pharmacy associations (e.g. American Pharmacist Association) as well as public health, medical, and pharmacy practitioners. Results will be submitted for presentation at local, regional or national conferences and for publication in peer-reviewed journals or other publications.

Process performance measures and key evaluation questions^	
Key evaluation question	Were procedures for using pharmacy claims data from Pharmacy Benefit Manager (PBM), insurer(s) or other source(s) to identify persons with HIV who failed to pick up prescribed ARVs by 30, 60 and 90 days developed?
Potential data sources	Project records
Performance measures	– Procedures for using pharmacy claims data from Pharmacy Benefit Manager (PBM), insurer(s) or other source(s) to identify persons with HIV who failed to pick up prescribed ARVs by 30, 60 and 90 days are developed
Key evaluation question	Was the procedure and intervention for persons who failed to pick up prescribed ARVs by 30 days (1 st line intervention) developed?
Potential data sources	Project records
Performance measures	– Procedure and intervention for persons who failed to pick up prescribed ARVs by 30 days (1 st line intervention) is developed
Key evaluation question	Was the procedure and intervention to address adherence to medications and potential barriers to retention in care for persons who failed to pick up prescribed ARVs by 60 days (2 nd line intervention) developed?
Potential data sources	Project records

Performance measures	<ul style="list-style-type: none"> – Process for sharing the pharmacy claims data from the PBM, insurer or other data source with the project clinics and/or pharmacies is developed and data sharing agreements if required are developed – Procedures for how the list of persons who failed to pick up prescribed ARVs by 60 days will be used to conduct the 2nd line intervention is developed – Intervention to address adherence barriers and potential retention in care barriers (2nd line intervention) is developed
Key evaluation question	Was procedure for health department to locate persons who failed to pick up prescribed ARVs by 90 days and to relink the patient to clinic (3 rd line intervention) developed?
Potential data sources	Project records
Performance measures	<ul style="list-style-type: none"> – Process for sharing the pharmacy claims data from the PBM, insurer or other data source with the health department is developed and data sharing agreements if required are developed – Procedures for how the list of persons who failed to pick up prescribed ARVs by 90 days will be used to conduct the 3rd line intervention is developed – Process for locating patients including use of Disease Intervention Specialists is developed – Process for re-linking patient to clinic is developed – Follow-up procedures are developed
Key evaluation question	Was pharmacy claims data from a partnered PBM, insurer or other source obtained?
Potential data sources	N/A
Performance measures	<ul style="list-style-type: none"> – Pharmacy claims data from a partnered PBM, insurer or other source is obtained
Key evaluation question	Were final MOUs and contracts with project partners including the PBM or insurer(s), project clinics and/or pharmacies and health department completed?
Potential data sources	Project records
Performance measures	<ul style="list-style-type: none"> – Necessary agreements with the clinic and/or pharmacy project sites and health department (e.g. Memorandum of Understandings, financial agreements [i.e. contracts] and clinic and/or pharmacy project sites work plans) are created – Data sharing agreements between project partners are developed

Key evaluation question	Were ethical approval(s) obtained?
Potential data sources	Project records
Performance measures	<ul style="list-style-type: none"> – Project IRB package approved, if required – Project clinic and/or pharmacy sites and health department IRB package(s) approved, if required
Key evaluation question	Using the pharmacy claims data, were lists of persons who failed to pick up prescribed ARVs by 30, 60 and 90 days created and 1 st , 2 nd and 3 rd line interventions conducted?
Potential data sources	Pharmacy claims data, Project records
Performance measures	<ul style="list-style-type: none"> – Lists of persons who failed to pick up prescribed ARVs by 30, 60 and 90 days are created – 1st, 2nd and 3rd line interventions are conducted
Key evaluation question	Was a process developed to inform prescribing clinics of patients who fail to pick up prescribed ARVs by 60 and 90 days, for both project clinics and non-project clinics?
Potential data sources	Project records
Performance measures	<ul style="list-style-type: none"> – Process for informing prescribing clinics of patients who fail to pick up prescribed ARVs by 60 and 90 days, for both project clinics and non-project clinics are developed
Key evaluation question	Was participant consent obtained, if required?
Potential data sources	Project records
Performance measures	<ul style="list-style-type: none"> – Participant consent is obtained, if required
Key evaluation question	Were project data collected, cleaned and transmitted to CDC?
Potential data sources	N/A
Performance measures	<ul style="list-style-type: none"> - List of appropriate clinical, pharmacologic, medical, laboratory, sociodemographic, process, outcome and other variables to collect is developed – Data collection tools are developed – Project database is developed – Standardized definitions are developed – Quality control procedures are developed – Data management plan of data from the PBM, insurer or other source of the pharmacy claims data, project clinic/pharmacy sites and health department is developed

	<ul style="list-style-type: none"> – Procedures for secure reporting and storage of data is developed – A system for secure data sharing between project partners (PBM or insurer, project clinic and pharmacy sites and health department) is developed – Project sites/partners collected the required data elements including baseline data – Conduct process and outcome monitoring of the project sites and provide project progress reports of specified outcomes to CDC on a quarterly (at minimum) basis. – Cleaned, analytic datasets of the required data elements are submitted to CDC quarterly (at minimum)
Key evaluation question	Was project data analyzed?
Potential data sources	Pharmacy claims data, clinic and/or pharmacy records, health department data
Performance measures	<ul style="list-style-type: none"> – Analysis plans are developed – Project data is analyzed
Key evaluation question	Were project results disseminated?
Potential data sources	Project records
Performance measures	<ul style="list-style-type: none"> – Project results are disseminated
Key evaluation question	Was final Data-to-Care Rx model produced?
Potential data sources	Project records
Performance measures	<ul style="list-style-type: none"> – Was a comprehensive Data-to-Care Rx implementation documented that includes a report to CDC with a detailed description of the implementation model and processes
Key evaluation question	Were all program activities completed according to awardee proposed timelines?
Potential data sources	Project records
Performance measure	<ul style="list-style-type: none"> – Program activities are completed according to project timelines*

^ Additional performance measures may be proposed by the applicant or by the Project Team

* Specific performance measures related to project timelines will be determined post-award

Outcome program performance measures and key evaluation questions^	
Key evaluation question	Were persons who failed to pick up prescribed ARVs by 30, 60, 90 days identified through use of the pharmacy claims data?
Potential data sources	Pharmacy claims data, project records
Performance measure	<ul style="list-style-type: none"> – Number of persons identified as failing to pick up prescribed ARVs by 30 days – Number of persons identified as failing to pick up prescribed ARVs by 60 days – Number of persons identified as failing to pick up prescribed ARVs by 90 days
Reporting frequency†	Quarterly, throughout implementation of project
Key evaluation question	Were prescribing clinics informed of patients who failed to pick up prescribed ARVs by 60 and 90 days?
Potential data sources	Project records
Performance measure	– Number of persons who failed to pick up prescribed ARVs by 60 and 90 days whose prescribing clinics were contacted
Reporting frequency†	Quarterly, throughout implementation of project
Key evaluation question	Did persons who failed to pick up prescribed ARVs by 30, 60, 90 days receive 1 st , 2 nd and 3 rd line interventions?
Potential data sources	Project records
Performance measure	<ul style="list-style-type: none"> – Number of persons who received 1st line intervention – Number of persons who received 2nd line intervention – Number of persons who received 3rd line intervention
Reporting frequency†	Quarterly, throughout implementation of project
Key evaluation question	Does the implementation model lead to re-linkage to clinic?
Potential data sources	Project clinic records, project health department records
Performance measure	Number and proportion of persons who failed to pick up prescribed ARVs after ≥90 days who were re-linked to clinic?
Reporting frequency†	Quarterly, throughout implementation of project
Key evaluation question	Does the service model lead to improved adherence to antiretroviral therapy?
Potential data sources	pharmacy claims data

Performance measure	<ul style="list-style-type: none"> – Number and proportion of persons adherent to their ARV therapy among persons who received 1st and/or 2nd and/or 3rd line interventions – Percentage increase in adherence pre*- and post*- 1st and/or 2nd and/or 3rd line intervention – Percentage difference in adherence among those that received only 1st line intervention but were ≥ 60 days late picking up ARVs, and those that received 2nd or 3rd line interventions
Reporting frequency†	Once, at end of implementation of project
Key evaluation question	Does the service model lead to improved viral load suppression?
Potential data sources	viral load tests reported to partnered health department
Performance measures	<ul style="list-style-type: none"> – Number and proportion of persons whose most recent viral load test in the calendar year showed that HIV viral load was suppressed (i.e., < 200 copies/mL) among persons who received 2nd and/or 3rd line interventions – Percentage increase in viral suppression pre*- and post*- 2nd and/or 3rd line intervention – Percentage difference in viral suppression among those that received only 1st line intervention but were ≥ 60 days late picking up ARVs, and those that received 2nd and/or 3rd line interventions
Reporting frequency†	Once, at end of implementation of project
Key evaluation question	Does service model lead to improved retention in care?
Potential data sources	Project clinic records, CD4/VL reported to partnered health department
Performance measures	<ul style="list-style-type: none"> - Number and proportion of persons who had two care visits that were at least 90 days apart during the calendar year, as measured by documented test results for CD4 count or viral load among persons who received 2nd and/or 3rd line interventions - Percentage increase in retention pre- and post- 2nd and/or 3rd line intervention - Percentage difference in retention among those that received only 1st line intervention but were ≥ 60 days late picking up ARVs, and those that received 2nd and/or 3rd line interventions
Reporting frequency†	Once, at end of implementation of project

^ Additional performance measures may be proposed by the applicant or by the Project Team

† Awardee reporting frequency to CDC. Mechanism for reporting will be determined post-award.

*pre- and post- measurement periods will be decided by the Project Team

ii. Applicant Evaluation and Performance Measurement Plan

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

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

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

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

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

In addition, the plan must describe:

- Plans for how applicant will respond to the evaluation questions, and use evaluation findings for continuous program quality improvement
- A data collection plan which includes the following: proposed data variables to collect; the process of collecting data from the PBM (or other pharmacy claims data source), the project clinic and/or pharmacy sites and health department; quality control procedures; procedures for secure reporting and storage of data; and a plan for secure data sharing between project partners (e.g., PBM, project clinic and/or pharmacy sites and health department)
- Baseline data that will be collected and a description of how baseline data will be collected
- Applicant's proposed performance measures (i.e., measures that applicant suggests that are in addition to the required performance measures), how these measures will be defined and calculated and data source(s) used to calculate the measures. Proposed performance measures should be aligned with the proposed data variables listed within the applicant's data collection plan and should be consistent with the Department of Health and Human Services HIV Core Indicators, if applicable
- Available data sources, feasibility of collecting appropriate evaluation and performance data
- SMART objectives to be achieved by project activities
- Description of how the applicant will comply with project data reporting requirements
- Data Management Plan (DMP) and plans for updating the DMP, if applicable, for accuracy throughout the lifecycle of the project. The DMP should provide a description of the data that will be produced using these FOA funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see: <http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-49>

c. Organizational Capacity of Awardees to Implement the Approach

The applicant should describe how its organization has the capacity to execute the project strategies and meet the project outcomes outlined in this FOA. The following are expected of the applicant:

- Access to or the ability to obtain pharmacy claims data from a Pharmacy Benefits Manager, insurer or other source that can be used to implement project activities.
 - At a minimum, the data must include the ARV prescription date, prescription pick up date and prescribing physician or provider. The “reverse out date” (the date that indicates that a prescription was filled but not picked up by the patient) is also highly recommended.
 - The pharmacy claims data source must be able to connect individual clients to project clinics and/or pharmacies.
 - Applicant should state the estimated number of HIV infected persons, from the partnered health department’s jurisdiction, who will be covered by the pharmacy claims data?
 - If the applicant does not currently have access to the required pharmacy claims data, the applicant must describe, in detail, how they will obtain the data, the timeline for procurement of the data and contingency plans for if they are unable to obtain pharmacy claims data from the intended source.
- If the applicant plans to partner with a Pharmacy Benefits Manager or other pharmacy claims data organization (i.e., make the PBM, insurer or other organization with the pharmacy claims data part of the Project Team) the applicant must include a Letter of Support from the partnered source.
- Applicants must describe how the project clinics were selected and should include Letters of Support from each collaborating clinic. The Letters of Support should include estimates of the total number of HIV-infected patients that receive care at their clinic and estimates of how many existing patients become disengaged from care per year. Letters of Support must also include language that data can be shared with the health department, for this project, or that approval to share data with the health department is anticipated.
- If applicant intends to use pharmacies as project sites, the applicant should describe how the project pharmacies were selected and should include Letters of Support from each collaborating pharmacy.
- If applicant is other than a health department, the applicant must have a Letter of Support from the proposed partnered health department. The Letter of Support should include the health department staff that will be responsible for health department program activities and the number of Disease Intervention Specialists that will be assigned to the project.
- The proposed health department partner should have experience with implementation of the current CDC Data-to-Care (D2C) public health strategy that uses HIV surveillance data (i.e., CD4 and HIV viral load test results reported to the health department) to identify HIV-diagnosed individuals not in care and to re-engage these individuals in care.
- If applicant is other than a health department, the applicant should have experience working with local or state health departments, preferably in HIV, STD or viral hepatitis prevention.
- Experience conducting interventions to improve adherence to medication therapy.
- Experience writing, awarding and managing contracts.
- Knowledge of local IRB requirements and patient consent and obtaining local IRB approval and consent.
- Experience working with medical clinics, medical providers and/or pharmacies and pharmacists.
- Experience in program management of multi-site projects and multi-partner projects.
- Program evaluation including collection of outcome and process monitoring data for continuous program improvement.
- Experience developing data systems, data collection, data management and data analysis.
- *Letters of support* from the following:

- Each collaborating clinic and/or pharmacy project site
 - The Letter of support from the project clinics must include estimates of the total number of HIV-infected patients that receive care at their clinic, estimates of how many existing patients become disengaged from care per year and language that data can be shared with the health department, for this project, or that approval to share data with the health department is anticipated
- Health department (if applicant is other than a health department)
 - The Letter of support must include the health department staff that will be responsible for health department program activities and the number of Disease Intervention Specialists that will be assigned to the project
- Pharmacy Benefits Manager or other pharmacy claims data organization (if applicant intends for the organization to be part of the Project Team)
- Consultants, if applicable

The applicant must include a clear delineation of the roles and responsibilities of project staff and their qualifications. Also, how consultants and partner organizations will contribute to achieving the project's outcomes, if applicable. Include information about any contractual organization(s) that will have a significant role(s) in implementing program strategies and achieving project outcomes. Specify who would have day-to-day responsibility for key tasks such as: leadership of project; monitoring the project's on-going progress; preparation of reports; program evaluation; and communication with other partners and CDC. Applicants may describe how they will assess staff competencies and develop a plan to address gaps through organizational and individual training and development opportunities.

The applicant must also describe its organizational infrastructure (e.g., resources, facilities, and technical and administrative systems) as it is related to the successful conduct of the proposed activities such as infrastructure that will allow the applicant to manage and monitor multiple project sites and data from multiple sources. Specify who would have day-to-day responsibility for key tasks such as: leadership of project; monitoring the project's on-going progress; preparation of reports; program evaluation; and communication with other partners and CDC.

CVs/Resumes and Organizational Charts should be included in the application. Applicants must name these files "CVs/Resumes" or "Organizational Charts" and upload it at www.grants.gov

d. Work Plan

The applicant should develop a work plan not to exceed 25 pages for all three years of the award. The work plan should give a detailed description on how the applicant intends to implement the proposed strategies to meet the outcomes of this FOA. As a cooperative agreement, CDC will provide feedback and technical assistance to the awardee to finalize the work plan post-award.

The work plan should be divided into three sections to address each of the three main strategies of the FOA and should do the following:

- 1) Strategy #1: Develop model to use pharmacy claims data to identify persons who fail to pick up prescribed ARVs and to intervene
 - a. Address each process performance measure from the *CDC Evaluation & Performance Measurement Strategy* section of this FOA.
 - b. List person responsible for completion of *each* activity.
 - c. State proposed timeline for completion of *each* activity and milestones for accomplishing tasks.
- 2) Strategy #2: Implement model
 - a. Address each process performance measure from the *CDC Evaluation & Performance*

Measurement Strategy section of this FOA.

b. List person responsible for completion of *each* activity.

c. State proposed timeline for completion of *each* activity and milestones for accomplishing tasks.

3) Strategy #3: Evaluate project outcomes and disseminate results

a. Address each process performance measure from the *CDC Evaluation & Performance Measurement Strategy* section of this FOA.

b. Address each outcomes performance measure from the *CDC Evaluation & Performance Measurement Strategy* section of this FOA.

c. List person responsible for completion of *each* activity.

d. State proposed timeline for completion of *each* activity and milestones for accomplishing tasks.

The work plan must also include the following:

- Description of how the applicant will work with CDC and other project partners to achieve program outcomes.
- Administration and assessment processes to ensure successful program implementation and quality assurance.
- A management plan outlining the proposed staff, their roles and responsibilities for accomplishing necessary program activities and the amount of time dedicated, by each staff member, to the FOA activities. Staff experience and educational background should be included.
- A management plan that describes how the applicant will manage, monitor and coordinate activities among the project sites and other project partners as well as how the applicant will address program implementation problems such as problems with client and clinic recruitment and enrollment, data sharing between project partners and data collection.
- A program performance monitoring plan that includes key evaluation questions, performance measures, data sources and timelines. The plan must include both outcomes and processes.
- A plan to finalize the service model and to provide a comprehensive Data-to-Care Rx implementation model that can be adopted by local and state health departments.

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 deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that 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.

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.

- The awardee will meet with CDC throughout the project period, but no less than bi-weekly (via teleconference), to provide updates on the planning, development and implementation of the project tasks.
- Project performance will be monitored using process and outcome measures as described in the *CDC Evaluation & Performance Measurement Strategy* section of this FOA.
- Project data will be submitted to CDC quarterly throughout the implementation phase of the project. Adjustments to program processes will be made, as needed, after review of the performance data.
- The awardee will develop project related materials (e.g. data collection forms, consent forms, data systems), evaluation plans and reports which will be reviewed and edited by CDC. It is expected that the awardee will first submit draft reports and project related materials to CDC for review. After CDC has reviewed the materials, CDC and the awardee will discuss suggested changes and the awardee will revise the materials before submission of final drafts.
- CDC will monitor awardee progress in implementing and completing program tasks via site visits, emails, conference calls, review of performance measure data, project reports, review of final evaluation report, and other methods as needed.
- CDC will ensure that work plans are feasible based on the project budget and that they are consistent with the intent of the FOA.
- CDC will ensure that the awardee is performing at a sufficient level given timelines.
- CDC will work with awardee to adjust work plans based on achievement of objectives

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

In a cooperative agreement, CDC and awardees share responsibility for successfully implementing the award and meeting identified outcomes. Thus, CDC staff members are substantially involved in the program activities, above and beyond grant monitoring. CDC activities for this program are as follows:

- CDC will have substantial involvement in the development of the project model, model procedures, development of analysis plans and analysis of project outcomes
- CDC will actively assist the awardee in developing required data elements, work plans, evaluation plans and plans to disseminate the finalized model
- CDC will review, make suggestions for improvement and edit all project reports and project-related materials (e.g. model procedures, evaluation plan, consent forms)
- CDC will provide subject matter expertise in HIV prevention for positives, current Data-to Care Rx model and statistical analysis
- CDC will provide technical assistance in data collection and analysis
- CDC will monitor implementation of program activities and progress. CDC will work with awardees through conference calls, site visits, email and review of data and progress reports to support program progress, program improvement and program outcomes
- CDC will be part of the Publication Committee and will assist the committee in determining planned publications, target journals, abstracts and presentations
- CDC will prepare and submit all necessary paperwork for federal clearances.

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: U65

Minority/Other Community-based HIV Prevention Project, Cooperative Agreements

- 3. Fiscal Year:** 2017
- 4. Approximate Total Fiscal Year Funding:** \$250,000
- 5. Approximate Project Period Funding:** \$2,000,000

This amount is subject to the availability of funds.

\$250,000 first year, \$875,000 year 2 and year 3

- Estimated Total Funding: \$2,000,000
- 6. Total Project Period Length:** 3 year(s)
- 7. Expected Number of Awards:** 1
- 8. Approximate Average Award:** \$250,000 Per Budget Period
\$250,000 first year, \$875,000 year 2 and year 3
- 9. Award Ceiling:** \$875,000 Per Budget Period

This amount is subject to the availability of funds.

- 10. Award Floor:** \$0 Per Budget Period
- 11. Estimated Award Date:** 09/29/2017
- 12. Budget Period Length:** 36 month(s)

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).

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
- Special district governments
- Independent school districts
- Public and State controlled institutions of higher education
- Native American tribal governments (Federally recognized)
- Public housing authorities/Indian housing authorities
- Native American tribal organizations (other than Federally recognized tribal governments)

Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

2. Additional Information on Eligibility

Domestic Institutions or organizations are eligible to apply. Foreign institutions are not eligible to apply. An individual is not eligible to apply for this cooperative agreement. Applicants must propose applications that are specific to one or more of the "Focus Areas of Programmatic Interest" (HIV/AIDS, Viral Hepatitis, STD or TB prevention). Applicants who do not comply with this requirement will be determined non-responsive and will not be reviewed.

Domestic institutions or organizations are eligible to apply. Foreign institutions are not eligible to apply. An individual is not eligible to apply for this cooperative agreement. Applicants must propose applications that are specific to one or more of the "Focus Areas of Programmatic Interest" (HIV/AIDS, viral hepatitis, STD or TB prevention). Applications that do not comply with this requirement will be determined non-responsive and will not be reviewed.

3. Justification for Less than Maximum Competition

4. Cost Sharing or Matching

Cost Sharing / Matching No
Requirement:

5. Maintenance of Effort

Maintenance of Effort is not required for this program

D. Application and Submission Information

1. Required Registrations

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

a. Data Universal Numbering System:

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

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

If funds are awarded to an applicant organization that includes sub-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 can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.

c. [Grants.gov](http://www.grants.gov):

The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the “Get Registered” option at www.grants.gov.

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

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	1. Click on http:// fedgov.dnb.com/webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http:// fedgov.dnb.com/webform) or call 1-866-705-5711 Image Description:
2	System for Award Management (SAM) formerly Central	1. Retrieve organizations DUNS number 2. Go to www.sam.gov and designate an	3-5 Business Days but up to 2 weeks and must be	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220 Image Description:

	Contractor Registration (CCR)	E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	renewed once a year	
3	Grants.gov	<p>1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR)</p> <p>2. Once the account is set up the E-BIZ POC will be notified via email</p> <p>3. Log into grants.gov using the password the E-BIZ POC received and create new password</p> <p>4. This authorizes the AOR to submit applications on behalf of the organization</p>	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

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

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC OGS staff at 770-488-2700 [Image Description](#) or e-mail OGS ogstims@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY

4. Submission Dates and Times

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

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

Due Date for Letter of Intent: **05/05/2017**

b. Application Deadline

Due Date for Applications: **06/05/2017**, 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.

LOIs will be accepted but not required for this FOA. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

Date for Information Conference Call

N/A

5. CDC Assurances and Certifications

All applicants are required to sign and submit “Assurances and Certifications” documents indicated at [http://wwwn.cdc.gov/grantassurances/\(S\(mj444mxct51lnrv1hljjmaa\)\)/Homepage.aspx](http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjmaa))/Homepage.aspx).

Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file “Assurances and Certifications” and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at [http://wwwn.cdc.gov/grantassurances/\(S\(mj444mxct51lnrv1hljjmaa\)\)/Homepage.aspx](http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjmaa))/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.

Duplication of Efforts

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

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

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

LOIs may be sent via email, U.S. express mail or delivery service to:

Arthur Lusby – FOA PS17-1709
Department of Health and Human Services
Services CDC Office of Financial Resources
Office of Grants Services
2920 Brandywine Rd, MS E-14 Atlanta, GA 30341
ALusby@cdc.gov

If you chose to submit a LOI, an additional copy must be sent via email, U.S. express mail or delivery service to:

Kathy Byrd, MD, MPH
Department of Health and Human Services
PHS, CDC, NCHHSTP
1600 Clifton Rd. NE, MS E45
Atlanta, GA 30329
Telephone number: 404-639-3083
Fax: 404-639-6127
Email address: KByrd@cdc.gov

The applicant's LOI should be written in the following format:

- List a descriptive title of proposed project
- Name, address, telephone number, and email address of the Principal Investigator/Project Director
- Name, address, telephone number, and email address of the primary contact for writing and submitting this application
- Number and title of this funding opportunity
- LOI should be a maximum of two pages, 12 point font, single spaced, one inch margins

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC Program staff to estimate and plan the review of submitted applications.

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package. Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

(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

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

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

a. Background

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

b. Approach

i. Purpose

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

ii. Outcomes

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

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the 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 the Strategies and Activities section of the CDC

Project Description.

1. Collaborations

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

2. Target Populations and Health Disparities

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

c. Applicant Evaluation and Performance Measurement Plan

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

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

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

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

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

d. Organizational Capacity of Applicants to Implement the Approach

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

11. Work Plan

(Included in the Project Narrative's page limit)

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

12. Budget Narrative

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

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

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

Indirect costs 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).

For guidance on completing a detailed budget, see Budget Preparation Guidelines at: [http:// www.cdc.gov /grants /interested in applying /application resources.html](http://www.cdc.gov/grants/interested_in_applying/application_resources.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 Mariana 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.

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Grantees will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide grantees and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded.

Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

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

14. Intergovernmental Review

Executive Order 12372 does not apply to this program.

15. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that 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.

16. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award,

recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

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 except as allowed by law.
- 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 generally is not allowed, unless the CDC provides written approval to the awardee.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
 - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See [Additional Requirement \(AR\) 12](#) for detailed guidance on this prohibition and [additional guidance on lobbying for CDC awardees](#).
- 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.

18. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection must include a Data Management Plan (DMP) as part of their evaluation and performance measurement plan. The DMP is the applicant's assurance of the quality of the public health data through the data's lifecycle and plans to deposit data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information:

<https://www.cdc.gov/grants/additionalrequirements/ar-25.html>

19. 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 OGS 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 OGS TIMS staff at 770- 488-2700 or by e-mail at ogstims@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 OGS 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 Grants.gov Online User Guide.

[https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=Get Started%2FGet Started. htm](https://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=GetStarted%2FGetStarted.htm)

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 [Image Description](#); or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 [Image Description](#); or e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

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

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

If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

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

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

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

i. Approach

ii. Evaluation and Performance Measurement

iii. Applicant's Organizational Capacity to Implement the Approach

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

i. Approach

Maximum Points:40

a. To what extent does the applicant describe a detailed plan to *develop the program model*? Does the applicant's plan include timelines for completion of *each* activity and milestones for accomplishing tasks? Are the applicant's plans feasible?

i. Does the applicant describe plans for using pharmacy claims data from Pharmacy Benefit Manager (PBM), insurer(s) or other source(s) to identify persons with HIV who failed to pick up prescribed ARVs by 30, 60 and 90 days? **(3 points)**

ii. Does the applicant describe plans for developing procedures and interventions for **each** of the following: persons who failed to pick up prescribed ARVs by 30 days (1st line intervention), 60 days (2nd line intervention) and 90 days (3rd line intervention)? **(3 points)**

iii. Does the applicant describe plans for sharing the pharmacy claims data from the PBM, insurer or other data source with the project clinics and/or pharmacies and health department including developing data sharing agreements if required? **(3 points)**

iv. Does the applicant describe plans for locating patients, who failed to pick up prescribed ARVs by 90 days, including the use of Disease Intervention Specialists? **(3 points)**

v. Does the applicant describe plans for re-linking patients who failed to pick up prescribed ARVs by 90 days to clinic or to pharmacy? **(3 points)**

b. To what extent does the applicant describe a detailed plan *to implement the program model*? Does the applicant's plan include timelines for completion of *each* activity and milestones for accomplishing tasks? Are the applicant's plans feasible?

i. Does the applicant describe a detailed plan to access pharmacy claims data from a partnered PBM, insurer or other source? **(3 points)**

ii. Does applicant describe plans for arranging for and finalizing agreements/contracts with project partners including the PBM or insurer(s), project clinics and/or pharmacies and health department including necessary Memorandum of Understandings, contracts and data sharing agreements? **(3 points)**

iii. Does applicant describe plans to use the pharmacy claims data, to develop a list of persons who failed to pick up prescribed ARVs by 30, 60 and 90 days and conduct 1st, 2nd and 3rd line interventions? **(3 points)**

iv. Does applicant describe plans to implement the 2nd line intervention in a sufficient number of clinics

to achieve enrollment of 400 clients? **(3 points)**

v. Does applicant describe plans to finalize the model? **(3 points)**

c. To what extent does the applicant describe a detailed plan to *evaluate project outcomes and disseminate results*? Does the applicant's plan include timelines for completion of *each* activity and milestones for accomplishing tasks? Are the applicant's plans feasible?

i. Does applicant describe plans to provide CDC with cleaned, analytic datasets of the required data elements, quarterly (at minimum)? **(5 points)**

ii. Does applicant describe plans to analyze project data? **(5 points)**

ii. Evaluation and Performance Measurement

Maximum Points:25

a. Does applicant describe how they will respond to the evaluation questions, and use evaluation findings for continuous program quality improvement? **(5 points)**

b. Does applicant include a detailed data collection plan which includes proposed data variables to collect, process of collecting data from the PBM (or other pharmacy claims data source), project clinic and/or pharmacy sites and health department, quality control procedures, procedures for secure reporting and storage of data, and a plan for secure data sharing between project partners (e.g., PBM, project clinic and/or pharmacy sites and health department)? **(5 points)**

c. Does applicant describe what baseline data will be collected and a description of how baseline data will be collected? **(5 points)**

d. Does applicant describe available data sources, feasibility of collecting appropriate evaluation and performance data? **(5 points)**

e. Does applicant propose SMART objectives to be achieved by project activities? **(5 points)**

iii. Applicant's Organizational Capacity to Implement the Approach

Maximum Points:35

a. Does the applicant give a detailed description of their access to or the ability to obtain pharmacy claims data from a Pharmacy Benefits Manager, insurer or other source that can be used to implement project interventions?

i. Does the applicant describe the pharmacy claims data source they will use for implementing the project and their access to this data? If the applicant does not currently have access to the pharmacy claims data, does the applicant *describe*, in detail, how they will obtain the data, the timeline for procurement and contingency plans if they are unable to obtain pharmacy claims data from the intended source? **(10 points)**

ii. Does applicant describe the variables contained within the data, specifically the ARV prescription date, prescription pick up date and prescribing physician or provider and (optional) "reverse out date?" **(2.5 points)**

iii. Does applicant state the estimated number of HIV infected persons, from the partnered health department's jurisdiction, who will be covered by the pharmacy claims data? **(2.5 points)**

b. Does the applicant include the necessary Letter(s) of Support? **(5 points total)**

Required Letters of support from all applicants: Letters of support from each proposed project clinic.

i. Do the Letters of support from the proposed project clinics include: estimates of the total number of

HIV-infected patients that receive care at their clinic, estimates of how many existing patients become disengaged from care per year and that data can be shared with the health department, for this project, or that approval to share data with the health department is anticipated?

Letters of support required, as applicable:

ii. If the applicant plans to partner with a Pharmacy Benefits Manager or other pharmacy claims data organization (i.e., make the PBM, insurer or other organization with the pharmacy claims data part of the Project Team), does the applicant include a Letter of Support from the partnered source?

iii. If applicant intends to use pharmacies as project sites, does the applicant include Letters of Support from each proposed pharmacy project site?

iv. If applicant is other than a health department, does the applicant include a Letter of Support from the proposed partnered health department?

1. Does the Letter of Support include the health department staff that will be responsible for health department program activities and the number of Disease Intervention Specialists that will be assigned to the project?

ii. If applicant intends to use consultants to assist with project activities, does the applicant include Letters of Support for each consultant?

c. Does the applicant or the proposed partnered health department have experience with implementation of the current Data-to-Care (D2C) public health strategy that uses HIV surveillance data (i.e., CD4 and HIV viral load test results reported to the health department) to identify HIV-diagnosed individuals not in care and to re-engage these individuals in care? **(5 points)**

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 project activities? Is an organizational chart included in the application? **(5 points)**

e. To what extent does the applicant propose a staffing plan that includes the following: **(5 points):**

i. Experience working with local or state health departments, preferably in HIV, STD or viral hepatitis prevention (if applicant is other than a health department)

ii. Experience conducting interventions to improve adherence to medication therapy

iii. Experience writing, awarding and managing contracts

iv. Experience working with medical clinics, medical providers and/or pharmacies and pharmacists

v. Experience in program management of multi-site projects and multi-partner projects

vi. Experience developing data systems, data collection, data management and data analysis

Budget

- Is the budget reasonable, itemized, clearly justified, and consistent with the intended use of the funds?
- Is the budget consistent with the proposed work plan?
- Does the budget include itemizations, justifications, scope, and deliverables for consultants, if applicable?
- Does the applicant's budget include allocation of funds to project clinic sites?

c. Phase III Review

Applications will be reviewed by an objective review panel. Rank order of applications is one factor in the funding decision. Another factor may also affect the funding decision: the proportion of the HIV population within the partnered health department's jurisdiction that is covered by the pharmacy claims data.

Review of risk posed by applicants.

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

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

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

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

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

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

2. Announcement and Anticipated Award Dates

Successful applicants may anticipate notice of funding by September 30, 2017.

F. Award Administration Information

1. Award Notices

Awardees will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the 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 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available

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

The HHS Grants Policy Statement is available

at <http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

The following administrative requirements apply to this project:

Generally applicable administrative requirements (ARs):

- 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
- AR-10: Smoke-Free Workplace
- AR-11: Healthy People 2010
- 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 Requirement⁵
- 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- 32: Executive Order 131410: Promoting Quality and Efficient Health Care in Federal Government (*If applicable applicants should be aware of the program’s current business needs and how they align with nationally adopted Public Health Information Network (PHIN) standards, services, practices, and policies when implementing, acquiring, and updating public health information systems.*)
- 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)

Organization Specific ARs:

- [AR-8: Public Health System Reporting](#) (Community-based non-governmental organizations)
- [AR-15: Proof of Non-profit Status](#) (Non-profit organizations)
- [AR 23: Compliance with 45 C.F.R. Part 87](#) (Faith-based organizations)

For more information on the CFR visit <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>

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, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	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
Payment Management System (PMS) Reporting	Quarterly reports due January 30, 2018; April 30, 2018; July 30, 2018; October 30, 2018; January 30, 2019.	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. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

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

Performance Measurement

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

Evaluation

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

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

b. Annual Performance Report (APR) (required)

The awardee must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but 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 awardees must submit the Annual Performance Report via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)

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

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

This report is due 90 days after the end of the 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.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)

- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

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

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

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

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

- <https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf>,
- https://www.fsrs.gov/documents/ffata_legislation_110_252.pdf
- <http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA>.

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

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The grantee must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the grantee did not pay any taxes during the reporting period.]

2) Quarterly Report: The grantee must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

“Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in

which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

- a. grantee name;
- b. contact name with phone, fax, and e-mail;
- c. agreement number(s) if reporting by agreement(s);
- d. reporting period;
- e. amount of foreign taxes assessed by each foreign government;
- f. amount of any foreign taxes reimbursed by each foreign government;
- g. amount of foreign taxes unreimbursed by each foreign government.

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

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

Program Office Contact

For programmatic technical assistance, contact:

Kathy Byrd, Project Officer

Department of Health and Human Services

Centers for Disease Control and Prevention

1600 Clifton Rd NE, MS-E-45, Atlanta, GA 30329

Telephone: (404) 639-3083

Email: KByrd@cdc.gov

Grants Staff Contact

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

Arthur Lusby, Grants Management Specialist

Department of Health and Human Services

Office of Grants Services

Grant Staff contact info update requested. (delete)

2920 Brandywine Rd, MS E-15

Atlanta, GA 30341

Telephone: (770) 488-2865

Email: ALusby@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726[Image Description](#).

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 Office of Financial Resources

Office of Grants Services

2920 Brandywine Road, MS E-14

Atlanta, GA 30341

Telephone: 770-488-2700[Image Description](#):

E-mail: ogstims@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY

1-888-232-6348[Image Description](#):

H. Other Information

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

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

For international FOAs:

- SF424
- SF424A
- Funding Preference Deliverables

I. Glossary

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

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see [http:// www.cdc.gov/ grants/ additional requirements/ index.html](http://www.cdc.gov/grants/additional_requirements/index.html). Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

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

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](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](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.

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

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

Healthy People 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 education, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

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

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

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

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

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

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>.

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

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

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

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

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

Work Plan: The summary of 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.

FOA-specific Glossary and Acronyms