## **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**



## Health Resources & Services Administration

HIV/AIDS Bureau Office of Training and Capacity Development

Rapid Antiretroviral Therapy (ART) Start in the Ryan White HIV/AIDS Program – Dissemination Assistance Provider Funding Opportunity Number: HRSA-20-076 Funding Opportunity Type: New Assistance Listings (CFDA) Number: 93.928

### NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Letter of Intent Requested by: January 2, 2020 (Optional)

## Application Due Date: March 3, 2020

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately! HRSA will not approve deadline extensions for lack of registration. Registration in all systems, including SAM.gov and Grants.gov, may take up to 1 month to complete.

#### Issuance Date: November 15, 2019

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Authority: Public Health Service Act, Section 2691 (42 U.S.C. § 300ff-101), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87).

## **EXECUTIVE SUMMARY**

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Special Projects of National Significance (SPNS) Program is accepting applications for fiscal year (FY) 2020 for a new initiative entitled *Rapid Antiretroviral Therapy (ART) Start in the Ryan White HIV/AIDS Program – Dissemination Assistance Provider*. The purpose of this initiative is to fund a single organization that will develop a compendium of promising rapid ART interventions. The recipient will systematically identify and document innovative practices and procedures of rapid ART interventions and promote the dissemination of these models for replication among Ryan White HIV/AIDS Program (RWHAP) and other providers serving people with HIV. Specifically, the intent of this initiative is to: 1) perform a comprehensive environmental scan to compile a collection of effective rapid ART interventions; 2) examine current policies in the administration of existing models at the clinic level and in system-wide settings; 3) document and disseminate successes, barriers and challenges of identified rapid ART models; 4) assess the adaptability of successful models; and 5) promote the replication of effective models and interventions among RWHAP and other providers serving people with HIV.

Funding Opportunity Title:	Rapid Antiretroviral Therapy (ART) Start in the Ryan White HIV/AIDS Program –
	Dissemination Assistance Provider
Funding Opportunity Number:	HRSA-20-076
Due Date for Applications:	March 3, 2020
Anticipated Total Annual Available FY 2020 Funding:	\$1,000,000
Estimated Number and Type of Award(s):	One (1) cooperative agreement
Estimated Award Amount:	Up to \$1,000,000 per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020 through August 31, 2023 (3 years)
Eligible Applicants:	Entities eligible for funding under Parts A – D of Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, including public health departments and institutions of higher education, state and local governments, nonprofit organizations, faith-based and community-based organizations, tribes and tribal organizations are eligible to apply. See <u>Section III.1</u> of this notice of funding opportunity (NOFO) for complete eligibility information.

#### Application Guide

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at <a href="http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf">http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf</a>, except where instructed in this NOFO to do otherwise.

#### **Technical Assistance**

HRSA strongly encourages all applicants to participate in a webinar for this funding opportunity to ensure the successful submission of the application. The purpose of the webinar is to assist potential applicants in preparing applications that address the requirements of the NOFO.

HRSA has scheduled the following technical assistance webinar:

Day and Date: Tuesday, December 17, 2019 Time: 1 p.m. – 3 p.m. ET Call-in Number: 800-857-5162 Participant Code: 9063639 Weblink: https://hrsa.connectsolutions.com/hrsa-20-076 Playback Number: 203-369-1420 Passcode: 121719

The webinar will also be recorded and available by Friday, December 19, 2019, along with Frequently Asked Questions (FAQ) that will be updated periodically, on the TargetHIV website at <a href="https://targethiv.org/library/nofos">https://targethiv.org/library/nofos</a>.

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## I. Program Funding Opportunity Description

#### 1. Purpose

This notice announces the opportunity to apply for fiscal year (FY) 2020 funding under the new 3-year program entitled Rapid Antiretroviral Therapy (ART) Start in the Ryan White HIV/AIDS Program – Dissemination Assistance Provider. The purpose of this Health Resources and Services Administration (HRSA) program is to fund a single organization that will develop a compendium of promising rapid ART interventions. The recipient will systematically identify and document innovative practices and procedures of rapid ART interventions and promote the dissemination of these models for replication among RWHAP and other providers serving people with HIV. Specifically, the intent of this program is to: 1) perform a comprehensive environmental scan to compile a collection of effective rapid ART interventions for people with HIV who are newly diagnosed and not currently engaged in care; 2) examine current policies in the administration of existing rapid ART start models at the clinic level and in system wide settings; 3) document and disseminate successes, barriers and challenges of identified models and interventions; 4) assess the adaptability of successful models and interventions employed; and 5) promote the replication of effective models and interventions among RWHAP and other providers serving people with HIV.

Examples of rapid ART models and interventions may include, but are not limited to:

- 1) Models and interventions which have shown effectiveness in accelerating the time from new HIV diagnosis to entry into care and initiation of ART treatment, including rapid eligibility determination for RWHAP services,
- 2) Models and interventions that demonstrate improved retention in care, and
- Models and interventions that demonstrate impact of a reduced time between initiating rapid ART and viral suppression, as well as having a sustained virological response.

#### **Program Requirements:**

For the purpose of this notice, the recipient is known as the **Dissemination Assistance Provider** (DAP).

The DAP will:

#### 1) Develop a Compendium of Rapid ART Interventions

 Identify and document practices and procedures of rapid ART interventions The DAP will identify existing practices and procedures of rapid ART models and interventions, specifically innovative service delivery models and the set of services that are responsive to the engagement and/or re-engagement needs of people with HIV.

The DAP will collect information on practices and procedures currently being implemented or previously implemented in the field by RWHAP and other public health service providers, or that have been identified in scientific literature. The

models and interventions should include systems-level, jurisdictional-level (e.g., Eligible Metropolitan Area (EMA), Transitional Grant Area (TGA), and State), and site-specific interventions from various organizational settings (e.g., rural, clinics without a pharmacy, low volume clinics).

#### Determine effective elements of models and interventions

The DAP will determine what elements make rapid ART interventions effective, by conducting literature reviews and interviewing key informants and staff involved with implementing the interventions to gather more detailed information about models and procedures, and their impact on specific HIV care continuum outcomes. In collaboration with HRSA, the DAP will utilize, review, and examine in detail relevant RWHAP Services Report (RSR) data, which includes accessing data through a data use agreement with HRSA.

#### • Document the interventions

The DAP will document the necessary staffing, resources, and services required to implement each rapid ART intervention. The DAP will develop and implement a methodology to document the relevant set of services required and specialized skills needed to implement these rapid ART interventions which can be replicated and implemented by RWHAP and other providers serving people with HIV nationwide. This includes describing the resources needed to translate and support programs in replicating the rapid ART interventions, and identifying and documenting any existing and available training, curricula, or toolkits that would facilitate replication.

#### • Conduct a cost analysis

For each rapid ART intervention, the DAP will collect cost information related to identified service delivery models/set of services.

The cost analysis will include documentation of the labor and programmatic costs of each rapid ART model and intervention. Labor costs should be assessed by the costs and hours spent by intervention staff on all rapid ART intervention activities, and be broken down into direct client contact and non-client contact hours (such as training, record keeping, and other administrative duties).

Programmatic costs will include all other intervention costs, such as facilities (e.g., rent), information technology (IT) and communications, printing, staff, transportation, supplies, and any other non-labor costs. Please note that any staff or IT costs relating to the evaluation of the intervention will not be included in assessing its cost, as this project is not funded to be an evaluation activity. Cost data should be regionally indexed, based upon each site's location, to show intervention cost differences across the United States.

#### • Catalog results

The DAP will catalog results of the environmental scan and create a compendium of models which will document practices, guidelines, methodology, intervention components, implementation, and costs of the rapid ART interventions. The DAP will develop an outline and timeline to produce a final

compendium for dissemination and support replication of the rapid ART interventions.

The DAP will package the compendium of rapid ART interventions for upload (or posting) to the <u>TargetHIV</u> website. All rapid ART intervention summaries in the compendium should include, but are not limited to:

- Priority population(s)/sub-population(s) of the model and intervention
- Level of care (i.e., clinic, community, jurisdictional, or systems-level)
- Specialized skills, resources, and staff needed
- Summary of the intervention components, including specific RWHAP services utilized (for more information regarding RWHAP eligible services, refer to <u>Policy Clarification Notice #16-02 Ryan White HIV/AIDS Program Services:</u> <u>Eligible Individuals and Allowable Uses of Funds</u>)<sup>1</sup>
- o Target outcome along the HIV care continuum

#### 2) Develop and Implement Dissemination and Replication Support Plans

#### Dissemination

The DAP will develop dissemination materials intended for replication among RWHAP and other providers serving people with HIV.

The dissemination plan will include a timeline for distribution, target audience, method, venue (where applicable) and identification of contacts for subject matter experts to provide TA and information on follow-up strategy.

The DAP will make available all dissemination materials through the TargetHIV website.

The DAP will analyze and provide summary reports of user analytics gathered from the TargetHIV website in order to gauge the impact and reach of the compendium.

Based on user analytics, the DAP will adjust the compendium and replication materials, as needed in order to improve accessibility among RWHAP recipients, subrecipient providers, and HRSA Health Center Program recipients providing HIV testing and utility across HIV treatment services.

#### • Promote and Support Replication of Effective Models

The DAP will identify potential RWHAP service providers interested in the replication of effective rapid ART models.

The DAP will provide direct TA to RWHAP providers on the replication and implementation of rapid ART models and interventions or indirectly through effective collaboration with other entities, such as RWHAP AIDS Education and Training Centers Program (AETCs) recipients. This includes developing

<sup>&</sup>lt;sup>1</sup> Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds available at <u>https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN\_16-02Final.pdf</u>

products, such as manuscripts for intervention manuals, online resources, webinars and other products that facilitate the provision of TA to RWHAP service providers.

#### 2. Background

The Special Projects of National Significance (SPNS) Program is authorized by Section 2691 of the Public Health Service Act (42 USC 300ff-101), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87). The SPNS Program supports the development of innovative rapid ART interventions to respond to the emerging needs of clients served by the RWHAP. The SPNS Program also evaluates the effectiveness of these approaches' and/or interventions' design, implementation, utilization, cost, and health-related outcomes while promoting dissemination and successful replication. Studies show that initiation of ART on the same day, next day, or within a week of HIV diagnosis, (defined here as rapid ART initiation), can increase engagement in care, increase the proportion of individuals who achieve and maintain viral suppression, and reduce the amount of time between treatment initiation and viral suppression.<sup>2,3,4</sup>

Additionally, two large, randomized controlled trials demonstrating optimal time to initiate ART<sup>5,6</sup> yielded a 50 percent reduction in morbidity and mortality among individuals with HIV who immediately received ART compared to those delaying initiation. The AIDS Education and Training Center's National Coordinating Resource Center published a clinical guide for the implementation of rapid ART approaches.<sup>7</sup>

There have been limited data regarding the effort and uptake of rapid ART initiation activities within the RWHAP. However, the RWHAP has the benefit of providing comprehensive care including core medical, case management, and other support services that improve the likelihood of achieving higher rates of viral suppression. Identification and dissemination of rapid ART models, and making these available to RWHAP providers interested in their replication, can result in significant improvements in clinical outcomes among people with HIV, especially among those who experience challenges engaging in care between initial HIV diagnosis and the time ART is prescribed.

<sup>5</sup> INSIGHT START Study Group, Lundgren JD, Babiker AG, et al. Initiation of antiretroviral therapy in early asymptomatic HIV infection. N Engl J Med. 2015; 373(9):795-807. Available at:

http://www.ncbi.nlm.nih.gov/pubmed/26192873.

<sup>&</sup>lt;sup>2</sup> Rosen S, Maskew M, Fox MP, et al. Initiating antiretroviral therapy for HIV at a patient's first clinic visit: The RapIT randomized controlled trial. PLoS medicine. 2016; 13(5):e1002015. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27163694.

<sup>&</sup>lt;sup>3</sup> Koenig SP, Dorvil N, Devieux JG, et al. Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: A randomized unblinded trial. PLoS medicine. 2017;14(7):e1002357. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28742880.

<sup>&</sup>lt;sup>4</sup> Pilcher CD, Ospina-Norvell C, Dasgupta A, et al. The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a US public health setting. Journal of acquired immune deficiency syndromes. 2017; 74(1):44-51. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27434707.

<sup>&</sup>lt;sup>6</sup> TEMPRANO ANRS Study Group, Danel C, Moh R, et al. A trial of early antiretrovirals and isoniazid preventive therapy in Africa. N Engl J Med. 2015; 373(9):808-822. Available at: http://www.ncbi.nlm.nih.gov/pubmed/26193126

<sup>&</sup>lt;sup>7</sup> AIDS Education and Training Center Program / National Coordinating Resource Center. Immediate ART Initiation: Guide for Clinicians. Available at: https://aidsetc.org/resource/immediate-art-initiation-guide-clinicians

#### Ending the HIV Epidemic: A Plan for America

In February 2019, the Administration announced a new initiative, <u>Ending the HIV</u> <u>Epidemic: A Plan for America</u>. This 10-year initiative beginning FY 2020 seeks to achieve the important goal of reducing new HIV infections in the United States to fewer than 3,000 per year by 2030. The first phase of the initiative will focus on 48 counties, Washington, D.C., San Juan, PR, and 7 states that have a substantial rural HIV burden. By focusing on these jurisdictions in the first phase of the initiative, the U.S. Department of Health and Human Services (HHS) plans to reduce new HIV infections by 75 percent within five years. Across the United States, the initiative will promote and implement the four Pillars to substantially reduce HIV transmissions – Diagnose, Treat, Prevent, and Respond. The initiative is a collaborative effort among key HHS agencies, primarily HRSA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

#### National HIV/AIDS Strategy: Updated to 2020

The National HIV/AIDS Strategy for the United States: Updated to 2020 (NHAS 2020) is a 5-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic. The RWHAP promotes robust advances and innovations in HIV health care using the National HIV/AIDS Strategy to end the epidemic as its framework. Therefore, to the extent possible, activities funded by RWHAP focus on addressing these four goals:

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

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

#### **HIV Care Continuum**

Diagnosing and linking people with HIV to HIV primary care, and ensuring people with HIV achieve viral suppression are important public health steps toward ending the HIV epidemic in the United States. The HIV care continuum has five main "steps" or stages that includes: HIV diagnosis, linkage to care, retention in care, antiretroviral use, and viral suppression. The HIV care continuum provides a framework that depicts the series of stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication. It also demonstrates the proportion of individuals with HIV who are engaged at each stage. The HIV care continuum allows recipients and planning groups to measure progress and to direct HIV resources most effectively. RWHAP recipients are encouraged to assess the outcomes of their programs along this continuum of care. Recipients should work with their community and public health partners to improve outcomes across the HIV care continuum. HRSA encourages

recipients to use the <u>performance measures</u> developed for the RWHAP at their local level to assess the efficacy of their programs and to analyze and improve the gaps along the HIV care continuum.

According to recent data from the <u>2017 Ryan White Services Report (RSR)</u>, the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2010 to 2017, HIV viral suppression among RWHAP patients who have had one or more medical visits during the calendar year and at least one viral load with a result of <200 copies/mL reported, has increased from 69.5 percent to 85.9 percent; additionally, racial/ethnic, age-based, and regional disparities have decreased.<sup>8</sup> These improved outcomes mean more people with HIV in the United States will live near normal lifespans and have a reduced risk of transmitting HIV to others.<sup>9</sup> Scientific advances have shown antiretroviral therapy (ART) preserves the health of people with HIV and prevents sexual HIV transmission. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner. Such findings underscore the importance of supporting effective interventions for linking people with HIV into care, retaining them in care, and helping them adhere to their ART.

#### Integrated Data Sharing and Use

HRSA and CDC's Division of HIV/AIDS Prevention support integrated data sharing, analysis, and utilization for the purposes of program planning, needs assessments, unmet need estimates, reporting, quality improvement, the development of your HIV care continuum, and public health action. HRSA strongly encourages RWHAP recipients to:

- Follow the principles and standards in the <u>Data Security and Confidentiality</u> <u>Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and</u> <u>Tuberculosis Programs: Standards to Facilitate Sharing and Use of</u> <u>Surveillance Data for Public Health Action.</u>
- Establish data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization.

Integrated HIV data sharing, analysis, and utilization approaches by state and territorial health departments can help further progress toward reaching the NHAS 2020 goals and improve outcomes on the HIV care continuum.

HRSA strongly encourages complete CD4, viral load (VL) and HIV nucleotide sequence reporting to the state and territorial health departments' HIV surveillance systems to benefit fully from integrated data sharing, analysis, and utilization. State and health departments may use CD4, VL, and nucleotide sequence data to identify cases, stage of HIV disease at diagnosis, and monitor disease progression. These data can also be used to evaluate HIV testing and prevention efforts, determine entry into and retention

<sup>&</sup>lt;sup>8</sup> Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2017. <u>http://hab.hrsa.gov/data/data-reports</u>. Published December 2018. Accessed April 1, 2019.

<sup>&</sup>lt;sup>9</sup> National Institute of Allergy and Infectious Diseases (NIAID). Preventing Sexual Transmission of HIV with Anti-HIV Drugs. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 Mar 29]. Available from: <u>https://clinicaltrials.gov/</u> NCT00074581 NLM Identifier: NCT00074581.

in HIV care, measure viral suppression, monitor prevalence of antiretroviral drug resistance, detect transmission clusters and understand transmission patterns, and assess unmet health care needs. Analyses at the national level to monitor progress toward ending the HIV epidemic can only occur if all HIV-related CD4, VL, and HIV nucleotide sequence test results are reported by all jurisdictions. CDC requires the reporting to the National HIV Surveillance System (NHSS) all HIV-related CD4 results (counts and percentages), all VL results (undetectable and specific values), and HIV nucleotide sequences.

**Minority HIV/AIDS Fund (MHAF) from the HHS Secretary's Office, HAB Technical Assistance, and Special Projects of National Significance (SPNS) Program** Through the Minority HIV/AIDS Fund from the HHS Secretary's Office and through HAB technical assistance cooperative agreements, HRSA HAB has a number of projects that may be useful for RWHAP recipients to consider. Some select examples are:

- Building Futures: Youth Living with HIV at <u>https://targethiv.org/library/hrsa-hab-building-futures-supporting-youth-living-hiv</u>
- The Center for Engaging Black MSM Across the Care Continuum (CEBACC) at https://targethiv.org/cebacc
- E2i: Using Evidence-Informed Interventions to Improve Health Outcomes among People Living with HIV at <a href="https://targethiv.org/e2i">https://targethiv.org/e2i</a>
- Using Community Health Workers to Improve Linkage and Retention in Care at <u>https://targethiv.org/chw</u>

Below are additional examples for specific populations, co-morbidities, and program areas: <u>https://targethiv.org/help/ta-directory</u>

Through its SPNS Program, HRSA's HAB funds demonstration project initiatives focused on the development of effective interventions to respond quickly to emerging needs of people with HIV receiving assistance under the RWHAP. Through these demonstration projects, SPNS evaluates the design, implementation, utilization, cost, and health related outcomes of innovative treatment models, while promoting dissemination, replication and uptake of successful interventions. SPNS findings have demonstrated promising new approaches to linking and retaining into care underserved and marginalized people with HIV. All RWHAP recipients are encouraged to review and integrate a variety of SPNS evidence-informed tools within their HIV system of care in accordance with the allowable service categories defined in <u>PCN 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds</u> as resources permit. SPNS related tools may be found at the following locations:

• Integrating HIV Innovative Practices (IHIP) (<u>https://targethiv.org/ihip</u>) Resources on the IHIP website include easy-to-use training manuals, curricula, case studies, pocket guides, monographs, and handbooks, as well as informational handouts and infographics about SPNS generally. IHIP also hosts technical assistance (TA) training webinars designed to provide a more interactive experience with experts, and a TA help desk exists for you to submit additional questions and share your own lessons learned.

## Replication Resources from the SPNS Systems Linkages and Access to Care (<u>https://targethiv.org/library/replication-resources-spns-systems-linkages-and-access-care</u>)

There are Intervention manuals for patient navigation, care coordination, state bridge counselors, data to care, and other interventions developed for use at the state and regional levels to address specific HIV care continuum outcomes among hard-to-reach people with HIV.

#### • Dissemination of Evidence Informed Interventions

(https://targethiv.org/library/dissemination-evidence-informed-interventions) The Dissemination of Evidence-Informed Interventions initiative runs from 2015-2020 and disseminates four adapted linkage and retention interventions from prior SPNS and MHAF from the HHS Secretary's Office initiatives to improve health outcomes along the HIV care continuum. The end goal of the initiative is to produce four evidence-informed care and treatment interventions (CATIs) that are replicable, cost-effective, capable of producing optimal HIV care continuum outcomes, and easily adaptable to the changing healthcare environment. Manuals are currently available at the link provided and will be updated on an ongoing basis.

#### II. Award Information

#### 1. Type of Application and Award

Type(s) of applications sought: New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

#### HRSA program involvement will include:

- Providing the expertise of HRSA SPNS personnel, providing program guidance, and identifying relevant resources to the project recipient.
- Facilitating effective collaborative relationships between the cooperative agreement recipient and other relevant community and program stakeholders.
- Providing guidance and leadership in the design and review of program activities, procedures, and tools necessary to accomplish the program goals and requirements set forth in Section I.1. of this NOFO.
- Analyzing program information and providing input and recommendations for implementing the project's activities related to rapid ART outcomes, as necessary in keeping with the changing trends and needs of RWHAP providers and the changing health care environment.
- Reviewing all program products prior to the compendium dissemination and assisting in the dissemination of program findings and other information developed as part of this project to the broader network of RWHAP and other providers serving people with HIV.

#### The cooperative agreement recipient's responsibilities will include:

- Collaborating and meeting with the assigned HRSA SPNS project officer and other HRSA staff, regularly to ensure program requirements set forth in Section I.1. of this NOFO are met.
- Identifying, cataloging, disseminating, and supporting the replication of innovative practices and procedures of rapid ART interventions to RWHAP and other providers serving people with HIV, interested in implementing these rapid ART models and interventions.
- Developing a cost analysis of effective rapid ART models.
- Developing supporting materials to the compendium that include procedural materials, as needed to enable HIV health care service providers to replicate and implement the models or interventions.
- Identifying RWHAP recipients or other providers administering HIV testing and/or HIV care and treatment services to replicate the identified rapid ART models and interventions.
- Providing TA for replication to RWHAP and other providers serving people with HIV.

#### 2. Summary of Funding

HRSA expects approximately \$1,000,000 to be available annually to fund one (1) cooperative agreement recipient. You may apply for a ceiling amount of up to \$1,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2020, through August 31, 2023 (3 years). The actual amount available will not be determined until enactment of the final FY 2020 federal appropriation. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for these purposes, HRSA can process applications and award funds in a timely manner.

Funding beyond the first year is subject to the availability of appropriated funds for *Rapid Antiretroviral Therapy (ART) Start in the Ryan White HIV/AIDS Program – Dissemination Assistance Provider* in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government. In addition, HRSA may reduce recipient funding levels beyond the first year if recipients are unable to fully succeed in achieving the goals listed in the application.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at <u>45 CFR part 75</u>.

### **III. Eligibility Information**

#### 1. Eligible Applicants

Entities eligible for funding under Parts A – D of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, including public health departments and institutions of higher education, state and local governments, nonprofit organizations, faith-based and community-based organizations, tribes and tribal organizations are eligible to apply.

#### 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

#### 3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in <u>Section IV.4</u> non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.

If for any reason, (including submitting to the wrong funding opportunity number or making corrections/updates), an application is submitted more than once prior to the application due date, HRSA will only accept your **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

### **IV. Application and Submission Information**

#### 1. Address to Request Application Package

HRSA *requires* you to apply electronically. HRSA encourages you to apply through <u>Grants.gov</u> using the SF-424 workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at <u>http://www.grants.gov/applicants/apply-for-grants.html</u>.

The NOFO is also known as "Instructions" on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately* 

responsible for reviewing the <u>For Applicants</u> page for all information relevant to desired opportunities.

#### 2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 Application Guide</u> provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 Application Guide</u> except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

See Section 8.5 of the Application Guide for the Application Completeness Checklist.

#### Application Page Limit

The total size of all uploaded files may not exceed the equivalent of **60 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.** 

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under this notice.

#### Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) You, on behalf of the applicant organization, certify by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
- 3) Where you are unable to attest to the statements in this certification, an explanation shall be included in Attachment 7: Other Relevant Documents.

See Section 4.1 viii of HRSA's <u>SF-424 Application Guide</u> for additional information on all certifications.

#### **Program-Specific Instructions**

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u>, (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), include the following:

#### i. Project Abstract

See Section 4.1.ix of HRSA's <u>SF-424 Application Guide</u>. List at the top of the page:

- Project Title
- Applicant Organization Name
- Address
- Project Director Name
- Contact Phone Numbers and Email Addresses

Include a brief summary description of the proposed project. Describe overall project goals and proposed services. Specify the funding amount requested for each year of the 3-year period of performance.

#### ii. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and well organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please use the following section headers for the narrative:

INTRODUCTION -- Corresponds to Section V's Review Criterion #1 (Need)

Briefly describe the purpose of the proposed project, as it responds to the purpose set forth in this NOFO. Discuss your organization's understanding of the challenges of rapid ART initiation. Use and cite demographic and/or other epidemiologic data whenever possible to support your assessment of the information provided. Include the data information gathering methods, when applicable.

Describe your understanding of the RWHAP, RWHAP services, and the HIV care continuum. Provide a clear understanding of the purpose of the project, clear descriptions of the roles and activities to identify innovative practices and procedures of rapid ART interventions.

NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1 (Need)

This section will help reviewers understand the community and/or organizations that you will serve with the proposed project.

Describe the need to identify rapid ART interventions for newly identified or recently diagnosed people with HIV who have never received ART, or people with

HIV who are out of care. Describe the potential benefit of identifying these models and interventions, cataloging them, and conducting a cost analysis of their implementation.

Describe any policy changes that need to be addressed in order for sites to implement rapid ART.

Describe the need for disseminating a compendium of rapid ART models and supporting their replication by RWHAP and other providers serving people with HIV that are interested in implementing rapid ART interventions within their program.

#### • METHODOLOGY -- Corresponds to Section V's Review Criterion #2 (Response)

Propose methods that you will use to address the stated needs and meet each of the previously described program requirements and expectations in this cooperative agreement. Discuss why your selected methodology is appropriate for this project. Describe the degree to which intervention site staff and stakeholders will be involved. Use the following headings to outline your response:

- Identify models and interventions
- Determine what elements of the identified models and interventions make them effective
- Conduct a cost analysis
- Develop the compendium of rapid ART interventions
- Disseminate the compendium of rapid ART interventions
- Support replication of the rapid ART interventions

#### Identify models and interventions:

Describe the process that your organization will use for identifying the rapid ART models and interventions including a literature scan and communicating with existing HIV and related health service providers, as well as federal, state, and/or local stakeholders. Provide a clear description of the roles and activities of your organization and any partners, if applicable.

Describe the methodology for systematically identifying and collecting information on a wide variety of interventions currently or previously implemented in the field by RWHAP and other providers serving people with HIV, or identified in the scientific literature.

#### <u>Determine what elements of the identified models and interventions make them</u> <u>effective:</u>

Describe the methodology of determining the effective elements of the identified models and interventions. This may include interviews with key informants and staff involved with implementing the models and/or interventions to gather more detailed information about the model and/or intervention and its impact on specific

HIV care continuum outcomes. The methodologies proposed should be relevant and able to identify elements of effective models and interventions.

Describe the proposed methodology for utilizing retrospective analyses of clientlevel and clinical outcome data, including review and evaluation of relevant RSR data. Discuss process elements and expected outcomes.

#### Conduct a cost analysis:

Propose a methodology to review and document the labor and programmatic costs of each intervention. The methodology used should result in a breakdown of all costs required to implement each intervention. If applicable, include a methodology to conduct a cost-effectiveness study to implement these interventions.

#### Develop a compendium of Rapid ART interventions:

Briefly describe your organization's ability to identify, catalog, and compile summaries of rapid ART interventions to engage or re-engage people with HIV.

Describe how you will document the models and interventions. Describe how the compendium will be prepared and packaged.

#### Disseminate the compendium of Rapid ART interventions:

Describe your plan for the rapid deployment of the compendium. Provide an outline of your dissemination plan identifying appropriate venues and target audiences, including but not limited to, HIV and related health care service providers, program administrators, and policy makers. Include the process you will utilize and incorporate outreach, collaboration, communication, and information dissemination.

#### Support replication of the Rapid ART interventions:

Describe how you will work collaboratively with national stakeholders and TA providers, including AETCs, to identify and solicit programs, and support replicating an intervention.

Describe how you will transfer knowledge to clinical providers and communitybased organizations serving people with HIV.

Describe methods of information dissemination. These may include, but are not limited to, webinars, trainings, workbooks, curricula and tool kits that are printed and or available in electronic form and designed to promote the replication and implementation of rapid ART interventions appropriate for the target group.

Describe anticipated TA needs of HIV providers interested in implementing rapid ART interventions, and how you will address them across the following domains: program development, implementation, sustainability, and program integration.

 WORK PLAN -- Corresponds to Section V's Review Criteria #2 (Response) and #4 (Impact)

Describe the activities or steps that you will use to achieve each of the objectives proposed during the entire period of performance in the Methodology section. Use a timeline that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including developing the application.

Provide a work plan that delineates goals for the 3-year project period. The work plan is to be used as a tool to manage the initiative by measuring progress, identifying necessary changes, and quantifying project accomplishments. The work plan should directly relate to your Methodology and the program requirements of this announcement.

Identify proposed staff members (in-kind and cooperative agreement-supported) responsible for all aspects of planning and design, compilation and dissemination. The work plan should clearly include written: (1) goals; (2) objectives that are specific, time-framed, and measurable; (3) action steps; (4) staff responsible for each action step; and (5) anticipated dates of completion.

Goals should be included in the work plan for the entire proposed 3-year project period. Objectives and action steps are required in the work plan only in relation to goals set for year one. First year objectives should describe key action steps or activities that you will undertake. Include the project's work plan as **Attachment 1**, and provide a succinct complementary description and an explanation of the work plan in the application narrative.

#### Logic Model

Include in **Attachment 1** an accompanying logic model for designing and managing the project. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this notice, the logic model should summarize the connections between the:

- Goals of the project, (e.g., objectives, reasons for proposing the intervention, if applicable);
- Assumptions, (e.g., beliefs about how the program will work and support resources. Base assumptions on research, best practices, and experience.);
- Inputs, (e.g., organizational profile, collaborative partners, key personnel, budget, other resources);
- Target population, (e.g., the individuals to be served);
- Activities, (e.g., approach, listing key intervention, if applicable);
- Outputs, (i.e., the direct products or deliverables of program activities); and
- Outcomes, (i.e., the results of a program, typically describing a change in people or systems).

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. You can find additional information on developing logic models at the following website:

http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

 RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion #2

Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges.

Discuss the strength of your methodology in identifying and responding to these challenges.

Discuss relevant challenges encountered in implementing similar work plans and how these were resolved.

 EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria #3 (Evaluative Measures) and #5 (Resources/Capabilities)

Describe how you plan to evaluate ongoing processes and the progress towards the goals and objectives of the proposed project. Include descriptions of the inputs, (e.g., organizational profile, collaborative partners, key personnel, budget, and other resources), key processes, and expected outcomes of the funded activities.

Describe your methods to outline the outcome and process elements of gathering and evaluating data to measure maximum impact on practice and policy affecting standards of care and best practices of rapid ART interventions for people with HIV.

Describe your plan for doing the cost analysis for the rapid ART interventions selected to be included in the final compendium.

Describe how the proposed project personnel, (including any consultants, subrecipients, and contractors, if applicable), have the necessary knowledge, experience, training, and skills in assessing intervention effectiveness, cataloging, and developing compendiums.

Describe the capacity of the proposed project staff to provide TA to RWHAP and other providers serving people with HIV, interested in implementing rapid ART models and interventions.

#### ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion #5 (Resources/Capabilities)

Succinctly describe your organization's current mission and structure, scope of current activities, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Include an organizational chart. Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings. Describe how you will routinely assess and improve the unique needs of target populations of the communities served.

Include a project organizational chart as **Attachment 5**. The chart should be a one-page figure that depicts the project structure for the proposed project, not your entire organization. It should include subrecipients, contractors, and other significant collaborators, if applicable.

Describe specific organizational capabilities that will contribute to successfully implementing the proposed activity. Describe the organizational skills, capabilities, and resources, including staff that will contribute to your organization's ability to carry out the proposed activity. Discuss any examples of previous projects that reflect the expertise of proposed personnel in working collaboratively with RWHAP-funded organizations, state and local health departments, and/or health care organizations.

Describe your organization's experience and expertise working with HIV care and treatment service providers. Describe your organization's experience and expertise in working with people with HIV, assessing HIV service delivery systems (nationwide), working with RWHAP recipients, and implementing projects related to the RWHAP.

Describe your organization's experience and expertise in cataloging information, conducting a cost analysis, developing a compendium of promising practice interventions, and/or written materials of this scope, and the ability of key personnel to successfully disseminate findings of effective models and interventions.

#### NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support	(3) Evaluative Measures and
Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

#### iii. Budget

See Section 4.1.iv of HRSA's <u>SF-424 Application Guide</u>. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan and, by carefully following the approved plan, can avoid audit issues during the implementation phase.

**Reminder:** The Total Project or Program Costs are the total allowable costs, (inclusive of direct **and** indirect costs), incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the *Rapid Antiretroviral Therapy (ART) Start in the Ryan White HIV/AIDS Program – Dissemination Assistance Provider* program requires the following: Separate line item budgets for each year of the 3-year project period, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs as appropriate **(Attachment 6)**.

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245), Division B, § 202 states, "None of the funds appropriated in this title shall be used to

pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 4.1.iv Budget – Salary Limitation of HRSA's <u>SF-424 Application Guide</u> for additional information. Note that these or other salary limitations may apply in the following FY, as required by law.

#### iv. Budget Narrative

See Section 4.1.v. of HRSA's SF-424 Application Guide.

In addition, the *Rapid Antiretroviral Therapy (ART) Start in the Ryan White HIV/AIDS Program – Dissemination Assistance Provider* program requires the following:

If funds will be sub-awarded or expended on contracts, describe how your organization will ensure that costs are allowable and funds are properly documented.

#### v. Attachments

Provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status, (if applicable), will not count toward the page limit. You must clearly label **each attachment**.

#### Attachment 1: Work Plan and Logic Model (required)

Attach the work plan for the project that includes all information detailed in <u>Section IV.2.ii. Project Narrative</u>. Also include the required logic model in this attachment.

**Attachment 2**: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's <u>SF-424 Application Guide</u>) (required)

Keep each job description to one page in length, as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff. Also, please include a description of your organization's timekeeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

#### Attachment 3: Biographical Sketches of Key Personnel (required)

Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch.

## **Attachment 4**: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific) (required)

Provide any documents that describe proposed collaborations or working relationships between your organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Make sure any letters of agreement are signed and dated. Attachment 5: Project Organizational Chart (required)

Provide a one-page figure that depicts the organizational structure of the project.

**Attachment 6:** Line Item Budgets Spreadsheet for Years 1 through 3 (required) Submit line item budgets for each year of the proposed project period as a single spreadsheet table, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs.

#### Attachment 7: Other Relevant Documents

Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated and specifically indicate a commitment to the project/program, (in-kind services, dollars, staff, space, equipment, etc.).

## 3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If you have already completed Grants.gov registration for HRSA or another federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (<u>http://www.dnb.com/duns-number.html</u>)
- System for Award Management (SAM) (<u>https://www.sam.gov</u>)
- Grants.gov (<u>http://www.grants.gov/</u>)

For further details, see Section 3.1 of HRSA's SF-424 Application Guide.

**<u>SAM.GOV</u>** ALERT: For your SAM.gov registration, you must submit a <u>notarized letter</u> appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation

requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at <u>SAM.gov</u>.

# If you fail to allow ample time to complete registration with SAM or Grants.gov, you will not be eligible for a deadline extension or waiver of the electronic submission requirement.

#### 4. Submission Dates and Times

#### Application Due Date

The due date for applications under this NOFO is *March 3, 2020 at 11:59 p.m. Eastern Time.* 

HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's <u>SF-424 Application Guide</u> for additional information.

#### 5. Intergovernmental Review

Rapid ART Start in the Ryan White HIV/AIDS Program – Dissemination Assistance *Provider* is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's <u>SF-424 Application Guide</u> for additional information.

#### 6. Funding Restrictions

You may request funding for a period of performance of up to 3 years, at no more than \$1,000,000 per year, (inclusive of direct **and** indirect costs). The actual amount available will not be determined until enactment of the final FY2020 federal appropriation. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division B of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245), pursuant to the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (P.L. 116-59), Division A, § 101(8), are in effect at the time this NOFO is posted. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply, as required by law in subsequent appropriations acts for FY 2020. HRSA will issue an NOA that references the final FY 2020 appropriations act.

You cannot use funds under this notice for the following purposes:

- Any charges that are billable to third party payers, (e.g., private health insurance, prepaid health plans, Medicaid, Medicare);
- To directly provide medical or support services, (e.g., HIV care, counseling and testing) that supplant existing services;
- Cash payments to intended recipients of RWHAP services;
- Purchase, construction of new facilities or capital improvements to existing facilities;
- Purchase or improvement to land;
- Purchase vehicles;
- Fundraising expenses or lobbying activities and expenses;
- Syringe Services Programs (SSPs). Some aspects of SSPs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy. See <a href="https://www.aids.gov/federal-resources/policies/syringe-services-programs/">https://www.aids.gov/federal-resources/policies/syringe-services-programs/;</a>
- To develop materials designed to directly promote or encourage, intravenous drug use or sexual activity, whether homosexual or heterosexual;
- Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (nPEP) medications or the related medical services. (Please note that RWHAP recipients and subrecipient providers may provide prevention counseling and information to eligible clients' partners – <u>see June 22, 2016 RWHAP and PrEP</u> <u>program letter</u>); and/or
- International travel.

You are required to have the necessary policies, procedures, and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures, and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at <u>45 CFR § 75.307</u>.

#### 7. Other Submission Requirements

#### Letter of Intent to Apply (optional)

The letter should identify your organization and its intent to apply, and briefly describe the proposal. HRSA will *not* acknowledge receipt of letters of intent.

Send the letter via email by January 2, 2020 to:

HRSA Digital Services Operation (DSO) Please use the HRSA opportunity number as email subject (HRSA-20-076) <u>HRSADSO@hrsa.gov</u>

Although HRSA encourages letters of intent to apply, they are not required. You are eligible to apply even if you do not submit a letter of intent.

### V. Application Review Information

#### 1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The *Rapid ART Start in the Ryan White HIV/AIDS Program – Dissemination Assistance Provider* has six (6) review criteria:

Criterion 1: Need	5 points
Criterion 2: Response	35 points
Criterion 3: Evaluative Measures	15 points
Criterion 4: Impact	15 points
Criterion 5: Resource/Capabilities	20 points
Criterion 6: Support Requested	10 points
TOTAL	100 points

See the review criteria outlined below with specific detail and scoring points.

## *Criterion 1:* NEED (5 points) – Corresponds to Section IV's Introduction and Needs Assessment

The extent to which the application demonstrates the problem and associated contributing factors to the problem.

• The extent to which the applicant fully demonstrates understanding and knowledge of factors that impede initiation of rapid ART.

- The extent to which the applicant fully demonstrates understanding of the RWHAP, RWHAP services, and the HIV care continuum.
- The extent to which the applicant demonstrates the purpose of the project and provides a clear description of the roles and activities, as well as describes the overall approach of how the applicant will identify rapid ART interventions to engage people with HIV.
- The extent to which the applicant fully describes the need for a comprehensive resource catalog of rapid ART models and interventions to deliver active HIV linkage and retention in care leading to improved health outcomes for people with HIV.

## *Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's Methodology, Work Plan, Resolution of Challenges*

The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities, (scientific or other), described in the application are capable of addressing the problem and attaining the project objectives.

i. Methodology (15 points)

- Strength and feasibility of the proposed plan for identifying, cataloging, and disseminating effective elements of rapid ART interventions among RWHAP and other providers serving people with HIV.
- Strength of the applicant's ability to identify, catalog, disseminate, and support the replication of rapid ART interventions to engage newly identified or recently diagnosed people with HIV who have never received ART, or people with HIV who are out of care.
- Strength of the applicant's description of how the proposed project will enhance the dissemination of rapid ART interventions for HIV treatment and care serving people with HIV.
- Strength and clarity of the methodology, with criteria, that will be used to determine effective elements of the rapid ART interventions.
- Strength and clarity of the proposed methodology for utilizing retrospective analyses of client-level and clinical outcome data, including relevant RSR data.
- Strength and clarity of the applicant's methodology to catalog information and develop a compendium of rapid ART interventions.
- ii. Work Plan (15 points)
  - Strength and feasibility of the work plan, including the action steps that will be used to achieve each of the activities proposed during the project, such as compile a compendium of rapid ART interventions and conduct cost analysis of the interventions.
  - The extent to which the goals of the work plan address the program strategies the applicant describes in the Methodology section of the narrative, such as compile a compendium and conduct cost analysis.
  - The extent to which the work plan identifies the staff responsible for accomplishing each action step.

- Strength, clarity, and feasibility of the applicant's goals identified in the work plan for each year of the 3-year project period (**Attachment 1**).
- Evidence the applicant's objectives for the 3-year project period are specific to each goal, time-framed, and measurable.
- Strength and clarity of the logic model (**Attachment 1**) for designing and managing the proposed project.
- iii. Resolution of Challenges (5 points)
  - The extent to which the applicant clearly identifies possible challenges that are likely to be encountered during the project, and clearly describes realistic and appropriate responses to be used to resolve those challenges encountered.

## *Criterion 3: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity*

The strength and effectiveness of the method proposed to evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project.

- Strength and clarity of the method(s) proposed to determine effective elements of the rapid ART models and interventions and the costs associated with the interventions.
- Strength and clarity of the method(s) proposed to determine the overall project results.
- The extent to which the applicant clearly outlines the process and outcome elements of the evaluation and the possible measures for maximum impact on practice and policy affecting the establishment of standards of care, as well as best practices of improved health outcomes for people with HIV.
- Strength and clarity of the elements or domains for the process and outcome elements of the methodology to conduct cost analysis to assess labor, and programmatic costs incurred by the interventions and effectiveness of interventions.

*Criterion 4: IMPACT (15 points) – Corresponds to Section IV's Work Plan* The extent to which the proposed project has a public health impact and the project will be effective, if funded. This may include the effectiveness of plans for dissemination of project results, the impact results may have on the community or the target population, the extent to which project results may be national in scope, and the degree to which the project activities are replicable.

- Strength, feasibility, and timeliness of activities in the proposed work plan to disseminate the compendium of rapid ART interventions and to support replication of these interventions to target audiences.
- Strength of ability to manage and reassess the dissemination and replication efforts of project outcomes by measuring progress, identifying necessary changes, and quantifying project accomplishments.

- Strength and clarity of proposed resources, such as manuals, or other proposed tools and TA activities to help RWHAP and other providers serving people with HIV.
- Strength and feasibility of potential partners and networks identified by the applicant that will promote replication of the identified rapid ART models and interventions.
- Strength of the dissemination plan to include venues geared toward HIV primary care and other health and social service providers.
- The extent to which the applicant identifies and supports replication of effective rapid ART interventions to clinical providers and community-based organizations serving people with HIV.
- Strength of the applicant's outline of how the project will contribute to the goals to end the HIV epidemic, as well as serve as a complement to TA efforts for HIV care and treatment strategies of the RWHAP.

*Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity, Organizational Information* The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

- Strength of the proposed key project staff's capability in assessing public health interventions and model service delivery, analyzing health care services costs.
- Strength of the proposed key project personnel's capability to provide training and TA in the support of replication, disseminating and promoting the compendium rapid ART interventions to RWHAP providers, and other providers serving people with HIV.
- Strength of the proposed project staff's, (to include consultants, subrecipients, and contractors, if applicable), capability to develop effective comprehensive TA products, such as the final compendium required in this project.
- Evidence of the organization's experience in providing TA to RWHAP and other providers serving people with HIV.
- Evidence of organization's experience in providing a nationwide assessment on HIV service delivery and developing compendiums, and/or written materials of this scope.
- Evidence of the organization's experience in assessing approaches and interventions, working with people with HIV, HIV service delivery systems, RWHAP recipients, and implementing projects in RWHAPs.

## *Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's Budget and Budget Narrative*

The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, the complexity of the project activities, and the anticipated results.

• The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.

- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.
- Strength and clarity of the applicant's budget justification narrative for each year of the 3-year project period, and its appropriateness to the proposed work plan.

#### 2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors (e.g., geographical distribution) described below in selecting applications for award.

See Section 5.3 of HRSA's SF-424 Application Guide for more details.

#### 3. Assessment of Risk

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (<u>45 CFR § 75.205</u>).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information, (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the <u>Federal Awardee Performance and Integrity</u> <u>Information System (FAPIIS)</u>. You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in <u>FAPIIS</u> in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed, as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

HRSA will report to FAPIIS a determination that an applicant is not qualified (<u>45 CFR §</u> <u>75.212</u>).

### VI. Award Administration Information

#### 1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 1, 2020. See Section 5.4 of HRSA's <u>SF-424 Application Guide</u> for additional information.

#### 2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's SF-424 Application Guide.

#### **Requirements of Subawards**

The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards. See <u>45 CFR § 75.101 Applicability</u> for more details.

#### **Data Rights**

All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular federally supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's data rights.

#### **Human Subjects Protection**

Federal regulations (<u>45 CFR part 46</u>) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

#### 3. Reporting

Award recipients must comply with Section 6 of HRSA's <u>SF-424 Application Guide</u> and the following reporting and review activities:

- 1) **Progress Report**(s). The recipient must submit a progress report to HRSA on an annual basis. HRSA will provide further information in the NOA.
- 2) Integrity and Performance Reporting. The Notice of award will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45 CFR part 75 Appendix XII</u>.

#### VII. Agency Contacts

You may request additional information, and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Beverly Smith Grants Management Specialist Division of Grants Management Operations, OFAM Health Resources and Services Administration 5600 Fishers Lane, Mailstop 10NWH04 Rockville, MD 20857 Telephone: (301) 443-7065 Email: BSmith@hrsa.gov

You may request additional information regarding the overall program issues, and/or technical assistance related to this NOFO by contacting:

Adan Cajina, MSc Chief, Demonstration and Evaluation Branch Attn: Rapid Antiretroviral Therapy (ART) in the Ryan White HIV/AIDS Program – Dissemination Assistance Provider (HRSA-20-076) Office of Training and Capacity Development, HIV/AIDS Bureau Health Resources and Services Administration 5600 Fishers Lane, Room 9N108 Rockville, MD 20857 Telephone: (301) 443-3180 Fax: (301) 594-2511 Email: ACajina@hrsa.gov or SPNS@hrsa.gov You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035) Email: <u>support@grants.gov</u> Self-Service Knowledge Base: <u>https://grants-</u> portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center Telephone: (877) 464-4772 TTY: (877) 897-9910 Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

#### VIII. Other Information

#### Technical Assistance

HRSA has scheduled the following technical assistance:

#### Webinar

Day and Date: Tuesday, December 17, 2019 Time: 1 p.m. – 3 p.m. ET Call-in Number: 800-857-5162 Participant Code: 9063639 Weblink: https://hrsa.connectsolutions.com/hrsa-20-076 Passcode: 203-369-1420 Passcode: 121719

The webinar will also be recorded and available by Friday, December 19, 2019, along with Frequently Asked Questions (FAQ) that will be updated periodically, on the TargetHIV website at <u>https://targethiv.org/library/nofos</u>.

#### Tips for Writing a Strong Application

See Section 4.7 of HRSA's SF-424 Application Guide.