U.S. Department of Health and Human Services

HIV/AIDS Bureau

Division of State HIV/AIDS Programs (DSHAP)

Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV

Funding Opportunity Number: HRSA-22-155

Funding Opportunity Type(s): New

Assistance Listings (AL) Number: 93.899

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2022

Application Due Date: June 21, 2022

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 may take up to 1 month to complete.

Issuance Date: April 21, 2022

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See Section VII for a complete list of agency contacts.

Authority: Consolidated Appropriations Act, 2022 (P.L. 117-103), Division H, Title II and 42 U.S.C. § 300ff-101 (§ 2691 of the Public Health Service Act).

508 COMPLIANCE DISCLAIMER

Note: Persons using assistive technology may not be able to fully access information in this file. For assistance, please email or call one of the HRSA staff in Section VII. Agency Contacts.

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2022 *Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV*. This program is supported with funding from the U.S. Department of Health and Human Services (HHS) Minority HIV/AIDS Fund (MHAF) and the HRSA HIV/AIDS Bureau (HAB) Special Projects of National Significance (SPNS) Program. The purpose of this program is to develop, implement, and evaluate protocols for successful use of long-acting injectable (LAI) antiretroviral (ARV) medication within clinical practice.

This cooperative agreement will fund one (1) organization that will serve as the Coordination and Evaluation Provider (CEP) to provide technical assistance, capacity development, and evaluation to support ten (10) demonstration sites in the development and pilot implementation of protocols for a novel LAI ARV HIV treatment. The CEP will select and fund organizations that have the capacity and infrastructure to implement novel HIV treatment methods and collect direct patient care data, targeting organizations in jurisdictions funded for the Ending the HIV Epidemic (EHE) initiative.

Funding Opportunity Title:	Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV
Funding Opportunity Number:	**HRSA-22-155**
Due Date for Applications:	June 21, 2022
Anticipated Total Annual Available FY 2022 Funding:	$1,500,000
Estimated Number and Type of Award(s):	One cooperative agreement
Estimated Annual Award Amount:	$1,500,000 in year 1 $2,000,000 in year 2 $2,000,000 in year 3 $1,500,000 in year 4

Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2022 through August 31, 2026 (4 years)
Eligible Applicants:	Eligible applicants include entities eligible for funding under Parts A-D of Title XXVI of the Public Health Service (PHS) Act, including public and nonprofit private entities, state and local governments, academic institutions; local health departments; nonprofit hospitals and outpatient clinics; community health centers receiving support under Section 330 of the PHS Act; faith-based and community-based organizations; colleges and universities; and Indian Tribes or Tribal organizations with or without federal recognition. See Section III.1 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, except where instructed in this NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance:

Topic: Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV NOFO TA Webinar
Time: Thursday, May 12, 2022 02:00 PM Eastern Time (US and Canada)

Join ZoomGov Meeting
https://hrsa-gov.zoomgov.com/j/1609021516?pwd=N2Z2cDJiOHA0VnBlRUVsbEtwdDBEZz09

Meeting ID: 160 902 1516
Passcode: 3yvewW2g
One tap mobile
+16692545252,,1609021516#,,,,*75613614# US (San Jose)
+16468287666,,1609021516#,,,,*75613614# US (New York)

Dial by your location
+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
+1 669 216 1590 US (San Jose)
833 568 8864 US Toll-free
Meeting ID: 160 902 1516
Passcode: 75613614
Find your local number: https://hrsa-gov.zoomgov.com/u/a7o1uaRqg

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV cooperative agreement Increasing viral suppression and client retention in care are critical components of meeting the goals of the National HIV/AIDS Strategy (2022-2025) and ending the HIV epidemic. In order to reach these goals, it is imperative for HIV care communities to address health care inequities. With the advent of FDA-approved long-acting injectable (LAI) antiretroviral (ARV) medication formulations, initiatives that promote, facilitate, and evaluate the uptake and ongoing utilization of LAI ARV medication may improve clinical outcomes for people with HIV, especially for minority populations who continue to face disparate health care inequities and stigma. This project is designed to develop protocols, implement them and modify as needed, to increase uptake of LAI ARV medications among people of color with HIV, since LAI ARV medications may offer benefits in addressing health inequities and achieving viral suppression.

In addition to alleviating challenges associated with oral medications, ongoing utilization of LAI ARV medications in lieu of oral regimens may potentially reduce HIV-related stigma and enhance protection of health privacy. While there are some unique clinical and social benefits to this injectable drug formulation, some aspects of its distribution, administration requirements, and billing have already hindered uptake and utilization within the Ryan White HIV/AIDS Program (RWHAP). As minority populations have historically experienced significant disparities in accessing care and treatment, including the health literacy and access to health care coverage options necessary to engage in care, developing interventions to increase the uptake of LAI ARV medication formulations will help to proactively address and potentially reduce or prevent disparities minority communities may face in accessing this breakthrough therapy.

The main objective of this program is to develop and implement protocols for successful use of LAI ARV medication within clinical practice. This program will fund 1 organization to serve as the Coordination and Evaluation Provider (CEP). The CEP must have the capacity and infrastructure (e.g., staffing/personnel, trainings, clinical systems, data collection and reporting, protocol and implementation evaluation) to support development, implementation, and refinement of LAI ARV medication administration protocols with the goal of replicating and expanding successful protocols. The recipient will solicit and subaward up to 10 demonstration sites (subrecipients) to implement these co-developed protocols and collect data from direct patient care, with priority given to entities located within EHE jurisdictions. HRSA anticipates that through evaluation and scale-up of LAI ARV medication administration protocols, patients with historic difficulty accessing or continuing oral HIV therapy can be bridged to this treatment modality, thus improving viral suppression and retention in care, especially among racial and ethnic minorities.

2. Background

Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV is authorized by Consolidated Appropriations Act, 2022(P.L. 117-103), Division H, Title II and 42 U.S.C. § 300ff-54(c)(1)(B) § 2601 of the Public Health Service Act.

Since 2010, the Department of Health and Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) has implemented national strategies and priorities that focus on reducing HIV-related health inequities among priority populations, with a primary goal of ensuring all persons with HIV have access to high-quality treatment and care that is non-stigmatizing, culturally sensitive, and aligns with evidence-based standards of care.[1] However, the HIV epidemic today still disproportionately impacts racial and ethnic minority populations.

As of 2019, the Centers for Disease Control and Prevention (CDC) reported that among people newly diagnosed with HIV in the United States, 44 percent identified as Black, 30 percent as Latinx, and roughly 2 percent identified as Asian, American Indians/Alaska Natives, and/or native Hawaiians and Other Pacific Islanders. However, while representing 76 percent of new HIV diagnoses in the U.S. in 2019, these groups represented only 32.5 percent of the U.S. population (13 percent, 18 percent, and 1.5 percent, respectively), illustrating HIV's disproportionate impact on communities of color, identified as priority populations for ending the HIV epidemic.[2]

Furthermore, new HIV infections reported by race between 2015 and 2019 indicate decreases of 17 percent among Whites and 18 percent among Asians, but no decline or change in rates for Black or Latinx populations in the U.S. during that time. [3] While this lack of progress in Black and Latinx communities speaks more directly to prevention efforts and accessibility of prevention measures (e.g., pre-exposure prophylaxis) in minority communities, it also illustrates the continued impact of HIV on populations already experiencing disproportionately unfavorable social determinants of health. In 2019, only 76 percent of all people with HIV received HIV care, only 58 percent were retained in care, and only 66 percent were virally suppressed, compared with 80.8 percent retention and 88.1 percent suppression among clients receiving HIV care through RWHAP funded sites.[4,5] When coupled with the data regarding minority populations representing roughly one-third of the total U.S. population, but more than three-fourths of new HIV infections, this disparity further demonstrates the disproportionate burden of viral suppression within minority communities.

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[1] U.S. Office of Infectious Disease Policy (OIDP). U.S. HIV Statistics. OIDP, June, 2021. https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics

[2] U.S. Centers for Disease Control and Prevention (CDC). HIV in the United States and Dependent Areas. CDC, August, 2021. https://www.cdc.gov/hiv/statistics/overview/ataglance.html

[3] ibid

[4] ibid

[5] Health Resources & Services Administration (HRSA). Ryan White HIV/AIDS Program Annual Client-Level Data Report, 2019. HRSA, October, 2021. https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/data/rwhap-annual-client-level-data-report-2019.pdf

The first LAI ARV medication regimen (cabotegravir/rilpivirine) was approved by the U.S. Food and Drug Administration (FDA) in January 2021, with guidelines for monthly injectable use in patients who are virally suppressed at the time of transitioning to the LAI ARV medication from their current regimen of likely oral medications. As the first ARV formulation that does not require daily administration, this LAI ARV medication formulation provides a novel treatment modality for HIV. As of the release date of this NOFO, the current LAI ARV medication is now approved for injection every 2 months, requiring appointment attendance for injection at least 6 times per year versus the typical 4 or less annual visits for patients on daily oral regimens. The importance of increasing the uptake of this injectable is to eliminate the need for daily medication adherence and has significant implications for reducing stigma for patients currently taking oral HIV medications.

An important framework in the RWHAP is the HIV care continuum, which depicts the series of stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication to achieve viral suppression. As HIV providers work to improve outcomes along this continuum, many providers are implementing rapid start protocols for faster patient access to ARVs. These protocols seek to expedite access to and use of ARV medications for clients either new to HIV care or re-engaging in HIV care after any period of time off ARV medications. As LAI ARV medication guidelines evolve, this formulation may also become a useful tool within rapid start protocols to foster engagement in care and accelerate time to viral suppression, which not only increases quality of life and lifespan, but also prevents sexual transmission of HIV to negative partners.

Strategic Frameworks and National Objectives

National objectives and strategic frameworks like Healthy People 2030, the National HIV/AIDS Strategy (NHAS) (2022 – 2025); the Sexually Transmitted Infections National Strategic Plan for the United States (2021 – 2025); and the Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021 – 2025) are crucial to addressing key public health challenges facing low-income people with HIV. These strategies detail the principles, priorities, and actions to guide the national public health response and provide a blueprint for collective action across the federal government and other sectors. The RWHAP supports the implementation of these strategies and recipients should align their organization's efforts, within the parameters of the RWHAP statute and program guidance, with these strategies to the extent possible.

Expanding the Effort: Ending the HIV Epidemic in the U.S.

According to recent data from the 2020 Ryan White Services Report (RSR), the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2016 to 2020, 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 84.9 percent to 89.4 percent. Additionally, racial/ethnic, age-based, and regional disparities reflected in viral

suppression rates have significantly decreased.[6] For example, the disparities in viral suppression rates between Black/African Americans and white clients have decreased since 2010.[7] 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 through sexual contact.[8]

In February 2019, the Ending the HIV Epidemic in the U.S (EHE) initiative was launched to further expand federal efforts to reduce HIV infections. This 10-year initiative 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 initiative promotes and implements four strategies to substantially reduce HIV transmissions – Diagnose, Treat, Prevent, and Respond. The initiative is a collaborative effort among key HHS agencies, primarily HRSA, CDC, the National Institutes of Health (NIH), the Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

For the RWHAP, the EHE initiative expands the program's ability to meet the needs of clients, specifically focusing on linking people with HIV who are either newly diagnosed, diagnosed but currently not in care, or are diagnosed and in care but not yet virally suppressed, to the essential HIV care, treatment, and support services needed to help them achieve viral suppression.

This project will support EHE initiative efforts by developing protocols that address barriers to LAI ARV medication administration in communities that have shown disparities in HIV health outcomes and prioritizing demonstration sites in EHE jurisdictions.

Using Data Effectively: Integrated Data Sharing and Use

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

- Follow the principles and standards in the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action.

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[6] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2020. https://ryanwhite.hrsa.gov/data/reports. Published December 2021. Accessed December 2, 2021.

[7] Black/African American clients went from 81.3 percent viral suppression in 2016 to 86.7 percent in 2020, while 89.4 percent of white clients were virally suppressed in 2016 and 92.5 percent in 2020; therefore the gap in viral suppression between these two groups decrease from 8.1 percentage points different to 5.8 percentage points different.

[8] 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: https://clinicaltrials.gov/ NCT00074581 NLM Identifier: NCT00074581.

- Establish data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization.

Integrated data sharing, analysis, and utilization of HIV data by state and territorial health departments can help further progress toward reaching the HIV National Strategic Plan 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 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 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 in the U.S. 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.

Program Resources and Innovative Models

HRSA has a number of projects and resources that may assist RWHAP recipients with program implementation. These include a variety of HRSA HAB cooperative agreements, contracts, and grants focused on specific technical assistance (TA), evaluation, and intervention activities. A list of these resources is available on TargetHIV. Recipients should be familiar with these resources and are encouraged to use them as needed to support their program implementation.

In addition, many RWHAP Special Projects of National Significance (SPNS) projects have demonstrated promising new approaches for linking and retaining priority populations into care. As resources permit, RWHAP recipients are encouraged to review and integrate these tools within their HIV system of care in accordance with the allowable service categories defined in PCN 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds. Examples of these resources include:

- E2i: Using Evidence-Informed Interventions to Improve Health Outcomes among People Living with HIV

E2i uses an implementation science approach to evaluate and understand existing and new intervention strategies that can be used in RWHAP provider settings. Once interventions or strategies are demonstrated and evaluated using implementation science, manuals, guides, interactive online tools, publications, and instructional materials are developed and disseminated for replication and integration into RWHAP provider settings.

- Integrating HIV Innovative Practices (IHIP)

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 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

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

The Dissemination of Evidence-Informed Interventions initiative ran from 2015-2020 and disseminated four adapted linkage and retention interventions from prior SPNS and the Minority HIV/AIDS Funds (MHAF) from the HHS Secretary's Office initiatives to improve health outcomes along the HIV care continuum. The initiative produced 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 health care environment. Manuals are currently available at the link provided and will be updated on an ongoing basis.

HRSA HAB also recognizes the importance of addressing emerging issues, as well as supporting the needs of special populations. To help recipients in responding to these critical issues, HRSA HAB funds projects to provide technical assistance and resources for recipients. Examples of projects include:

- Building Futures: Supporting Youth Living with HIV
- The Center for Engaging Black MSM Across the Care Continuum (CEBACC)
- Using Community Health Workers to Improve Linkage and Retention in Care
- Engage Leadership through Employment, Validation, and Advancing Transformation and Equity (ELEVATE)
- Ending Stigma through Collaboration and Lifting All to Empowerment (ESCALATE)

II. Award Information

1. Type of Application and Award

Type of applications sought: New

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

HRSA program involvement will include:

- Make available experienced HRSA personnel to inform, support, or participate in planning, developing, and/or delivering cooperative agreement activities.
- Ensure cooperative agreement activities build upon past progress, needs assessment and evaluation results, success, and lessons learned by providing access to materials and information from previous work in this area.
- Coordinate communication and develop partnerships with personnel from HRSA, other state and federal agencies, including other TA providers focused on equitable access to LAI ARV medication and other federally funded training and capacity building programs.
- Participate in the design, development, direction, and/or delivery of procedures, strategies, tools, training, TA, and peer learning activities, including the selection of sites to implement and evaluate the protocols.
- Provide ongoing monitoring and review of the design, development, direction, and/or delivery of cooperative agreement activities, including procedures, data collection and evaluation activities, and quality improvement efforts for accomplishing the goals of the cooperative agreement, as stated in Section I.1 of this NOFO.
- Participate, as appropriate, in conference calls, meetings, and learning sessions that are conducted to support cooperative agreement activities.
- Review and provide substantive and stylistic input on cooperative agreement materials and activities.
- Inform methods for evaluating the process and outcomes of cooperative agreement activities, and use evaluation findings to inform future work.
- Participate in the dissemination of cooperative agreement activities, progress and results (e.g., formal or informal presentations to internal and external stakeholders, presentations at national or regional conference), including best practices and lesson learned.

The cooperative agreement recipient's responsibilities will include:

- Engage the community in all aspects of the project, including the selection of demonstration sites, identification of populations that will benefit from LAI ARV, and protocol development, implementation and assessment.
- Identify social and structural barriers to administration and sustained use of LAI ART to inform protocol development and implementation.
- Develop protocols for LAI ARV medication administration and client follow-up and retention, as well as engagement in related health care activities (e.g., screenings, tests, assessments) and assess the training and TA needs of CEP and subrecipient staff related to implementing the protocols to build capacity and use of LAI ARV medications among people with HIV, and ensure equitable access to LAI ARV medication for minority populations with HIV.
- Identify and subaward up to 10 demonstration sites (subrecipients) to implement these protocols and collect data from direct patient care, with priority given to entities located within EHE jurisdictions.
- Establish measures and methods for assessing needs and evaluating the process and outcome of cooperative agreement activities, and use findings to improve future work.
- Develop and update culturally appropriate tools (e.g., in multiple languages, with diverse populations represented), training, and/or TA for recipient and subrecipient staff, and people with HIV to implement and maintain LAI ARV medication therapy.
- Identify, assess, and disseminate best practices for implementing and maintaining LAI ARV medication therapy for people with HIV.
- In close collaboration with HRSA HAB, identify or develop strategies and messages for how health equity principles can be used to increase client engagement in care and maintain LAI ARV medication therapy.
- Develop methods and models for peer learning opportunities across recipient and subrecipient staff, building on and leveraging currently available opportunities (e.g., meetings, conferences).
- In response to feedback from HRSA HAB and/or subrecipients, and people with HIV, modify approaches to the content, design, and/or delivery of tools, training, and TA to improve their quality, utility, effectiveness, and impact.
- Disseminate promising or best practices, project accomplishments, results from project evaluation activities, and other pertinent information to key stakeholders and constituents. Dissemination should occur throughout the duration of the project and not only upon conclusion, and should occur using TargetHIV for public-facing documents (e.g., protocols, toolkits, manuscripts).

- Plan for sustainability of project activities and resources after the period of federal funding ends. NOTE: HRSA expects the recipient and subrecipients to sustain key elements of their project (e.g., strategies, services, interventions, resources), including those that have been effective in improving practices and that have led to improved outcomes for the target populations.
- Ensure meaningful support and collaboration with key stakeholders including people with HIV who may receive LAI ARV medications in design, development, implementation, and evaluation and any potential re-design of all activities and protocols, including the development of this application.
- Develop a multi-year evaluation plan comprised of both quantitative and qualitative data, as well as process and impact outcomes.
- Provide HRSA HAB with a complete, updated, and accessible copy of all federally supported materials, including online content, prepared under this cooperative agreement in an electronic zip file format on a quarterly basis for the duration of the period of performance.

2. Summary of Funding

HRSA estimates $1,500,000 to be available in year 1 to fund 1 recipient. Funding for years 2 and 3 is estimated at up to $2,000,000 each year, and funding for the final project year, year 4, is estimated at up to $1,500,000.

The period of performance is September 1, 2022 through August 31, 2026 (4 years). Funding beyond the first year is subject to the availability of appropriated funds for *Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV* in subsequent fiscal years, satisfactory progress, and a decision that continued funding is in the best interest of the Federal Government. HRSA may reduce funding levels beyond the first year if the recipient is 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 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include entities eligible for funding under Parts A-D of Title XXVI of the Public Health Service (PHS) Act, including public and nonprofit private entities, state and local governments, academic institutions; local health departments; nonprofit hospitals and outpatient clinics; colleges and universities; community health centers receiving support under Section 330 of the PHS Act; faith-based and community-based

organizations; and Indian Tribes or Tribal organizations with or without federal recognition. Proof of applicant status (e.g., proof of non-profit status) may be requested or required.

2. Cost Sharing/Matching

Cost sharing/matching not required for this program.

3. Other

HRSA may not consider an application for funding if it contains any of the non-responsive criteria below:

- Exceeds the ceiling amount
- Fails to satisfy the deadline requirements referenced in Section IV.4

NOTE: Multiple applications from an organization are not allowable.

HRSA will only accept your last validated electronic submission, under the correct funding opportunity number, before 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 Grants.gov using the SF-424 workspace application package associated with this notice of funding opportunity (NOFO) following the directions provided at Grants.gov: HOW TO APPLY FOR GRANTS.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for HRSA-22-155 in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. *You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.*

2. Content and Form of Application Submission

Application Format Requirements

Section 4 of HRSA's *SF-424 Application Guide* provides general instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, etc. You must submit the information outlined in the HRSA *SF-424 Application Guide* in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide* 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 HRSA *SF-424 Application Guide* for the Application Completeness Checklist.

Application Page Limitation

The total size of all uploaded files may not exceed the equivalent of **60 pages** when printed by HRSA. The page limit includes the project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO.

Please note: Effective April 22, 2021, the abstract is no longer an attachment that counts in the page limit. The abstract is the standard form (SF) "Project_Abstract Summary." Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. If you use an OMB-approved form that is not included in the workspace application package for HRSA-22-155 it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit.

It is therefore important to take appropriate measures to ensure your application does not exceed the specified page limit. Any application exceeding the page limit of 60 will not be read, evaluated, or considered for funding.

Applications must be complete, within the maximum specified page limit, and validated by Grants.gov under HRSA-22-155 before the deadline.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) You certify on behalf of the applicant organization, 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. § 3354).

3) If you are unable to attest to the statements in this certification, you must include an explanation in *Attachment 10: Other Relevant Documents*.

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

Program-Specific Instructions

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

i. *Project Abstract*

Use the Standard OMB-approved Project Abstract Summary Form that is included in the workspace application package. Do not upload the abstract as an attachment or it may count toward the page limitation. For information required in the Project Abstract Summary Form, see Section 4.1.ix of HRSA's *SF-424 Application Guide.*

NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, the table below provides a crosswalk between the narrative language and where each section falls within the review criteria. Any forms or 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 Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget Narrative	(6) Support Requested

ii. *Project Narrative*

This section provides a comprehensive description of all aspects of the proposed project. It should be succinct, self-explanatory, consistent with forms and attachments, and organized in alignment with the sections and format below 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. Include a discussion that exhibits an expert understanding of the issues related to the activities included in this NOFO. Describe how the proposed project will address the goals of this cooperative agreement outlined in Section I.1. Briefly describe the applicant organization and any collaborators.

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

Describe your understanding of and relevant work related to the NHAS and HIV Care Continuum with close detail to past work on collaborative clinical protocol development and implementation.

Describe the current state of health care access, engagement, treatment, and viral suppression activities for people with HIV nationwide and provide an assessment of any challenges and strategies which may impact your work on this project, specifically addressing identified inequities and disparities among minority populations, including social and structural barriers (e.g., poor health literacy, insufficient health care coverage, staffing or scheduling, geographic access) to administration and sustained use of LAI ARV medications.

- METHODOLOGY -- Corresponds to Section V's Review Criterion #2 – Response

  Discuss the methods and approaches you will use to address the stated purpose and goals in Section I.1., and meet each of the recipient responsibilities listed in Section II.1. of this NOFO. Include innovative strategies, procedures, and activities (including involvement of people with HIV for design, implementation, and evaluation of interventions) for meaningful collaboration with HRSA HAB, other local, state, and federal agencies, and direct care subrecipient organizations to efficiently implement the proposed project and effectively meet the purpose and goals of the cooperative agreement.

  Identify why any selected or proposed methodologies are appropriate for this project, and how the chosen methodologies align with the overview provided in the Needs Assessment section and will contribute to the success of the project over the entire period of performance.

  Describe how your organization will foster involvement of relevant community partners (e.g. people with lived experience, direct care providers, support service providers, and AIDS Education and Training Center (AETC) staff) through all stages of the project, including development of the criteria for selection of implementation sites and identification of populations that will benefit from LAI ARV medication.

  Describe how your organization will identify and select subrecipients, including factors that contribute to that decision, and how you will ensure a diverse representation among the subrecipients (geographic, facility type, urban/rural, provider type, model of care, population(s) served, etc.). Also describe how your organization will prioritize subrecipient selection from EHE jurisdictions when possible.

  Describe how your organization would support subrecipients in identifying people of color with HIV eligible for LAI ARV medication protocols, any proposed ongoing tracking or support measures to foster continued LAI ARV medication utilization, and any proposed data collection elements or strategies outlined in Section II.1 of this NOFO.

Describe how your organization will foster involvement of relevant community partners (e.g. people with lived experience, direct care providers, support service providers, and AIDS Education and Training Center (AETC) staff) through all stages of the project, including development of the criteria for selection of implementation sites and identification of populations that will benefit from LAI ARV medication.

Describe how you will assess, in collaboration with HRSA HAB, best practices for protocol implementation to increase uptake and continued utilization of LAI ARV medications, and to engage people with HIV in HIV care utilizing LAI ARV medications, especially communities of color. Use and cite data whenever possible to support the information provided.

Propose a plan addressing how you will design the protocols to support their sustainability after the period of performance. HRSA expects recipients to sustain key elements of their projects (e.g., strategies or services and interventions) which have been effective in improving practices and those that have led to improved outcomes (e.g., viral suppression, appointment attendance, equitable enrollment and access to protocols) and participant (patient and staff) satisfaction (stigma, time spent, attitudes and believes around LAI ARV medications) for the target population. Successful protocols will need to address local social and structural barriers to accessing and engaging in HIV care, so the proposed plan should discuss how barriers will be assessed (e.g., insurance/payment methods, health literacy, physical/geographic, time or staffing) and incorporate approaches to address them throughout the project period.

- WORK PLAN -- Corresponds to Section V's Review Criteria #2 – Response, and #4 – Impact.

  The work plan is a tool to actively manage the project. Provide a work plan that clearly delineates your goals for the 4-year period of performance. Describe the action steps you will use over the duration of the 4-year period of performance to implement the methods discussed in the Methodology section, including methods for assessing subrecipient or your own TA needs, updating existing tools and training, developing new tools and training, project implementation, dissemination, training of subrecipients, sustainability, evaluation, and meaningful collaboration. Be sure all methods discussed in the methodology section are included and appropriately described in the work plan, and identify any appropriate and foreseeable milestones over the period of performance.

  Identify proposed staff members (in-kind and cooperative agreement-supported) responsible for each activity in the work plan. The work plan should be presented in a table format and include goals, objectives, action steps, and outcomes that are SMARTIE (specific, measurable, achievable, realistic, timely, inclusive, and equitable), over the entire period of performance broken out by each year of the project.

  Consider Year 1 action steps, including, but not limited to:

- Hiring appropriate staff;
- Developing subrecipient selection and monitoring processes;
- Identifying meaningful support and collaboration with key stakeholders (e.g., people with lived experience, direct care providers, support service providers, AETC staff) in planning, designing, and implementing all activities, including developing the subrecipient selection process;
- Developing selection criteria, including prioritizing subrecipients in EHE jurisdictions, and making awards to subrecipients;
- Developing LAI ARV medication administration protocols in conjunction with selected subrecipients;
- Establishing quality control mechanisms that align with HRSA's review processes;
- Addressing Institutional Review Board (IRB) and Health Insurance Portability and Accountability Act requirements, as needed;
- In conjunction with subrecipients, identifying relevant data to be collected throughout the period of performance and site-specific means for collecting each measure;
- Establishing a mechanism for the subrecipients to submit evaluation data;
- Establishing the multisite evaluation plan;
- Completing a baseline assessment of each subrecipient to ascertain strengths, weaknesses, opportunities, and threats to successful participation in the project.

Consider Years 2 and 3 action steps, including, but not limited to:

- Implementing site-specific LAI ARV medication protocols for all selected subrecipients, to include relevant enrollment or marketing materials or relevant content for patients and stakeholders;
- On a continual basis (at least quarterly), reviewing and, if needed, revising site-specific LAI ARV medication protocols as desired or as necessary changes are identified;
- Establishing a means of ongoing cooperation and communication, at least semi-annually, among subrecipients to share project updates (e.g., protocol changes, insights, lessons learned, best practices, implementation hurdles or difficulties);
- Enrolling eligible patients into LAI ARV medication protocols;
- Providing support and TA to subrecipients as needed to foster program success;
- Coordinating CEP data analysis staff and individual subrecipient data collection and evaluation staff to review data at least quarterly, including both quantitative and qualitative elements;
- Modifying mechanisms for subrecipient data evaluation submission as needed;
- Identifying and begin implementing sustainability plans to continue treatment for eligible and interested patients after this period of performance.

Consider Year 4 action steps, including, but not limited to:

- As needed, transitioning all protocol processes to non-project-funded sustainability processes to ensure patient continuity of care and continued use of LAI ARV medications as desired;
- Continuing collection of relevant quantitative and qualitative data at least quarterly through the first half of the final project year, while not enrolling any new participants into the data during the final project year.
- Continuing joint site-specific subrecipient and CEP data evaluation and analysis at least quarterly, and presenting final project data at the end of year 4.

In addition to the work plan, provide a detailed logic model for designing and managing the project. A logic model is a one-page diagram that presents the conceptual framework for the project and explains links among each program element. While many versions of logic models exist, for purposes of this NOFO the logic model should summarize all connections between the:

- Goals of the project (e.g., 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);
- Priority population (e.g., the individuals to be served);
- Activities (e.g., approach, listing key intervention, if applicable);
- Outputs (i.e., the direct products 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 timeline used during program implementation; the logic model provides the "how to" steps. You can find additional information on developing logic models at the following website: https://www.acf.hhs.gov/sites/default/files/documents/prep-logic-model-ts_0.pdf.

Submit the work plan as **Attachment 1** and logic model as **Attachment 2**.

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

  Discuss challenges or potential risks likely to adversely affect program outcomes that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you plan to use to resolve or decrease such challenges. Discuss challenges and risks, real or potential, with partner organizations, identified resources, effectively addressing identified health inequities, social and structural barriers, health literacy, and processes for maintaining engagement of all participants.

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

Describe the anticipated or intended outcome or impact of proposed activities on subrecipients and people with HIV. Describe the plan for the program performance evaluation that will contribute to continuous quality improvement (CQI) using a quality improvement framework (e.g. Lean, Model for Improvement) to make changes to the protocol to achieve higher rates of acceptance, viral suppression, engagement in care, and patient/staff satisfaction. The program performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of the 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 the systems and processes that will support your organization's performance through effective tracking of performance outcomes (e.g., retention, appointment attendance, patient and staff satisfaction, recruitment information stratified by race, gender, ethnicity, age), including a description of how the organization will collect and manage quantitative and qualitative process, outcome, and cost data (e.g., assigned skilled staff, data collection modalities in addition to data management and analysis) in a way that allows for accurate and timely reporting of performance outcomes.

Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, describe the data collection strategy to collect, analyze, and track data to measure process and impact/outcomes, and explain how the data will be used to inform program development and service delivery.

Describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.

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

  Provide information on your organization's current mission, values, structure, and scope of work. Describe the ability, capacity, expertise, and experience held by your organization and any subcontractors/partners/collaborators that demonstrate an ability to fulfill the stated purpose in Section I.1., and the recipient responsibilities listed in Section II.1. of this NOFO. Describe past performance managing collaborative federal grants, including examples of the extent to which deliverables were met. A minimum 3-year story of experience doing work directly related to the proposed project should be included. Provide information on your organization's capacity for subrecipient collaboration as well as data collection and evaluation.

  Provide a staffing plan and job descriptions for key personnel as **Attachment 3**. Provide biographical sketches of key personnel as **Attachment 4**. The staffing plan, job descriptions, and biographic sketches should support the narrative description of your ability, capacity, expertise, and experience described in the narrative.

Provide an organizational chart for the proposed project as **Attachment 5**. The organizational chart should be a one-page figure that depicts the organizational structure of only the proposed activities to be funded through this cooperative agreement, not of the entire organization, and it should include any relevant subcontractors and other significant partners or collaborators.

NOTE: Applicants have the option to submit proposals with collaborating organizations if the partnership enhances the capability and approach of the cooperative agreement's purpose and goals. The applicant must clearly demonstrate that both the applicant and partner(s) bring the requisite experience and expertise in ensuring equitable access to health care options for people with HIV, health literacy, enrollment in health care coverage options at the state and local level and the HIV service provider level, as well as program evaluation. If this is applicable, provide any relevant letters of agreement or contract documents exhibiting partner commitment to the proposed project as **Attachment 6**. Applications proposing partners/collaborators must provide information on how you will monitor and assess performance by partner organizations, and how the individual efforts of the partner organization will help to implement the activities in the cooperative agreement overall work plan and logic model.

iii. *Budget*

The directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's *SF-424 Application Guide* and the additional budget instructions provided below. A budget that follows the *Application Guide* will ensure that, if HRSA selects your application for funding, you will have a well-organized plan and, by carefully following the approved plan, may 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) you incur to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by you to satisfy a matching or cost-sharing requirement, as applicable.

Awarded funds may be used to support the design, planning, implementation, and evaluation of LAI ARV medication protocols.

Because of the data and evaluation requirements of the project, including collection and reporting of relevant quantitative and qualitative outcome, process, and cost measures, proposed staffing plans and budget must include a component to oversee the implementation of multi-site evaluation activities and a data coordinator's time and effort to assist in data collection and reporting.

Project Activity Budget: You must submit a separate program-specific line-item budget for each year of the 4-year period of performance. Upload this budget as **Attachment 7**. Note: if indirect costs are included in the budget, please attach a copy of your organization's indirect cost rate agreement as **Attachment 9**, which will not count toward the page limit.

As required by the Consolidated Appropriations Act, 2022 (P.L. 117-103), Division H, § 202 "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 *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. *Budget Narrative*

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

In addition, *Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV* requires the following:

Provide a budget narrative that explains the amounts requested for each line of the budget in section B.6. The budget narrative should specifically describe how each line item will support the achievement of project objectives. For subsequent budget years, the narrative should highlight the changes from year 1 or clearly indicate that there are no substantive budget changes during that period of performance. Do not use the budget narrative to expand the project narrative.

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 limitation.** Your indirect cost rate agreement and proof of non-profit status (if applicable) will not count toward the page limitation. **Clearly label each attachment**. You must upload attachments into the application. HRSA will not review/open any *hyperlinked* attachments.

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in Section IV.2.ii. Project Narrative. Describe how your organization will ensure proper documentation of funds for subawards and expended contract funds.

Attachment 2: Logic Model

Attach the logic model for the project that includes all information detailed in Section IV.2.ii. Project Narrative.

Attachment 3: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's *SF-424 Application Guide*)

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 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 4: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in *Attachment 3*, 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 5: Project Organizational Chart

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

Attachment 6: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific)

Provide any documents that describe 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 7: Budget

Provide a separate, detailed, line-item budget for each year (1-4) of the project.

Attachment 8: Tables, Charts, etc.

This attachment should give more details about the proposal (e.g., Gantt or PERT charts, flow charts).

Attachment 9: Indirect Cost Rate Agreement

If indirect costs are included in the budget, provide a copy of your organization's indirect cost rate agreement.

Attachments 10–15: 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. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The UEI, a "new, non-proprietary identifier" assigned by the System for Award Management (SAM.gov), will replace the Data Universal Numbering System (DUNS) number.

Effective April 4, 2022:

- You can register in SAM.gov and you will be assigned your UEI (SAM) within SAM.gov.
- You will no longer use UEI (DUNS) and that number will not be maintained in any Integrated Award Environment (IAE) systems (SAM.gov, CPARS, FAPIIS, eSRS, FSRS, FPDS-NG). For more details, visit the following webpages: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update.

You must register with 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 you are an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or you have an exception approved by the agency under 2 CFR § 25.110(d)). For

your SAM.gov registration, you must submit a notarized letter appointing the authorized Entity Administrator.

If you are chosen as a recipient, HRSA will not make an award until you have complied with all applicable SAM requirements. If you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed not qualified to receive an award, and HRSA may 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 two separate systems:

- Dun and Bradstreet (https://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (https://sam.gov/content/home | SAM.gov Knowledge Base)
- Grants.gov (https://www.grants.gov/)

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

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. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages. Instead, 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.gov.

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 *June 21, 2022 at 11:59 p.m. ET*. 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 *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV is not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's *SF-424 Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a period of performance of up to 4 years, at no more than $1,500,000 each in years 1 and 4, and $2,000,000 each in years 2 and 3 (inclusive of direct and indirect costs). 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 H of the Consolidated Appropriations Act, 2022 (P.L. 117-103) apply to this program. See Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in following fiscal years, as required by law.

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

- Charges that are billable to third party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare, Department of Housing and Urban Development funding for housing services, other RWHAP funding including the AIDS Drug Assistance Program);
- To directly provide housing or health care services (e.g., HIV care, counseling, testing) that duplicate existing services;
- Provision of medications and general health care;
- International travel;
- Pre-Exposure Prophylaxis (PrEP) or non-occupational post-exposure prophylaxis (nPEP) medications or related medical services. As outlined in the June 22, 2016 RWHAP and PrEP program letter, the RWHAP legislation provides grant funds to be used for the care and treatment of people with HIV, thus prohibiting the use of RWHAP funds for PrEP medications or related medical services, such as physician visits and laboratory costs. However, RWHAP Part C recipients and subrecipients may provide prevention counseling and information, which should be part of a comprehensive PrEP program;
- HIV test kits;
- Cash payments to intended recipients of services;
- Syringe Service Programs (SSP) – Purchase of sterile needles or syringes for the purposes of hypodermic injection of any illegal drug. Some aspects of SSPs

are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy (see: https://www.hiv.gov/federal-response/policies-issues/syringe-services-programs);

- Development of materials designed to directly promote or encourage intravenous drug use or sexual activity, whether homosexual or heterosexual;
- Purchase, shipping, or storage of medications, including LAI ARV medications;
- Purchase or improvement of land; and
- Purchase, construction, or major alterations or renovations on any building or other facility (see 45 CFR part 75 – subpart A definitions).

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 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. Any program income earned by the recipient must be used under the addition/additive alternative. You can find post-award requirements for program income at 45 CFR § 75.307.

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.

Six review criteria are used to review and rank *Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV* applications. Below are descriptions of the review criteria and their scoring points.

Criterion 1: NEED (10 points) – Corresponds to Section IV's *Introduction and Needs Assessment*

- The extent to which the applicant exhibits expertise in nationwide collaborations with state and federal agencies, including other providers.
- The extent to which the applicant demonstrates a thorough understanding of the HIV Care Continuum, NHAS, inequities and disparities in HIV clinical outcomes and access to services, and the current state of LAI ARV medication distribution and administration, and provides an assessment of the challenges and strategies that may impact the program.
- The extent to which the applicant demonstrates a thorough understanding of strategies and practices to address disparities in access and use of LAI ARV medication.
- The extent to which the applicant demonstrates service to minority communities and a thorough understanding of and best practices to assist providers serving people of color with HIV.

Criterion 2: RESPONSE (20 points) – Corresponds to Section IV's *Methodology and Work Plan*

Methodology (10)

- The strength of the proposed project in relation to the overall goal of collaborating with and overseeing subrecipients in order to increase their capacity to enroll and engage people with HIV in LAI ARV medication protocols, ensure equitable access and maximize utility of the protocols, and evaluate outcomes.
- The strength of the proposed methods that will be used to address the stated needs and meet each of the previously described program requirements and expectations in Section II.1, including involving community stakeholders, and

assessing and addressing social and structural barriers (both existing and anticipated).

- The strength of the proposed process of developing effective tools and strategies for collaboration, LAI ARV medication administration protocols, and how these strategies and tools will meet the goals of the cooperative agreement as outlined in Section I.1.

Work Plan and Logic Model (10)

- The extent to which the work plan includes clear, specific, and realistic goals and objectives for each year of the 4-year period of performance that will meet the requirements of the program and correspond to the described methodology.
- The extent to which the logic model summarizes connections between the project goals, supporting models and/or research, resources including staff and collaborative partners, the organizational profile, the target population, activities proposed, outputs or direct products of the activities, and outcomes or anticipated results of the program.
- The extent to which the activities of the work plan are measurable and achievable and includes project activity, action steps, intended target population, measurable outcomes, target end dates and the person(s) responsible for each step during each year of the 4-year period of performance.
- The strength of the proposed plan for assessing best practices and protocol successes for LAI ARV medication administration, and determining which subrecipients may require TA.

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's *Evaluation and Technical Support Capacity*

- The strength of the proposed plan for program performance evaluation and CQI.
- The extent that the evaluation plan monitors ongoing processes and the progress towards the goals and objectives of the project.
- The strength and feasibility of the proposed methods to be employed by staff to ensure that proposed activities are being successfully documented and completed, based on the overall work plan.
- The strength and feasibility of proposed performance measures and benchmarks for process and outcome evaluation. The strength of the proposed data collection strategy to collect, analyze, and track quantitative and qualitative data at the provider and client levels to measure process and impact/outcomes, including cost data, and explain how the data will be used to inform program development in the subsequent activities of the project. The ability to track and stratify data by race, ethnicity, age, gender, and payor status should be indicated.

- The extent that the applicant demonstrates an understanding of any potential obstacles for implementing the program performance evaluation and how those obstacles will be addressed.

Criterion 4: IMPACT (20 points) – Corresponds to Section IV's *Work Plan*

- The strength of the proposed process and outcome measures in the work plan to assess the impact of the activities on the HIV care continuum, the NHAS, and health equity.
- The strength of the proposed method for disseminating best practice models and methodologies, project accomplishments, and results.
- The extent to which the applicant demonstrates how tools, resources, protocols developed, and approaches used will inform and support future reproducibility to improve outcomes in other organizations providing HIV care.

Criterion 5: RESOURCES/CAPABILITIES (25 points) – Corresponds to Section IV's *Evaluation and Technical Support Capacity, and Organizational Information*

- The strength of the applicant organization's current mission and structure, and scope of the current activities in relation to the proposed project.
- The strength and clarity of the project organizational chart depicting the proposed activities to be funded through this cooperative agreement including any subrecipients and other significant partners/collaborators (**Attachments 3, 4, 5, and 6)**.
- The extent that the applicant demonstrates experience relative to working with RWHAP recipients and subrecipients and key stakeholder organizations; providing TA and developing materials and resources, and supporting peer learning opportunities across RWHAP recipients and subrecipients to realize RWHAP care and treatment system-level changes.
- The extent that the applicant clearly demonstrates that the applicant and any partners bring experience and expertise in health equity, health literacy, ensuring equitable access to health care options for people with HIV, and enrollment in health care coverage options at the local, state, and HIV service provider levels.
- The strength of the proposed methods to monitor and assess performance methods and activities being completed by partner organizations and/or subrecipients and how the individual efforts of the partner organization(s) will help to implement the activities in the cooperative agreement overall work plan.
- The strength of the expertise of staff as it relates to the program requirements as delineated in Section II.1.
- The strength of the organizational capacity of any partner organizations and specific areas of organizational expertise.

- The extent that the applicant demonstrates expertise in nationwide collaborations with national organizations, state and federal agencies, and other coordination and/or evaluation centers or HIV care providers focused on care delivery.
- The extent that the applicant demonstrates expertise in quantitative and qualitative program evaluation.
- The extent that the applicant demonstrates significant experience developing and disseminating clinical care protocols, toolkits, and other resources for diverse audiences.

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Section IV's *Budget and Budget Narrative*

This includes the reasonableness of the proposed budget for each year of the 4-year period of performance in relation to objectives and the anticipated results. The extent to which the application:

- Provides budget line items that are adequately justified and appropriate for proposed project activities;
- Clearly identifies key personnel who have adequate time devoted to the project to achieve project objectives; and
- Provides a clear justification of proposed staff, contracts, and other resources.

2. Review and Selection Process

The objective review process provides an objective evaluation of applications 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. 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 (45 CFR § 75.205).

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.

HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk 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 (45 CFR § 75.212).

VI. Award Administration Information

1. Award Notices

HRSA will release the Notice of Award (NOA) on or around the start date of September 1, 2022. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

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

If you are successful and receive a NOA, in accepting the award, you agree that the award and any activities thereunder are subject to:

- all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award,
- other federal regulations and HHS policies in effect at the time of the award or implemented during the period of award, and
- applicable statutory provisions.

Accessibility Provisions and Non-Discrimination Requirements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The

HHS Office for Civil Rights (OCR) provides guidance on complying with civil rights laws enforced by HHS. See Providers of Health Care and Social Services and HHS Nondiscrimination Notice.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals, see Fact Sheet on the Revised HHS LEP Guidance and Limited English Proficiency.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see Discrimination on the Basis of Disability.
- HHS-funded health and education programs must be administered in an environment free of sexual harassment. See Discrimination on the Basis of Sex.
- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see Conscience Protections for Health Care Providers and Religious Freedom.

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws or call 1-800-368-1019 or TDD 1-800-537-7697.

The HRSA Office of Civil Rights, Diversity, and Inclusion (OCRDI) offers technical assistance, individual consultations, trainings, and plain language materials to supplement OCR guidance and assist HRSA recipients in meeting their civil rights obligations. Visit OCRDI's website to learn more about how federal civil rights laws and accessibility requirements apply to your programs, or contact OCRDI directly at HRSACivilRights@hrsa.gov.

Executive Order on Worker Organizing and Empowerment

Pursuant to the Executive Order on Worker Organizing and Empowerment, HRSA strongly encourages applicants to support worker organizing and collective bargaining and to promote equality of bargaining power between employers and employees. This may include the development of policies and practices that could be used to promote worker power. Applicants can describe their plans and specific activities to promote this activity in the application narrative.

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, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See 45 CFR § 75.101 Applicability 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 grant-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 copyright license and data rights.

Human Subjects Protection

Certificate of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, HRSA-supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to the award. For additional information which may be helpful in ensuring compliance with this term and condition, see Centers for Disease Control and Prevention (CDC) Additional Requirement 36 (https://www.cdc.gov/grants/additional-requirements/ar-36.html).

3. Reporting

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

1) **Progress Report**(s). The recipient must submit a progress report to HRSA on a quarterly basis. More information will be available in the NOA.

2) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

Note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at 2 CFR § 200.340 - Termination apply to all federal awards effective August 13, 2020. No additional termination provisions apply unless otherwise noted.

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 Helene Smith
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
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:

Susan Robilotto, D.O., Director, Division of State HIV/AIDS Programs
Attn: *Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV*
HIV/AIDS Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 09W52
Rockville, MD 20857
Telephone: (301) 443-6554
Email: srobilotto@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 dial 606-545-5035)
Email: support@grants.gov
Self-Service Knowledge Base

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). Always obtain a case number when calling for support. For assistance with submitting in the EHBs, contact the HRSA Contact Center, Monday–Friday, 7 a.m. to 8 p.m. ET, excluding federal holidays at:

HRSA Contact Center
Telephone: (877) 464-4772 / (877) Go4-HRSA
TTY: (877) 897-9910

Web: http://www.hrsa.gov/about/contact/ehbhelp.aspx

VIII. Other Information

Technical Assistance

HRSA has scheduled following technical assistance:

Topic: Increasing Uptake of Long-Acting Injectable Antiretrovirals Among People with HIV NOFO TA Webinar
Time: Thursday, May 12, 2022 02:00 PM Eastern Time (US and Canada)

Join ZoomGov Meeting
https://hrsa-gov.zoomgov.com/j/1609021516?pwd=N2Z2cDJiOHA0VnBlRUVsbEtwdDBEZz09

Meeting ID: 160 902 1516
Passcode: 3yvewW2g
One tap mobile
+16692545252,,1609021516#,,,,*75613614# US (San Jose)
+16468287666,,1609021516#,,,,*75613614# US (New York)

Dial by your location
+1 669 254 5252 US (San Jose)
+1 646 828 7666 US (New York)
+1 551 285 1373 US
+1 669 216 1590 US (San Jose)
833 568 8864 US Toll-free
Meeting ID: 160 902 1516
Passcode: 75613614
Find your local number: https://hrsa-gov.zoomgov.com/u/a7o1uaRqg

Join by SIP
1609021516@sip.zoomgov.com

Join by H.323
161.199.138.10 (US West)
161.199.136.10 (US East)
Meeting ID: 160 902 1516
Passcode: 75613614

Tips for Writing a Strong Application

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