U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



HIV/AIDS Bureau
Division of Policy and Data
Special Projects of National Significance

Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set

Funding Opportunity Number: HRSA-21-083 Funding Opportunity Type: New Assistance Listings (CFDA) Number: 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Letter of Intent Requested by: January 15, 2021

Application Due Date: February 16, 2021

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 16, 2020

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Authority: 42 USC § 300ff-101 (§ 2691 of the Public Health Service Act).

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Special Projects of National Significance (SPNS) Program is accepting applications for a new 4-year cooperative agreement entitled, *Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set.* HRSA will award one System Coordination Provider (SCP) to select, fund, and work with up to 10 Ryan White HIV/AIDS Program (RWHAP) Part B recipients, and HIV surveillance and Medicaid programs to build capacity to report high-quality HIV viral suppression data to the Centers for Medicare & Medicaid Services (CMS) as part of the annual state Medicaid Adult Core Set reporting. The SCP will work with state RWHAP, HIV surveillance, and Medicaid programs to develop, implement, and evaluate strategies to improve the collection and reporting of HIV viral suppression data to the Adult Core Set. In addition, the SCP will promote the dissemination and replication of effective strategies and lessons learned for adoption across other states.

Funding Opportunity Title:	Building Capacity to Improve Collecting
	and Reporting Viral Suppression Data to
	the Medicaid Adult Core Set
Funding Opportunity Number:	HRSA-21-083
Due Date for Applications:	February 16, 2021
	-
Anticipated Total Annual Available	\$4,000,000
FY 2021 Funding:	
Estimated Number and Type of Award(s):	Up to 1 cooperative agreement
Estimated Award Amount:	Up to \$4,000,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	August 1, 2021 through
	July 31, 2025
	(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; and Indian Tribes or Tribal organizations with or without federal recognition.
	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 http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Thursday, December 10, 2020

Time: 1 p.m. – 2:30 p.m. ET Call-In Number: 1-888-790-3413 Participant Code: 8618937

Weblink:https://hrsa.connectsolutions.com/pre_application_webinar_for_hrsa_21_

083/

Playback Number: 1-800-879-3693

Passcode: 12820

The webinar will be recorded and should be available within 10 business days at https://targethiv.org/library/nofos. Answers to questions posed during and after the webinar will also be posted there.

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set cooperative agreement, as a Special Project of National Significance. This initiative seeks to develop strategies to build capacity among HIV surveillance and Medicaid programs for reporting high-quality HIV viral suppression data to comply with reporting of the HIV Viral Load Suppression (HVL-AD) measure on the Medicaid Adult Core Set. The Centers for Medicare & Medicaid Services (CMS) Child and Adult Core Set Annual Review Workgroup has encouraged efforts to create partnerships among federal agencies (CMS, Centers for Disease and Control and Prevention (CDC), and HRSA); Medicaid and public health agencies; and managed care plans to help states gain access to the laboratory data required to measure viral suppression. Recommendations from the workgroup include the sharing of information and lessons learned across states as necessary. This initiative seeks to support the implementation of the recommendations from the HIV/AIDS Health Improvement Affinity Group (HHIAG) with the ultimate goals of improving health outcomes for people with HIV through more efficient and complete strategies in the reporting of viral suppression measures. HRSA will award one (1) System Coordination Provider (SCP) to select, fund, and work with up to 10 RWHAP Part B states and their associated HIV surveillance and Medicaid programs. There are three (3) goals of the program:

- 1. Build capacity of up to 10 states to report high-quality (i.e., accurate and complete) HIV viral suppression data to Medicaid with the goal of improving reporting of the viral suppression measure (HVL-AD) to CMS as part of annual reporting of the Medicaid Adult Core Set (Implementation Phase).
 - The SCP will facilitate and work with the selected states on the implementation and piloting of strategies through the adoption of the Institute of Healthcare Improvement (IHI) Breakthrough Series Learning Collaborative Model as its framework to achieve improvements.
 - i. Strategies may include 1) establishing work plans to achieve the goals of the project; 2) putting in place workflows to submit the HVL-AD data to Medicaid; 3) developing or updating key documents to enhance data sharing or data linkage. 4) implementing legal, privacy, and confidentiality policies, processes, and frameworks, 5) utilizing secure platforms, interoperability standards, and confidential matching algorithms, and 6) promoting collaboration and implementing demonstration pilot tests to operationalize improvements in the reporting of HVL-AD data among states utilizing the learning collaborative concept of

¹ For purposes of this NOFO, "states" include the District of Columbia.

- continuous quality improvement approach of Plan, Do, Study, Act (PDSA) cycles.
- b. The SCP will work with the states in assembling a panel of experts and stakeholders in the planning and development of effective strategies. Also, the SCP will help states identify challenges as well as assist the states in piloting small changes through continuous quality improvement activities through PDSA cycles to describe tests, adaptations, and recommended changes that bring improvements in the collection and reporting of HIV viral suppression data.
- 2. **Evaluate the project** (ongoing evaluation). The SCP will develop and conduct a rigorous, mixed method, multi-site evaluation.
- 3. Disseminate and replicate innovative, sustainable strategies (Sustainability and Dissemination Phase). The SCP will work with RWHAP Part B states and HRSA staff to disseminate and promote the replication of findings and lessons learned from the project. The dissemination audience will include participating states and other jurisdictions not funded under this project. As part of the dissemination goal, the SCP will develop and disseminate a Technical Toolkit that provides detailed guidance on how states can implement data sharing and data linkages to report the HVL-AD measure to CMS as part of annual Adult Core Set reporting and lessons learned from the initiative. Improved HIV viral suppression data reported to the Medicaid Adult Core Set should also be reported to CDC.

2. Background

The Ryan White HIV/AIDS Program (RWHAP) funds direct health care and support services for over half a million people diagnosed with HIV in the United States. RWHAP funds are awarded to cities, states, and local community-based organizations to deliver efficient and effective HIV care, treatment, and support services for low-income people with HIV. Since the program's inception in 1990, RWHAP has developed a comprehensive system of safety net providers who deliver high-quality, innovative HIV health care.

The RWHAP has five statutorily defined Parts (Parts A through D and Part F) that provide funding for core medical and support services, technical assistance, clinical training, and the development of innovative models of care to meet the needs of different communities and populations affected by HIV.

The Strategic Framework

The RWHAP supports the implementation of the National HIV/AIDS Strategy for the United States: Updated 2020 (NHAS 2020). This strategy is a 5-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic. The plan also provides a blueprint for collective action across the federal government and other sectors to help achieve the strategy's vision.

To ensure that RWHAP aligns with the National HIV/AIDS Strategy, to the extent possible, activities funded by the program focus on addressing the plan's 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 support services needed (e.g., mental health and substance use disorders services) to achieve HIV viral suppression. The RWHAP also provides technical assistance and training initiatives and promotes the effective use of data to enhance recipients' capacity to implement programs that support the strategy's objectives.

Expanding the Effort: Ending the HIV Epidemic: A Plan for America

In February 2019, the Administration launched the Ending the HIV Epidemic: A Plan for America (EHE) initiative to further expand federal efforts to reduce HIV infections. This 10-year initiative, which began in 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 is focused 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. 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, 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).

HIV Care Continuum

Diagnosing and linking people with HIV to 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 stages that include: 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 performance measures 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 2018 Ryan White Services Report (RSR), the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2014 to 2018, 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 81.4 percent to 87.1 percent. Additionally, racial/ethnic, age-based, and regional disparities reflected in viral suppression rates have decreased.² 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.³ 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.

Using Data Effectively: 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, conducting needs assessments, determining unmet need estimates, reporting, quality improvement, enhancing the HIV care continuum, and public health action. HRSA strongly encourages RWHAP Part F 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 data sharing, analysis, and utilization of HIV data 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 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

² Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2018. http://hab.hrsa.gov/data/data-reports. Published December 2019. Accessed December 2, 2019.

³ 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.

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.

The Intersection of Medicaid and the RWHAP

Medicaid plays an important role in health care coverage for adults, covering 67 million adults.⁴ Nearly one-third of RWHAP clients in 2018 were covered by Medicaid.⁵

CMS administers the Child and Adult Core Set annual measure reporting program in response the Social Security Act (Section 1139B), as amended by Section 2701 of the Affordable Care Act. The measure reporting program requires the Secretary of the U.S. Department of Health and Human Services to identify and publish a core set of health care quality measures for pediatric and adult Medicaid enrollees. The 2020 Adult Core Set includes 33 measures spanning primary care access and prevention care, maternal and perinatal health, care of acute and chronic conditions, behavioral health, experience of care, and long-term services and supports. Among the Adult Core Set, CMS has included the HRSA HIV viral suppression measure (HVL-AD) under the Care of Acute and Chronic Conditions. HRSA works closely with CMS on the HVL-AD by serving as the measure steward (i.e., responsible for maintaining and making necessary updates to the measure) for the HIV viral suppression measure. Collaboration with CMS is important, because this measure must accurately assess the health outcomes of people with HIV also served outside of the Ryan White HIV/AIDS Program.

On an annual basis, states voluntarily report on Adult Core Set measures to CMS. CMS prepares and releases a report annually that summarizes state progress in reporting measures for the federal fiscal year (FFY). Forty-five states voluntarily reported at least one Adult Core Set measure with a median of 20 Adult Core Set measures for the FY2018 annual report (released September 2019). Fourteen states reported at least 25 Adult Core Set measures. CMS publicly reports data on Core Set measures that are reported by at least 25 states and that meet CMS standards for the HIV viral data quality. CMS standards for data quality include 1) the measure was publicly reported for each of the most recent three years, 2) the measure was reported by a set of at least 20 states that used the Core Set specifications in all three years, and 3) no specification changes occurred during all three years.⁶ During FY2018, six states (Delaware, Louisiana, Nevada, New York, Rhode Island, and Texas) reported data for the HVL-AD measure compared to five states in FY2017 (Delaware, Louisiana, New York, Rhode Island, and Texas) and four states in FY2016 (Delaware, Louisiana, New York, and Rhode Island). From October 2016 - December 2017, the HHIAG was co-led by CDC,

⁴ July 2020 Medicaid and CHIP Enrollment Data Highlights is available at https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html.

⁵ Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2018. http://hab.hrsa.gov/data/data-reports. Published December 2019.

⁶ Criteria for Using the Child and Adult Core Set Measures to Assess Trends in State Performance in Medicaid and the Children's Health Insurance Program. https://www.medicaid.gov/medicaid/quality-of-care/downloads/methods-brief-ffy-2019.pdf. Published September 2020.

HRSA, and CMS, with participation from public health departments and Medicaid agency staff. The HHIAG developed and implemented state action plans that would lead to increased submission of viral suppression data to Medicaid, and improve health outcomes for people with HIV enrolled in Medicaid. Through in-person meetings, learning calls and other resources, and individualized technical assistance, many of the 19 participating states successfully established new or refined existing data sharing agreements, matched data or streamlined data-matching processes, and generated an HIV care continuum for Medicaid beneficiaries that could be used in quality improvement and data-to-care activities. For example, Washington and California each developed interagency data sharing strategies within their state for RWHAP Part B programs and Medicaid programs in order to use data to link individuals to services and reduce duplication of care coordination.⁷

The HHIAG demonstrated the power of collaboration across state agencies to improve data-to-care activities. Participants formed new or strengthened existing relationships, shared knowledge about how their agencies operate and work with different data sources. However, creating the infrastructure for cross-agency partnerships required an investment of time and resources. Without dedicated resources, implementation of action plans was limited by available resources, including staff time, and evolving priorities.⁸

Building upon the recommendations of the Child and Adult Core Set Annual Review Workgroup as well as the lessons learned from HHIAG about successful collaborations, this HRSA HAB initiative will focus on improving viral suppression data reporting by promoting and expanding currently limited data sharing or data linkage activities between state health departments and Medicaid programs. The end goal of this initiative is reporting complete and accurate HVL-AD as part of annual Core Set reporting to CMS. Improved collection of HIV viral suppression data reported to the Medicaid Adult Core set will also improve the data reported to CDC.

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.

⁷ Dorr, H. Targeted Policy Resource Series: States Strengthen Medicaid-Ryan White Collaboration to Improve Care Coordination for People Living with HIV.

⁸ Davies, C., Klein, P. W., Okoye, I. D., Heitgerd, J., Shapatava, E., Ihiasota, I., ... & Hauck, H. (2019). Short-Term Outcomes and Lessons Learned From the Federal HIV Health Improvement Affinity Group for State Medicaid/Children's Health Insurance Program Agencies and State Health Departments. JAIDS Journal of Acquired Immune Deficiency Syndromes, 82, S62-S68.

⁹ National Academy For State Health Policy. Toolkit: State Strategies to Improve Health Outcomes for People Living with HIV. 2017. Available at: https://www.nashp.org/toolkit-state-strategies-to-improve-health-outcomes-for-people-living-with-hiv/#toggle-id-2-closed. Accessed August 3, 2020.

HRSA program involvement will include:

- Contributing to, reviewing, and approving documents including webinar content, capacity building documents, publications, learning collaborative materials, and other resources prior to printing, dissemination, or implementation;
- Collaborating in the design, operation, direction, timeline, and evaluation of activities including capacity building, meetings, training activities, guides, tools, and workshops;
- Assisting with the coordination, planning, development, and implementation of all phases of the project;
- Facilitating partnerships and communication with other federal partners and other RWHAP recipients;
- Working in collaboration with the recipient on ensuring participating states meet selection criteria protocol outlined under this notice;
- Working in collaboration with the recipient on ensuring adherence to established timeline:
- Ongoing review of activities, procedures, measures, and technical assistance (TA) tools to be established and implemented for accomplishing the goals of the cooperative agreement;
- Providing the expertise of HRSA personnel and other relevant resources to support the efforts of the initiative activities;
- Facilitating the dissemination of program findings, best practices, and other information developed as part of this project to the broader network of state, city, and/or local health departments; and
- Facilitating access to education and training resources available through the national and regional RWHAP AIDS Education and Training Centers (AETCs), TargetHIV.org, and other HRSA supported resources.

The cooperative agreement recipient's responsibilities will include:

Building Capacity of States

- Select up to 10 RWHAP Part B jurisdictions and their corresponding HIV surveillance and Medicaid programs to build the capacity to collect and report the HIV viral suppression measure as part of reporting the annual Adult Core Set to CMS.
- Fund participating Part B jurisdictions and their corresponding HIV surveillance and Medicaid program to implement the changes required for reporting of HVL-AD measure as part of reporting the annual Adult Core Set to CMS.
- Oversee and monitor state strategies and activities to improve the collection and reporting of the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.
- Align and coordinate activities, messaging, and materials with RWHAP funded organizations that are supporting data linkages. These include the RWHAP Data Integration, Systems, and Quality (DISQ) Training and Technical Assistance (T/TA), RWHAP Data Support, and CAREWare.
- Facilitate and work with the selected states on the implementation and piloting of strategies to use the data to drive improvement through the adoption of the Institute for Healthcare Improvement (IHI) Learning Collaborative Model as a framework. The framework includes assisting the

- states in piloting small changes through continuous quality improvement activities through PDSA cycles.
- In consultation with HRSA, review and modify timelines, as needed, to meet the desired phases of the project.

Evaluating the Project

Assess and evaluate : 1) states' barriers and facilitators to reporting HIV viral suppression to the CMS Adult Core Set, 2) implementation activities and progress towards reporting of viral suppression , and 3) the effectiveness of the jurisdictions' activities. Applicants are not limited to these categories and can propose additional evaluation categories.

Disseminating Effective Strategies for Replication

- o Develop a technical toolkit.
- In collaboration with participating states and HRSA, disseminate findings broadly to health department agencies (including those not funded under this project), federal partners, and other stakeholders.

SCP Overall Project Timeline

HRSA expects the recipient to propose a timeline of activities across each year of the project. The timeline would include four phases comprised of a) Planning (Year 1), b) Implementation (Years 2 and 3), and c) Sustainability and Dissemination (Year 4).

2. Summary of Funding

HRSA estimates approximately \$4,000,000 to be available annually to fund one SCP recipient. You may apply for a ceiling amount of up to \$4,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is August 1, 2021, through July 31, 2025 (4 years). Funding beyond the first year is subject to the availability of appropriated funds for the SPNS program in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

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

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; and community health centers receiving support under Section 330 of the PHS Act. Domestic faith-based and community-based organizations, tribes, and tribal organizations are also 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.

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 http://www.grants.gov/applicants/apply-for-grants.html.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for each NOFO you are reviewing or preparing in the workspace application package 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

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 included in the page limit may not exceed the equivalent of **60 pages** when printed by HRSA. The page limit includes the abstract,

project and budget narratives, and certain attachments 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. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-083, 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.

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to 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. § 3321).
- 3) Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 8: 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 SF-424 Application Guide.

- List at the top of the page:
 - o Project Title
 - o Applicant Organization Name
 - o Address
 - o Project Director Name
 - o Contact Phone Numbers and Email Address
- Describe overall project goals and proposed services, including the names of the participating states. Refer to Section IV.2.ii Methodology for State Selection and Monitoring for selection criteria.
- Describe how you will work with the participating states to improve reporting of the Adult Core Set across the RWHAP Part B, HIV surveillance, and Medicaid programs.
- Briefly describe how you will build capacity among states to collect and report the

HVL-AD measure as part of reporting the Adult Core Set to CMS.

- Briefly describe how you will evaluate the project.
- Briefly describe dissemination and replication strategies.
- Specify the funding amount requested for each year of the four-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 <u>Criteria #1 Need</u>
 This section should briefly describe the proposed project, its purpose, and overall activities. Briefly describe your organization and any collaborating organizations that will help to meet the goals of the project. Describe the overall approach and activities that will lead to an improvement in reporting the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criteria #1 Need This section should demonstrate your understanding of the Medicaid Adult Core Set and reasons for states to report the HVL-AD measure to CMS. Identify up to 10 participating states and their challenges in collecting and reporting HVL-AD measure as part of reporting the annual Adult Core Set to CMS. Describe the major areas where participating states need to build capacity in order to collect and report the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.

<u>Legal, privacy and confidentiality issues around collecting and reporting HVL-AD data</u>

Describe how the proposed project will address issues of confidentiality and privacy surrounding the use of client-level health data taking into consideration that states have varying levels of legal and regulatory protections that govern HIV privacy and confidentiality.

Describe any applicable State regulations regarding the sharing of clinical and laboratory data, and whether they exceed HIPAA requirements ¹⁰ for the protection of disclosure of information regarding people with HIV.

Describe any applicable regulatory processes within participating states and how the project will ensure the timely, confidential, and secure transfer of data within those limitations.

¹⁰ See Summary of the HIPAA Privacy Rule at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html and Summary of the HIPAA Security Rule at: http://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html

Describe the procedures for the electronic and physical protection of participant information and data. Describe how you will assist the participating states in identifying any person-level data with the potential for disclosure of Protected Health Information (PHI).

METHODOLOGY -- Corresponds to Section V's Review <u>Criteria #2 Response</u>, <u>#3</u>
 Evaluative Measures, and #4 Impact

State Selection and Monitoring

Describe how states meet the criteria mentioned below. State selection criteria should include:

- States that have not submitted the viral suppression measure to the Medicaid Adult Core Set, or states that have submitted the viral suppression measure, but the data were not included in the Adult Core Set Report because of data quality issues.
- A mixture of states with varying rates of HIV diagnoses per CDC https://www.cdc.gov/nchhstp/atlas/index.htm.
- A mixture of states with and without Medicaid expansion.
- A mixture of states that have and do not have data sharing agreements, data use agreements, and/or MOUs between the state Medicaid program, RWHAP, and HIV surveillance.
- A mixture of states with various types of databases and/or various levels of integration or IT capacity.
- Part B jurisdictions cannot be rated moderate or high risk by HRSA's Division of Financial Integrity (DFI) and have adequate infrastructure and personnel capacity to participate in the project.

Describe a plan on how you will execute formal written agreements (e.g., contracts, budgets, work plans, business associate agreements) with participating states to implement the changes required to share or link data across RWHAP Part B, HIV surveillance, and Medicaid programs with the goal of reporting the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.

Three letters of commitment from each of the participating programs in the states are required in this application (Attachment 6). Each state should have a letter of commitment from the RWHAP Part B, the HIV surveillance, and the Medicaid program. All letters of commitment must include the following:

- Demonstrate a willingness to report the Medicaid Adult Core Set by improving their RWHAP, HIV surveillance, and Medicaid data sharing or data linkage.
- Specifically indicate a commitment to the program (e.g., dedicated staff, time commitment, etc.).
- Identify a primary liaison for each of the key partner agencies.

Describe the mechanism for funding states, in order to enable their participation in the project. Describe the protocol for oversight, monitoring, and tracking expenses of states. Describe the calculation of the amount of funding each state will receive based on states' needs and information technology (IT) infrastructure.

Please provide a subaward budget line item and narrative for all participating states. See Section IV, Budget Narrative for details.

Build Capacity of States

1. Development of State Scope of Work and Work Plan

Provide a brief summary on the scope of work around establishing partnerships with states that include major milestones, corresponding dates, and reports. These dates should also be reflected in the work plan (Attachment 1). A finalized timeframe will be decided upon in partnership with HRSA that allows participating states to implement this project prior to the start of Year 2.

2. Capacity Building

Describe how you will work with each state to build capacity to collaborate among key partners in the state, create solutions and innovations to existing problems, and monitor progress of implementing the action plan. Describe the strategies to:

- Enhance communication and interaction among key stakeholders
- Provide, monitor, and support the implementation of action plans
- Track progress of and changes to the state action plans
- Communicate progress and challenges requiring immediate attention of the HRSA project officer assigned to this cooperative agreement or other federal stakeholders
- Leverage existing HRSA, CMS, CDC, and the Office of the National Coordinator for Health Information Technology (ONC) resources and tools

IHI developed a learning collaborative model to assist health care organizations in making improvements in the quality of their service delivery while reducing costs. In 2003, IHI published a white paper in its Breakthrough Series using its Collaborative Model. 11 The model employs a team-based approach utilizing outside experts in topical areas as faculty to assist organizations in piloting small changes through PDSA cycles. If proven successful, these changes will be incorporated at an organizational or systems level and shared with other organizations. Additional information on the quality improvement (QI) and PDSA techniques of the IHI Collaborative Model are available through the National Quality Center Quality Academy. 12

Describe how you will accomplish the following.

 Follow the IHI Breakthrough Series Learning Collaborative Model or alternative model. If proposing an alternative model, please describe the model and its key components and activities. Describe why it is more advantageous than the IHI Model to meeting the goals of this project

¹¹ IHI (2003) *The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement*. IHI Innovation Series white paper. Boston: Institute for Healthcare Improvement; 2003. Accessed from http://www.ihi.org/IHI/Results/WhitePapers/TheBreakthroughSeriesIHIsCollaborativeModelforAchieving+BreakthroughImprovement.htm

¹² See http://www.nationalqualitycenter.org/index.cfm/17263

- Assemble a panel of experts in the planning and development of effective strategies
- Use virtual, in-person, or a combination of methods to convene a learning collaborative
- Plan, host, and facilitate the learning sessions and action periods
- Build capacity of states through small-scale pilot testing through PDSA cycles with collaborating organizations within their states

Evaluation

Describe how you will design, implement, and conduct a rigorous, mixed-method, multi-site evaluation to assess the effectiveness of activities implemented by the selected states to improve reporting of the HVL-AD measure as part of reporting the annual Medicaid Adult Core Set to CMS.

HRSA recommends that the evaluation capture, at a minimum, the following key quantitative and qualitative process and outcome measures:

- Activities
- Facilitators
- Barriers
- Costs staff and infrastructure
- Progress along path to CMS reporting (requires baseline data)
- Number and percentage of states at different steps of linkage/sharing
- Number and percentage of states reporting to CMS

Discuss the evaluation approach you will use to gather information. The evaluation approach must include the theoretical framework (e.g., theory, conceptual model, logic model) that you will use to design the multi-site evaluation. Provide the rationale for its selection.

Describe the approach to working collaboratively with the states as well as other stakeholders in leading data collection and reporting efforts for the multi-site evaluation.

Describe how you would ensure objectivity of the evaluation, reduce bias in the execution of the evaluation, and how you would address conflicts of interest.

Dissemination of Findings

Describe a plan for the development and dissemination of tools and materials to the participating states and other states not funded under this project (i.e., sharing lessons learned and best practices at regular intervals during implementation). Tools and materials must include, at a minimum:

- Technical toolkit that provides a step-by-step guide for states to collect and report the HVL-AD measure as part of reporting the annual Adult Core Set to CMS. The toolkit should include best practices for data sharing and data linkage specific to RWHAP, HIV surveillance, and Medicaid data, technical coding for how to integrate common data systems, etc.
- Webinars to share best practices and practical guidance for states to collect

and report HVL-AD measure as part of reporting the annual Adult Core Set to CMS.

- Manuscripts submitted to peer-reviewed journals for publication.
- Presentations at the bi-annual National Ryan White Conference and the Annual CMS Quality Conference.

Describe a plan for disseminating tools and materials that facilitate replication of the data sharing or data linkage program after the period of performance that result in collecting and reporting the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.

Describe the plan for establishing and maintaining a presence on TargetHIV.org including promoting materials/webinars and storing tools and materials for distribution.

WORK PLAN -- Corresponds To Section V's Review <u>Criterion #2 Response</u>
 Corresponds to Section V's Review Criterion #2 Response

Briefly describe in narrative form the activities and steps that you will use to achieve each of the objectives proposed during the entire period of performance in the previous 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. Include a detailed work plan as Attachment 1.That work plan must include clearly written (1) goals; (2) objectives that are specific, measurable, achievable, realistic, and time-framed (SMART); (3) action steps or activities; (4) staff responsible for each action step; and (5) anticipated dates of completion. Among key activities that you should address in the timeline include, but are not limited to, procurement, implementation, configuration, installation, testing, documentation, and training.

RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review <u>Criterion</u>
 #2 Response

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 (e.g., delays establishing or refining data sharing agreements, delays around Institutional Review Board (IRB) approval, matching different data systems, cross-agency differences and priorities within states, Medicaid reforms that may be barriers to states' goals).

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

Describe the proposed staff's (including consultants and contractors, if applicable) knowledge and expertise in the following required areas:

- Project management applying project management principles and frameworks
- **Knowledge** Expert knowledge of policy and regulatory requirements regarding state Medicaid systems and HIV programs.

 Technical skills - related to sharing, management, and linkage of data systems

Describe the proposed staff's (including consultants and contracts, if applicable) knowledge and expertise in the following <u>supplemental</u> areas:

- Advertising, promoting, and hosting multi-media capacity-building and support to states to successfully:
 - Conduct data sharing or data linkage activities across RWHAP Part B, HIV surveillance, and Medicaid data systems;
 - Report the HIV viral suppression measure annually to CMS as part of the Medicaid Adult Core Set;
- Addressing legal, privacy, and confidentiality policy, processes, and frameworks to improve and support data sharing in states (e.g., provide legal counsel).
- Working with state RWHAP Part B, HIV surveillance, and/or Medicaid programs.
- Working with states to integrate and sustain systems improvements once this SPNS program ends; and
- Sharing knowledge of billing coding structure of Medicaid vs. RWHAP (e.g., CPT, ICD 10).

Describe your previous experience and organizational capacity to conduct an evaluation on data sharing or data linkage with an emphasis of linking RWHAP, HIV surveillance, and Medicaid data. In the description include:

Proposed key personnel (including any consultants, sub-recipients, and contractors, if applicable) and their knowledge, experience, training, and skills with evaluating data sharing or linkage projects.

The experience of proposed key project staff (including any consultants and subcontractors) in collaborative writing and publishing study findings in peer-reviewed journals.

The experience of proposed key project staff in making presentations to local communities, at state and national conferences, and to policymakers.

Your knowledge of and experience with the submission of IRB materials for review and obtaining approvals and renewals for all data collection instruments, informed consents, and evaluation materials. Include any training in human subjects research protection by proposed project staff.

ORGANIZATIONAL INFORMATION -- Corresponds To Section V's Review
 <u>Criterion #5 Resources/Capabilities</u>
 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.

Describe your experience in or support of collecting and reporting measures to the Medicaid Adult Core Set; matching client-level data across datasets; resolving

issues related to collecting, matching, and reporting client level data across datasets; and providing and managing capacity building activities germane to this project.

Include a one-page project organizational chart (Attachment 5) depicting the organizational structure of the project (not the entire organization), and include contractors (if applicable) and other significant collaborators.

Include a staffing plan with job descriptions for key personnel (Attachment 2) including qualifications, and brief job descriptions to include the roles and responsibilities; including who will manage/oversee the various project activities. See Section 4.1. of HRSA's SF-424 Application Guide for additional information.

Include short biographical sketches of key project staff (each not to exceed one page in length) as Attachment 3. See Section 4.1 of HRSA's SF-424 Application Guide for information on the content for the sketches. If a biographical sketch is included for an individual not yet hired, you must attach a letter of commitment signed by the individual.

If you will use consultants and/or contractors to provide any of the proposed services, describe their roles and responsibilities on the project. Include signed letters of agreement, memoranda of understanding, and brief descriptions of proposed and/or existing contracts related to the proposed program (Attachment 4).

Discuss how the organization will follow the approved work plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings.

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 <u>SF-424 Application Guide</u> 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, 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.

In addition, *Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set* program requires separate line item budgets for each year of the four (4) year period of performance, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs as appropriate (Attachment 7). As a reminder, you may apply for a ceiling amount of up to \$4,000,000 per year. Your budget should include annual subawards for up to a

maximum of 10 RWHAP Part B states.

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 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</u> <u>Application Guide</u> 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, the Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set initiative requires the following:

Overall Budget Narrative: Provide a budget narrative that explains the amounts requested for each line of the budget in Section B. 6., Object Class Categories. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Show how each item in the "other" category is justified. For subsequent budget years, the narrative should highlight the changes from year 1, or clearly indicate that there are no substantive budget changes during the period of performance. Do NOT use the budget narrative to expand the project narrative. The recipient should budget for required in-person and/or virtual site visit travel to each state at least annually. Please note that a revised budget may be required after the initial post-award meeting with HRSA.

Subaward Budget Narrative: Include a description of projected funding to be provided to the proposed states. The amount allotted for each state must include sufficient funds to cover projected costs associated with improving viral suppression reporting through promoting and expanding currently limited data sharing and data linkage activities between health departments and state Medicaid programs, including any partial or full-time-equivalent staff per participating state

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, (3) Evaluative Measures, and (4) Impact
Work Plan	(2) Response

Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested

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. **Clearly label each attachment**.

Attachment 1: Work Plan

Attach the detailed work plan for the project that includes all information requested in <u>Section IV.2.ii</u>. <u>Project Narrative</u>. The work plan should include a description of measurable objectives for the four-year period. Also, describe how your organization will ensure that subawarded or contracted funds are properly documented and executed to ensure proper compliance with federal accounting principles.

Attachment 2: 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, major responsibilities, and key qualifications of proposed project staff positions. Also, please include a description of your organization's timekeeping process that ensures you will comply with the federal standards related to documenting personnel costs.

Attachment 3: Biographical Sketches of Key Personnel

Keep each biographical sketch to one page in length as much as is possible. Include the qualifications of proposed project staff in relation to the specific job description included in Attachment 2.

Attachment 4: Project-specific Letters of Agreement, Letters of Commitment, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts Include signed letters of agreement, memoranda of understanding, and brief descriptions of proposed and/or existing contracts related to the proposed project. Provide documents that describe working relationships between your organization and other entities and programs cited in the proposal; excluding state-related recipients (see Attachment 6, below). Documents that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverables. Sign and date all letters of agreement.

Attachment 5: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project. Include and clearly notate any current and/or proposed collaborating organizations, consultants and/or subcontractors, and their roles to carry out aspects of the proposed project.

Attachment 6: Letters of Commitment from All Proposed States Include letters of commitment. Letters of commitment identify state needs, barriers, and goals for the data sharing or linkage, demonstrate a willingness to improve their RWHAP, HIV surveillance, and Medicaid data sharing or data linkage to accomplish the goals of this program, specifically indicate a commitment to the program (in-kind services, dollars, staff, space, equipment, etc.) and include activities with or by state Medicaid programs. Three letters of commitment from each of the participating programs in the states are required in this application. Each state should have a letter of commitment from the RWHAP Part B, the HIV surveillance, and the Medicaid programs. Letters of commitment in this attachment will not be counted towards the page limit.

Attachment 7: Line Item Budgets Spreadsheet for Years 1 through 4
Submit line-item budgets for each year of the proposed period of performance as a single spreadsheet table, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs.

Attachments 8-11: Other Relevant Documents Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated.

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. At a future, to-be-determined date, the *DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following pages: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update.

You must also 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 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)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, 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 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.

*Currently, the Grants.gov registration process requires information in three separate systems:

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

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

SAM.GOV 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 forms themselves are no longer part of HRSA's application packages and 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 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 *February 16, 2021 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 <u>SF-424 Application Guide</u> for additional information.

5. Intergovernmental Review

The Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set is a program 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 \$4,000,000 per year (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 A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) and Continuing Appropriations Act, 2021 and Other Extensions Act (P.L. 116-159) 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. Awards will be made subsequent to enactment of the FY 2021 appropriation. The NOA will reference the FY 2021 appropriation act and any restrictions that may apply. Note that these or other restrictions will apply as required by law in subsequent appropriations acts for FY 2021.

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;
- Lobbying activities and expenses;
- Reimbursement of pre-award costs; 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 45 CFR § 75.307.

7. Other Submission Requirements

Letter of Intent to Apply

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 15, 2021 to:

HRSA Digital Services Operation (DSO)
Please use the HRSA opportunity number as email subject (HRSA-21-083)
HRSADSO@hrsa.gov

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

Criterion 1: NEED (10 points) – Corresponds to Section IV's <u>Introduction</u> and <u>Needs</u> <u>Assessment</u>

- The strength and clarity of the applicant's description of the proposed project, its purpose, and overall activities.
- The strength and clarity of the applicant's description of the organization and any collaborators that will help meet the goals of the project.
- The strength and clarity of the applicant's description of the overall approach and activities that will lead to an improvement in reporting the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.
- The extent to which the application demonstrates understanding of the Medicaid Adult Core Set and reasons for states to report the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.
- The strength and clarity of the applicant's identification of up to 10 participating states and their challenges in collecting and reporting the HVLD-AD measure.

- The strength and clarity of the major areas where states need to develop capacity in order to collect and report the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.
- The strength and extent to which the applicant addresses issues of confidentiality and privacy surrounding the use of client-level health data taking into consideration that states have varying levels of legal and regulatory protections that govern HIV privacy and confidentiality.
- The strength and extent to which the applicant addresses any applicable State regulations regarding the sharing of clinical and laboratory data, and whether they exceed HIPAA requirements for the protection of disclosure of information regarding people with HIV.
- The strength and extent to which the applicant addresses any applicable regulatory processes within participating states and how the proposed project will ensure the timely, confidential and secure transfer of data within those limitations.
- The strength and extent to which the applicant addresses the procedures for the electronic and physical protection of participant information and data and how the applicant will assist the participating states in identifying any person-level data with the potential for disclosure of Protected Health Information (PHI).

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's <u>Methodology</u>, <u>Work Plan</u>, and <u>Resolution of Challenges</u>

State Selection and Monitoring (10 points)

- The strength and clarity of the applicant's assessment of states that meet the criteria outlined in Section IV, Project Narrative, Methodology, State Selection and Monitoring.
- The strength and feasibility of the plan to execute formal written agreements (e.g., contracts, budgets, work plans, business associate agreements) with the participating states to implement the changes required to share or link across RWHAP Part B, HIV surveillance, and Medicaid programs.
- The applicant's inclusion of three letters of commitment from each of the participating states as required in this application (Attachment 6). Each state should have a letter of commitment from their RWHAP Part B, HIV surveillance, and the Medicaid programs.
- The strength and clarity of the applicant's description of the mechanism for funding states, the protocol for state oversight, monitoring, and tracking expenses, and the calculation of the amount of funding each state will receive based on each state's needs and IT infrastructure.

Methodology (8 points)

Development of State Scope of Work and Work Plan

 The strength and clarity of the applicant's summary on the scope of work around establishing partnerships with states that include major milestones, corresponding dates, and report.

Capacity Building (7 points)

 The strength and clarity of how the applicant will work with each state to build capacity to promote collaboration among key partners in the state, create solutions and innovations to existing problems, and monitor progress of implementing the action plan. The applicant's description of the strategies should address how they will:

- Enhance communication and interaction among key stakeholders
- o Provide, monitor, and support the implementation of action plans
- Track progress of and changes to the state action plans
- Communicate progress and challenges requiring immediate attention of the HRSA project officer assigned to this cooperative agreement or other federal stakeholders
- Leverage existing HRSA, CMS, CDC, and ONC resources and tools
- The strength and clarity of how the applicant would apply the IHI Breakthrough Series Learning Collaborative model, or an alternative model, to facilitate and support states' capacity building. The description must address how the applicant will:
 - o Provide a justification for the selected model.
 - Assemble a panel of experts in the planning and development of effective strategies
 - Use virtual, in-person, or a combination of methods to convene a learning collaborative
 - o Plan, host, and facilitate the learning sessions and action periods
 - Build capacity of states through small-scale pilot testing through PDSA cycles with collaborating organizations within their states

Work Plan (7 points)

- The strength and clarity of the work plan to achieve each of the components proposed in the Methodology section during the four-year project period/period of performance (Attachment 1).
- The extent to which the work plan includes clearly written: (1) goals, (2) objectives that are specific, measurable, achievable, realistic and time-framed (SMART); (3) action steps and activities; (4) staff responsible for each action step; and (5) anticipated dates of completion.

Resolution of Challenges (3 points)

- The clarity of the discussion of the challenges impacting the effective implementation of the program.
- The clarity and feasibility of the approach, strategies, and techniques to resolve anticipated challenges.

Criterion 3: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV's Methodology

The strength and clarity of the applicant's description of how they will design, implement, and conduct rigorous, mixed-methods, multi-site evaluation to assess the effectiveness of activities implemented by the selected states to improve reporting to CMS the HVL-AD measure on the Medicaid Adult Core Set. The applicant's description of the evaluation should include key evaluation goals mentioned in Section IV's Methodology.

• The strength and clarity of the evaluation approach. The evaluation approach must include the theoretical framework (e.g., theory, conceptual model, logic

- model, etc.) that the applicant will use to design the multi-site evaluation and the rationale for its selection.
- The strength and clarity of the approach to working collaboratively with the states as well as other stakeholders in leading data collection and reporting efforts for the multi-site evaluation.
- The strength and clarity of how the applicant would ensure objectivity of the evaluation and how you would address conflicts of interest.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Methodology

- The strength and clarity of the plan throughout the four-year period of performance for the development and dissemination of interim tools and materials to the participating states and other states not funded under this project (i.e., sharing lessons learned and best practices at regular intervals during implementation). Refer to Section IV's Methodology for details on tools and materials.
- The strength and clarity of the plan for disseminating tools and materials that facilitate replication of the data sharing or data linkage program after the period of performance that results in collecting and reporting the HVL-AD measure as part of reporting the annual Adult Core Set to CMS.
- The strength and clarity of the plan for establishing and maintaining a presence on TargetHIV.org including promoting materials/webinars and storing tools and materials for distribution.

Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV's <u>Evaluation and Technical Support Capacity</u> and <u>Organizational Information</u>

Evaluation and Technical Support Capacity (10 points)

- The extent to which the application demonstrates proposed staff's (including consultants and contractors, if applicable) knowledge and expertise. See Section IV's Evaluation and Technical Support Capacity for details on the required areas of knowledge and expertise.
- The extent to which the application demonstrates how the proposed key personnel have the necessary knowledge, experience, training, and skills to 1) evaluate data sharing or data linkage projects, 2) collaboratively write and publish study findings in peer-reviewed journals, and 3) make presentations to local communities, at state and national conferences, and to policymakers.
- The strength and clarity of the applicant's narrative which demonstrates their knowledge of and experience with the submission of IRB materials for review and obtaining approvals and renewals for all data collection instruments, informed consents, and evaluation materials including any training in human subjects research protection by proposed project staff.
- The strength and clarity of the applicant's description of the systems and processes that will effectively support the evaluation including how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of outcomes.
- The strength and clarity of the applicant's plan to facilitate the transfer of aggregate RWHAP, HIV surveillance, and Medicaid data within each state for the evaluation at regular intervals in an electronic format.

- The strength and clarity of the applicant's plan to monitor data quality and data completeness of regular data submissions.
- The strength and clarity of the applicant's description of any potential obstacles for implementing the evaluation and the plan to address those obstacles.

Organizational Information (10 points)

- The extent to which the application describes the organization's current mission and structure, the scope of current activities, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations.
- The strength and clarity of the applicant's description of their experience in or support of collecting and reporting of measures to the Medicaid Adult Core Set; matching client level data across datasets; resolving issues related to collecting, matching, and reporting client level data across dataset; and providing and managing capacity building activities relevant to this project.
- The extent and clarity of demonstrated expertise related to sharing, management, and linkage of data systems.
- The clarity of the applicant's project organizational chart provided in Attachment 5

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

- 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.

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. 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 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 (45 CFR § 75.212).

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of August 1, 2021. 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 Notice of Award, 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 Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

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

Federal regulations (45 CFR part 46) 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. Further information will be available in the NOA.
- 2) **Final Report**. The recipient must submit a final report to HRSA within 90 calendar days after the period of performance ends that covers activities for the entire period of performance. Further information will be available in the NOA.
- Integrity and Performance Reporting. The NOA will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45 CFR</u> <u>part 75 Appendix XII</u>.

Please note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at <u>2 CFR § 200.340 - Termination</u> apply to all federal awards effective August 13, 2020.

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 10SWH03
Rockville, MD 20857

Telephone: (301) 443-7065 Email: <u>BSmith@hrsa.gov</u>

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

Adan Cajina, Chief

Special Projects of National Significance Branch

Attn: Building Capacity to Improve Collecting and Reporting Viral Suppression Data

to the Medicaid Adult Core Set Division of Policy and Data

HIV/AIDS Bureau

Health Resources and Services Administration

5600 Fishers Lane, Room 09NWH04

Rockville, MD 20857

Telephone: (301) 443-3180

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: support@grants.gov

Self-Service Knowledge Base: https://grants-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 the 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

HRSA has scheduled following technical assistance:

Webinar

Day and Date: Thursday, December 10, 2020

Time: 1 p.m. – 2:30 p.m. ET Call-In Number: 1-888-790-3413 Participant Code: 8618937

Weblink:

https://hrsa.connectsolutions.com/pre_application_webinar_for_hrsa_21_083/

Playback Number: 1-800-879-3693

Passcode: 12820

The webinar will be recorded and should be available within 10 business days at https://targethiv.org/library/nofos. Please note that this location will also contain answers to questions posed during and after the webinar. Be sure to check this site periodically before applications are due for any relevant clarifying information.

Tips for Writing a Strong Application

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