U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HIV/AIDS Bureau
Special Projects of National Significance

Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)

Funding Opportunity Number: HRSA-20-077
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Letter of Intent Requested by: December 31, 2019

Application Due Date: January 30, 2020

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

Issuance Date: November 1, 2019

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

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Special Projects of National Significance Program (SPNS) is accepting applications for a new 2-year capacity building demonstration project cooperative agreement entitled, *Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP).* The purpose of this demonstration project is to link people with HIV and Hepatitis C Virus (HCV) within the RWHAP to care by leveraging existing public health surveillance with clinical data systems. A Technical Assistance Provider (TAP) organization will be funded to select and provide targeted technical assistance to up to ten (10) RWHAP Part A and/or Part B jurisdictions (state, city, and/or local health departments) to focus jurisdictional efforts on improving existing collaboration between their HCV surveillance systems and RWHAP care providers.

Funding Opportunity Title:	Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)
Funding Opportunity Number:	HRSA-20-077
Due Date for Applications:	January 30, 2020
Anticipated Total Annual Available FY 2020 Funding:	$1,000,000
Estimated Number and Type of Award(s):	One (1) cooperative agreement
Estimated Award Amount:	Up to $1,000,000 per year dependent on the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020 through August 31, 2022 (2 years)
Eligible Applicants:	Eligible applicants include entities eligible for funding under RWHAP Parts A, B, C, and D of Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 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 at http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this NOFO to do otherwise.

Technical Assistance

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

HRSA has scheduled the following technical assistance:

Webinar
Day and Date: Tuesday, December 10, 2019
Time: 1:00 p.m. – 2:30 p.m. ET
Call-In Number: 1-888-455-9657
Participant Code: 2842784
Weblink: https://hrsa.connectsolutions.com/hrsa-20-077/
Playback Number: 1-888-277-9385
Passcode: 121019

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the *Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)* cooperative agreement. The purpose of this demonstration project is to link people with Hepatitis C Virus (HCV) and HIV within the RWHAP to care, by leveraging existing public health surveillance with clinical data systems. A Technical Assistance Provider (TAP) organization will be funded to select and provide targeted technical assistance to up to ten (10) RWHAP Part A and/or Part B jurisdictions (i.e., state, city, and/or local health departments) to focus jurisdictional effort on improving existing collaboration between their HCV surveillance systems and RWHAP care providers.

The goal of improving collaboration between HCV and HIV surveillance systems and RWHAP providers is to facilitate the sharing of data and identification of people with HIV and HCV who are not currently receiving care. When combined with clinical data from otherwise disparate databases, ideally, these improved processes for data sharing and exchange will allow people with HIV and HCV and in need of HCV treatment to be identified, linked, and retained in care; hence, leading to HIV viral suppression and cure of HCV. The TAP will work collaboratively with a contractor who will evaluate the overall effectiveness and impact of this project. Data use/sharing agreements may be required to allow for the interchange of aggregate data to conduct the evaluation.

The TAP will identify and fund jurisdictions in consultation with HRSA. To qualify, funded jurisdictions must:

- Commit to improving their HCV and HIV surveillance data sharing with RWHAP providers;
- Maintain their HCV and HIV surveillance data systems electronically;
- Periodically match the surveillance data between their HCV and HIV surveillance data systems for the purposes of linkage to care; and
- Be willing and able to share aggregate data with the TAP who will then share that data with the evaluation contractor to conduct the project's evaluation.

The TAP will select a combination of jurisdictions to include those who are currently directly funded by the Centers for Disease Control and Prevention (CDC) to improve their viral hepatitis surveillance and those who are not directly funded by the CDC (e.g., receive viral hepatitis surveillance funds through their state). HRSA will work in partnership with the TAP in reviewing and selecting the jurisdictions.

2. Background

This program is authorized by the Public Health Service Act, Section 2691 (42 USC § 300ff-101), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87). The HRSA HAB Special Projects of National Significance (SPNS) program supports the development of innovative approaches for HIV care to respond to the emerging needs

of clients served by the RWHAP.[1] The SPNS program also evaluates the effectiveness of these approaches' and/or interventions' design, implementation, utilization, cost, and health related outcomes, while promoting dissemination and successful replication.

Data to care is an important public health model to link and/or reengage individuals into care with the intention of retaining those individuals in care.[2] Data to care models are most successful when implemented as part of a broader strategy within a health department to evaluate linkage and retention of individuals overall. A 2018 study published in the Journal of the International AIDS Society indicates that of those individuals who are coinfected with HIV and HCV, most (86-98 percent) attained sustained virologic suppression of their HCV once treated; however, approximately one-half of individuals coinfected with HIV and HCV remained untreated.[3] It is imperative that health departments (state, city, and local) work to leverage data to care models to link individuals with HIV and HCV to care and work toward the development and implementation of a plan to treat and cure their HCV.

The U.S. Department of Health and Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) and the SPNS program collaborated from 2016-2019 to implement the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color* project.[4] As a result, jurisdictional data to care lessons learned emerged, which include:

- Analyzing population demographics of patients with HIV and HCV through matching of HIV and HCV surveillance data;
- Creating HIV and HCV surveillance registries that include laboratory reporting;
- Facilitating linkage to care or return to care for patients with HIV and HCV in such a way that it enables facilities/providers to communicate to other providers, health department (jurisdiction) and clinics with patient status (e.g., HCV care status of each patient, treatment barriers);
- Keeping performance measures simple and adaptable;
- Bridging electronic medical records (EMR) and other systems (e.g., CAREWare) whenever possible to enhance service delivery;
- Monitoring those at risk of re-infection; and
- Monitoring progress towards HCV elimination.

The *Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)* seeks to incorporate these lessons learned into additional jurisdictional data to care approaches.

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[1] Information on the Ryan White HIV/AIDS Program Part F: Special Projects of National Significance Program can be found at: http://hab.hrsa.gov/abouthab/partfspns.html, Accessed May 1, 2019.
[2] About Data to Care, Centers for Disease Control and Prevention, https://effectiveinterventions.cdc.gov/en/data-to-care/group-1/data-to-care/data-to-care-essential-elements, Accessed May 20, 2019.
[3] Sacks-Davis, R., Doyle, J. S., Rauch, A., Beguelin, C., Pedrana, A. E., Matthews, G. V., Hellard, M. E. (2018). Linkage and retention in HCV care for HIV-infected populations: early data from the DAA era. *Journal of the International AIDS Society*, *21 Suppl 2*(Suppl Suppl 2), e25051. doi:10.1002/jia2.25051
[4] Information on the Ryan White HIV/AIDS Program Part F: Special Projects of National Significance Program can be found at: http://hab.hrsa.gov/abouthab/partfspns.html, Accessed May 1, 2019.

Ending the HIV Epidemic: A Plan for America

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

National HIV/AIDS Strategy: Updated to 2020

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

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

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

HIV Care Continuum

Diagnosing and linking people with HIV to HIV primary care, and ensuring people with HIV achieve viral suppression are important public health steps toward ending the HIV epidemic in the United States. The HIV care continuum has five main "steps" or stages that 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 2017 Ryan White Services Report (RSR), the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2010 to 2017, HIV viral suppression among RWHAP patients who have had one or more medical visits during the calendar year and at least one viral load with a result of <200 copies/mL reported, has increased from 69.5 percent to 85.9 percent; additionally, racial/ethnic, age-based, and regional disparities have decreased.[5] 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.[6] Scientific advances have shown antiretroviral therapy (ART) preserves the health of people with HIV and prevents sexual HIV transmission. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner. Such findings underscore the importance of supporting effective interventions for linking people with HIV into care, retaining them in care, and helping them adhere to their ART.

Integrated Data Sharing and Use

HRSA and CDC's Division of HIV/AIDS Prevention support integrated data sharing, analysis, and utilization for the purposes of program planning, needs assessments, unmet need estimates, reporting, quality improvement, the development of your HIV care continuum, and public health action. HRSA strongly encourages RWHAP Part F 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.
- Establish data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization.

Integrated HIV data sharing, analysis, and utilization approaches by state and territorial health departments can help further progress toward reaching the NHAS 2020 goals and improve outcomes on the HIV care continuum.
HRSA strongly encourages complete CD4, viral load (VL) and HIV nucleotide sequence reporting to the state and territorial health departments' HIV surveillance systems to benefit fully from integrated data sharing, analysis, and utilization. State and health departments may use CD4, VL, and nucleotide sequence data to identify cases, stage of HIV disease at diagnosis, and monitor disease progression. These data can also be used to evaluate HIV testing and prevention efforts, determine entry into and retention in HIV care, measure viral suppression, monitor prevalence of antiretroviral drug

[5] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2017. http://hab.hrsa.gov/data/data-reports. Published December 2018. Accessed April 1, 2019.
[6] 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.

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

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

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

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

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

- **Integrating HIV Innovative Practices (IHIP) (https://targethiv.org/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 technical assistance (TA) training webinars designed to provide a more interactive experience with experts, and a TA help desk exists for you to submit additional questions and share your own lessons learned.

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

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

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

HRSA Program involvement will include:

- Providing the expertise of HRSA personnel and other relevant resources to the project;
- Providing criteria for selection of jurisdictions;
- Working in collaboration with the recipient on final selection of participating jurisdictions;
- Ongoing review of activities, procedures, measures, and technical assistance tools that will be developed and implemented in order to accomplish the goals of the cooperative agreement;
- Participating in the dissemination of project findings, best practices, and lessons learned, and reviewing all information products prior to dissemination;
- Facilitating the dissemination of project findings, best practices, evaluation data and other information developed as part of this project to the broader network of state, city, and/or local health departments;

- Providing informational resources and facilitating partnerships and communication with Regional AIDS Education and Training Centers (AETCs); state, local, and tribal health departments; and other stakeholders; and
- Facilitating access to education and training resources available through the national and regional AETCs, TARGETHIV (formerly known as the TARGET Center), and other HRSA supported resources.

The cooperative agreement recipient's responsibilities will include:

- Identifying up to ten (10) RWHAP Part A and/or Part B jurisdictions (i.e., state, city, and/or local health departments) that meet the minimum criteria HAB established to focus jurisdictional effort on improving existing collaboration between their HCV surveillance systems and RWHAP care providers.
- Establishing formal written agreements (e.g., subawards, contracts, memoranda of understanding, and letters of agreement) with the participating jurisdictions;
- Due to the short period of performance for this project, ensuring funds are used to improve existing data systems and **not** to purchase, develop, or implement new data systems;
- Identifying and establishing agreements with RWHAP providers in participating jurisdictions to coordinate data sharing and linkage of care to newly identified individuals;
- Delivering technical assistance (TA) to the participating jurisdictions incorporating the lessons learned through the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color* project (as noted in the Background section);
- Reviewing existing jurisdictional surveillance data sources and assisting jurisdictions in identifying people with HIV and HCV who are in need of linkage to care and/or HCV treatment;
- Providing TA to jurisdictions to help them facilitate their use of clinical data from otherwise disparate surveillance systems to allow people with HIV and HCV in need of HCV treatment to be identified, linked and retained in care leading to HIV viral suppression and cure of HCV;
- Assisting the jurisdictions with developing a linkage to care plan for people with HIV and HCV who are currently not in treatment;
- Collaborating with the RWHAP Regional AETCs to support increased outreach and training to providers in participating jurisdictions on treatment of HIV/HCV coinfection, including enhanced promotion of the AETC National Curriculum on HIV/HCV Coinfection;
- Assisting the jurisdictions with preparation of sustainability plans to maintain a data to care approach to link people with HIV and HCV in the RWHAP to care and to achieve cure of HCV. The recipient will submit the sustainability plans as part of the TAP final report;
- Working with HRSA HAB to develop project dissemination products, including, but not limited to a project manual to describe successful implementation strategies and costs required to implement across the range of participating jurisdictions;
- In collaboration with the participating jurisdictions and HRSA, disseminating findings, including best practices and lessons learned to foster rapid, efficient

replication of the project's data to care approaches by other jurisdictions within the RWHAP. Dissemination includes, but is not limited to:
    - Conducting a final in-person meeting at HRSA;
    - Presenting at national conferences, symposia, and other appropriate meetings;
    - Producing a webinar for HCV and HIV surveillance departments in jurisdictions not participating in the project;
    - Utilizing the RWHAP AETC Program and other HRSA supported entities such as TargetHIV to disseminate findings; and
    - Leading a Publications and Dissemination Committee.
- Completing all Institutional Review Board (IRB) requirements and/or data use/sharing agreements necessary to share aggregate data for all people with HIV with HRSA, the TAP and the evaluation contractor. Aggregate data include, but are not limited to, number of people with HIV identified and linked into HCV care through this funded effort, demographic characteristics, and patient outcomes if available by the end of the project (e.g., HCV cure achieved; sustained virological response (SVR 12) for this population. A timeframe for this activity will be decided in partnership with HRSA and must allow participating jurisdictions to be ready to implement linkage to HCV care by month six of year 2.

Overall Project Timeline

Within the first year of the project, the cooperative agreement recipient must:
- Finalize jurisdiction selection;
- Complete formal written agreements and other necessary documents with the participating jurisdictions;
- Complete IRB requirements;
- Establish data use/sharing agreements;
- Develop implementation plans;
- Provide specific TA to address the needs identified for each jurisdiction so they may complete combining clinical data from otherwise disparate databases with surveillance systems data; and
- Ensure jurisdictions identify people with HIV/HCV in need of HCV care.

Within the second year of the project, the cooperative agreement recipient must:
- Assist the jurisdictions with developing a linkage to care plan so they may begin to link to care those identified in need of HCV care at the end of year one;
- Implement the linkage to care plan;
- Collect data to evaluate progress toward meeting outcomes/objectives of the project;
- Ensure annual data security and confidentiality assessments with a statement signed by an overall responsible party certifying program compliance with CDC's National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) guidelines;
- Lead a dissemination and publications committee;
- Develop tools for replication across other jurisdictions (implementation manual, toolkit, project report, etc.);

- Submit replication tools to HRSA for approval and refine as necessary;
- Assist jurisdictions with preparation of their sustainability plans for inclusion in the final report; and
- Disseminate findings, best practices and lessons learned.

2. Summary of Funding

HRSA expects approximately $1,000,000 to be available annually to fund one (1) recipient. You may apply for a ceiling amount of up to $1,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year.

The actual amount available will not be determined until enactment of the final FY 2020 federal appropriation. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. The period of performance is September 1, 2020, through August 31, 2022 (2 years). Funding beyond the first year is subject to the availability of appropriated funds for *Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)* in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government. HRSA may reduce recipient funding levels beyond the first year if they are unable to fully succeed in achieving the goals listed in the application.

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

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include entities eligible for funding under RWHAP Parts A, B, C, and D of Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009.

2. Cost Sharing/Matching

Cost sharing/matching not required for this program.

3. Other

HRSA will consider applications that exceed the ceiling amount non-responsive and will not consider them for funding under this notice.

HRSA will consider applications that fail to satisfy the deadline requirements referenced in Section IV.4 non-responsive and will not consider them for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.

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

IV. Application and Submission Information

1. Address to Request Application Package

HRSA ***requires*** you to apply electronically. HRSA encourages you to apply through Grants.gov 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 provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 Application Guide* 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 *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 *Application Guide* for the Application Completeness Checklist.

Application Page Limit
The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your application does not exceed the specified page limit.**

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

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) You, on behalf of the applicant organization certify, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
3) Where you are unable to attest to the statements in this certification, an explanation shall be included in Attachment 9.

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

In addition to the information required in Section 4.1.ix of HRSA's *SF-424 Application Guide*, include the following:

- Briefly describe how you will conduct TA with the jurisdictions (state, city, and/or local health departments) to improve health outcomes for people with HIV in the RWHAP.
- Briefly describe the purpose of this capacity building demonstration project and the methodology you will use.
- Briefly describe how you will work with the proposed jurisdictions to create or improve data sharing and utilization across their HCV and HIV surveillance programs and subsequently with their RWHAP providers to enhance and improve linkage to care.
- Briefly describe how you will work collaboratively with a contractor (funded separately by HRSA) who will evaluate the overall effectiveness and impact of this project.

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 and will clearly describe the uniqueness and strength of the organization's approach for each of the section headers listed.

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. Clearly identify up to ten RWHAP Part A and/or Part B jurisdictions (state, city, and/or local health departments) to implement changes required to create or improve data sharing across the jurisdictions' HCV and HIV surveillance systems to improve retention, linkage, and re-engagement in HIV care and health outcomes for people with HIV in the RWHAP. The proposed jurisdictions should meet the criteria outlined in Section II.

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

    - Outline the preliminary needs of the proposed jurisdictions as they pertain to HCV and HIV surveillance systems and data sharing and utilization across the HCV and HIV surveillance programs.
    - Describe the process you will use to identify the needs of the selected jurisdictions which identifies the barriers (by jurisdiction) that prohibit data sharing across their HCV and HIV surveillance systems and utilization of this data with their RWHAP providers to enhance and improve linkage to care.
    - Discuss any potential barriers affecting the implementation of system changes to support the increased data sharing across participating HCV and HIV surveillance systems and present possible ways to address these barriers.
    - Discuss the existing relationships between the jurisdictions and their RWHAP clinics and any barriers to utilization of shared data by the RWHAP clinics to improve or expand care for people with HIV.
    - Describe the process you will use to incorporate lessons learned from the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color* project (as noted in the Background section) to develop tailored implementation plans for each jurisdiction.
    - Describe the process you will use to identify gaps of data sharing and utilization within each jurisdiction. Describe how you will use this information to identify process improvements.

    Use and cite demographic data whenever possible to support the information provided.

- *METHODOLOGY -- Corresponds to Section V's Review Criterion #2 Response and #4 Impact*

    Based on your assessment, propose up to ten (10) jurisdictions (state, city, and/or local health departments) that will be considered for final selection in collaboration with HRSA. These jurisdictions must meet the criteria outlined in Section II.

- Describe jurisdiction selection criteria that you used to select participating health departments. Criteria to assist you in the selection of jurisdictions should be based on the following, at a minimum:
    - Jurisdiction commits to improving their HCV and HIV surveillance data sharing to accomplish the goals of this project;
    - Jurisdiction must maintain their HCV and HIV surveillance data electronically;
    - Jurisdiction must periodically match the surveillance data between their HCV and HIV surveillance data systems for the purposes of linkage to care. A combination of jurisdictions to include those who are currently directly funded by the CDC to improve their viral hepatitis surveillance and those who are not directly funded (e.g., receive viral hepatitis surveillance funds through their state); and
    - Jurisdiction must be willing and able to share aggregate data with the TAP who will then share with the evaluation contractor to conduct the project's evaluation.
- Describe how the selection criteria ensured the identification and participation of a diverse group of jurisdictions. Include a letter of support from the state health department for jurisdictions that are not directly funded (Attachment 7).
- Propose a plan for executing formal written agreements with participating jurisdictions to implement the changes required to create or improve data sharing across HCV and HIV surveillance systems.
- Propose a plan for assisting jurisdictions with identifying and establishing agreements with their RWHAP providers to coordinate data sharing and linkage to care for newly identified individuals. A timeframe for this activity will be decided upon in partnership with HRSA, which allows participating jurisdictions to be ready to implement linkage to HCV care in year 2.
- Describe the methodology for monitoring the jurisdictions, including, among other items, implementation progress, the submission of invoices, and reimbursement for services in a timely manner.
- Letters of commitment from all proposed jurisdictions are required in this application (Attachment 4) to demonstrate a willingness to improve their HCV and HIV surveillance data sharing to accomplish the goals of this project.

Data use/sharing agreements may be necessary in order to share aggregate data with HRSA and the evaluation contractor.

- Propose a plan for obtaining IRB approval and executing data use/sharing agreements that may be necessary in order to share aggregate data with HRSA and the evaluation contractor. Data to be collected and shared in table format through these data use/sharing agreements may include, but are not limited to, number of people with HIV identified and linked into HCV care through this process, demographic characteristics and patient outcomes if available by the end of the project (e.g., HCV cure achieved; SVR 12) for this population.
- Additionally, each jurisdiction must identify a **change champion(s)** to support both project and organizational change to help build organizational

support for system change (Attachment 4). ***For the purposes of this NOFO, a change champion is defined as an individual who volunteers or is selected to facilitate change***.

Technical Assistance

- Describe your approach to assess TA needs (including technical and policy related needs) for each proposed jurisdiction.
- Discuss your planned method to customize selected system changes for each jurisdiction and identify existing barriers where improvement is needed.
- Describe your approach to develop a TA plan for guiding each jurisdiction through the implementation of customized system changes. This may include site visits, as well as virtual and in-person meetings in years 1 and 2.
- Describe the methods you will use to provide TA to the jurisdictions and your plan for assisting the jurisdictions with developing sustainability plans, including budget projections for continued program integration and ongoing activities across the participating jurisdictions after the funding period ends. HRSA expects the jurisdictions 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 for the target population. The jurisdictions' sustainability plans will be part of the final report for this project.

Data Collection

- Discuss how you will assist the participating jurisdictions by providing TA to support their data collection activities, including the following:
  - Training jurisdiction staff in use of data collection instruments and/or web-based data entry portals;
  - Regular monitoring of data collection and data sharing across their HCV and HIV surveillance systems and subsequently with their RWHAP providers to enhance and improve linkage to care; and
  - Remedial action when necessary to ensure data collection is of the highest quality.
- Describe your plan to report annually on participating jurisdictions' HIV and HCV care continuums, reflecting progress on the jurisdictions' improvements of health outcomes as a result of this project.
- Describe the procedures for the electronic and physical protection of participant information and data.
- Describe how you will assist the participating jurisdictions in identifying any person-level data with the potential for disclosure of Protected Health Information (PHI).
- Describe your plan to facilitate the transfer of aggregate HCV and HIV data for all people with HIV within each jurisdiction to HRSA and the evaluation contractor at regular intervals in an electronic format.

- Describe how you will monitor data quality and data completeness of regular data submissions.

Dissemination

- Describe your plan for the development and dissemination of tools and materials throughout the 2-year implementation period.
- Describe your plan to disseminate information to the participating jurisdictions and other health departments not funded under this project to promote replication and implementation of intervention activities.
- Describe your plan for promoting materials/webinars using the TargetHIV website.
- Describe your plan for generating manuscripts for peer-reviewed publication regarding outcomes of this project.
- Describe your plan to conduct a final in-person meeting at HRSA.

▪ *WORK PLAN -- Corresponds to Section V's Review Criterion #2 Response*

- Describe the activities or steps that you will use to implement each of the cooperative agreement responsibilities listed in Section II. 1. and achieve each of the objectives proposed during the entire period of performance in the Methodology section.
- Use a time line 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.
- The 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.
- The work plan should be included as Attachment 1.

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

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

- Outcomes (i.e., the results of a program, typically describing a change in people or systems).

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. **You can find additional information on developing logic models at the following website**: http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

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

  - Discuss challenges that you are likely to encounter (including working collaboratively with the evaluation contractor) in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion #3 Evaluative Measures, #4 Impact, and #5 Resources and Capabilities*

  - You must describe the plan for documenting and evaluating your program processes that will contribute to continuous quality improvement. The program process 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 staff, budget, and other resources), key processes, and expected outcomes of the funded activities.
  - You must describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of 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 performance outcomes. This includes cost data required to conduct a cost-analysis or cost-effectiveness study of the interventions implemented at each of the jurisdictions.
  - Describe current experience, skills, and knowledge, including individuals on staff with expertise in information technology systems as it pertains to data system interface and integration.
  - Describe experience as it relates to 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. This strategy includes identification of jurisdictional IRB requirements and any data use/sharing agreements necessary to share aggregate data in table format to HRSA and the evaluation contractor. Aggregate data include, but are not limited to, number of people with HIV identified and linked into HCV care through this process, demographic

characteristics and patient outcomes if available by the end of the project (e.g., HCV cure achieved; SVR 12) for this population.
- You must describe any potential obstacles for implementing the program process evaluation and your plan to address those obstacles.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion #5 Resources and Capabilities*

  - Succinctly describe your organization's current mission and structure, scope of current activities, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations.
  - Include 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).
  - 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 project (Attachment 4).

  Describe your organization's experience with the following:
  - Conducting TA with state, city, and/or local health departments to improve health outcomes for people with HIV in the RWHAP;
  - Developing data use/sharing agreements, tools to assist overcoming technical barriers such as data linkage and toolkits, specifically related to toolkits and web-based tools for state, city, and/or local health departments;
  - Gathering data/information to determine the needs of state, city, and/or local health departments related to the development and implementation of surveillance system changes;
  - Tailoring HCV and HIV intervention plans and strategies for specific organizations, and subsequent adaptations of established intervention plans;
  - Working collaboratively with independent, outside evaluators to evaluate technical assistance provided on a project; and
  - Monitoring subrecipients or partners on technical assistance projects.

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

iii. Budget

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

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

In addition, this program requires separate line item budgets for each year of the 2-year period of performance, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs as appropriate (Attachment 6). As a reminder, you may apply for a ceiling amount of up to $1,000,000 per year. Your budget should include annual subawards for up to ten RWHAP Part A and/or Part B jurisdictions (state, city, and/or local health departments) to implement projects

needed to create or improve their ability to share HCV and HIV data across their surveillance systems.

The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (P.L. 115-245), Division B, § 202 states, "None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II." See Section 4.1.iv Budget – Salary Limitation of HRSA's *SF-424 Application Guide* for additional information. Note that these or other salary limitations may apply in the following FY, as required by law.

iv. Budget Narrative

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

In addition, the *Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)* requires the following:

Subaward Budget Narrative: Include a description of funding to be provided to the jurisdictions. The amount allotted for each jurisdiction must include sufficient funds to cover projected costs associated with the implementation of interventions as well as the collection and submission of evaluation-related data, and partial or full time equivalent staff per participating jurisdiction. The recipient should budget for required site visit travel to each jurisdiction at least annually. A revised budget may be required after the details of interventions to be implemented are provided.

v. Attachments

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

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in Section IV.2.ii. Project Narrative. Also, include the required logic model in this attachment. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

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

Attachment 3: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length per person. In the event that

a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch.

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

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 5: Project Organizational Chart

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

Attachment 6: Line Item Budget

Include separate line item budgets for each year of the 2-year period of performance, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs as appropriate.

Attachment 7: Letters of Support from State Health Departments

Include here any letters of support from proposed jurisdictions with state health departments that are **not** currently directly funded by the CDC to improve their viral hepatitis surveillance.

Attachment 8: Tables, Charts, etc.

To give further details about the proposal (e.g., Gantt or PERT charts, flow charts).

Attachments 9-15: 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. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

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

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

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

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

- Dun and Bradstreet (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 notarized letter appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications and representations annually through SAM located at 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 *January 30, 2020, 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

Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP) is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

6. Funding Restrictions

You may request funding for a period of performance of up to 2 years, at no more than $1,000,000 per year (inclusive of direct **and** indirect costs). This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

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

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

- Charges that are billable to third party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare);
- Purchase or construction of new facilities, or capital improvement to existing facilities;
- Purchase of or improvement to land;
- Purchase of vehicles;
- International travel;
- Cash payments to intended recipients of RWHAP services;
- To develop materials designed to directly promote or encourage intravenous drug use or sexual activity;
- Costs of HCV treatment, HCV screening and any other charges that are billable to third party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare, HUD, other RWHAP funding including ADAP);
- Purchase of HCV medications;
- HIV testing;
- Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (nPEP) medications or the related medical services [RWHAP Part C and D recipients

may provide prevention counseling and information to eligible clients' partners (also see the June 22, 2016, RWHAP and PrEP program letter); and
- Syringe services programs (SSPs). Some aspects of SSPs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy. See https://www.aids.gov/federal-resources/policies/syringe-services-programs/.

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 *December 31, 2019* to:

HRSA Digital Services Operation (DSO)
Please use the HRSA opportunity number as email subject (HRSA-20-077)
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 *Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)* has six review criteria. See the review criteria outlined below with specific detail and scoring points.

Criteria	**Points**
Criterion 1: Need	10
Criterion 2: Response	35
Criterion 3: Evaluation Measures	15
Criterion 4: Impact	10
Criterion 5: Resources/ Capabilities	20
Criterion 6: Support Requested	10
Total	**100**

Criterion 1: NEED (10 points) – Corresponds to Section IV's Introduction and Needs Assessment
The extent to which the application demonstrates the problem and associated contributing factors to the problem.

- The extent to which the applicant demonstrates the need for the proposed jurisdictions to participate in this project using the criteria outlined in Section II.
- Strength and clarity of the applicant's description of the proposed jurisdictions' epidemiological data including incidence of HIV and HCV co-infection.
- Strength and clarity of the applicant's description of proposed jurisdictions' existing HIV and HCV surveillance systems and changes needed to improve identification of people with HIV and HCV and linkage to HCV care.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges
The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

i. Methodology (20 points)

- Strength and clarity of applicant's identification of proposed jurisdictions using the selection criteria in Section II to include a mixture of jurisdictions that:
  - Periodically match the surveillance data between their HCV and HIV surveillance data systems for the purposes of linkage to care; and
  - Are currently directly funded by the CDC to improve their viral hepatitis surveillance and those who are not directly funded (e.g., receive viral hepatitis surveillance funds through their state). A letter of support from the state health department for jurisdictions that are not directly funded should be included (Attachment 7).

- Strength and clarity of the proposed plan and methodology for the selection of jurisdictions; issuance of subawards; and management and monitoring of jurisdictions, including implementation progress.
- Uniqueness, strength and clarity of the proposed plan for assisting jurisdictions with identifying and establishing agreements with their RWHAP providers to coordinate data sharing and linkage to care for newly identified individuals.
- Strength and clarity of the proposed plan for executing formal written agreements with participating jurisdictions to implement the changes required to create or improve data sharing across HCV and HIV surveillance systems, allowing participating jurisdictions to be ready to implement linkage to HCV care in year 2.
- Strength and clarity of the proposed plan for obtaining IRB approval and executing data use/sharing agreements that may be necessary in order to share aggregate data with HRSA and the evaluation contractor.
- Evidence of intent to participate in the project in the form of memoranda of agreement/understanding or letters of support from proposed jurisdictions.
- Evidence of change champion(s) identified at each jurisdiction to support both project and organizational change to help build organizational support for system change. For the purposes of this NOFO, a change champion is defined as an individual who volunteers or is selected to facilitate change.
- Feasibility of approach to assess TA needs (including technical and policy related needs) for each proposed jurisdiction, including discussion of planned method to customize selected system changes for each jurisdiction and identification of existing barriers where improvement is needed.
- Uniqueness and feasibility of proposed methods to provide TA to the jurisdictions.
- Strength and clarity of how the applicant will assist the participating jurisdictions in data collection, including the following:
    - Training jurisdiction staff in use of data collection instruments and/or web-based data entry portals,
    - Regular monitoring of data collection and sharing of data across their HCV and HIV surveillance systems and subsequently with their RWHAP providers to enhance and improve linkage to care, and
    - Remedial action when necessary to ensure data collection is of the highest quality.
- Strength and clarity of the procedures for electronic and physical protection of participant information and data, including how the applicant will assist the participating jurisdictions in identifying any person-level data with the potential for disclosure of PHI.
- Feasibility of the plan to transfer aggregate HCV and HIV data for all people with HIV within each jurisdiction to HRSA and the evaluation contractor at regular intervals in an electronic format, including how data quality and data completeness of regular data submissions will be monitored.

ii. Work Plan (10 points)

- Strength, clarity and feasibility of the applicant's work plan and the goals for the 2-year project period, including adherence to key activity due dates as specified earlier in the announcement in the overall project timeline (Attachment 1).
- Extent to which the applicant's work plan addresses the program requirements described in the Methodology section of the Narrative.
- Extent to which the applicant's objectives and action steps for year one are specific to each goal, measurable, attainable, reasonable, and time-framed.
- Extent to which the applicant's work plan includes each planning, implementation, and evaluation activity; the staff responsible to accomplish each step; and anticipated dates of completion.

iii. Resolution of Challenges (5 points)

- Extent to which the applicant identifies possible organizational, administrative, regulatory, technological and human-related challenges that are likely to be encountered during the planning and implementation of the project described in the work plan.
- Extent to which the applicant identifies realistic and appropriate responses to be used to resolve those challenges.

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

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

- Strength of the applicant's capacity and plan to collect and report the required aggregate data to the evaluation team.
- Evidence the applicant has identified the IRB requirements of the proposed jurisdictions.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV's Methodology and Evaluation and Technical Assistance Capacity

- Strength and clarity of the cost-effectiveness study of the interventions implemented at each of the jurisdictions.
- Uniqueness, strength and clarity of the plan for the development and dissemination of tools and materials throughout the 2-year implementation period.
- Strength and feasibility of applicant's plan for assisting the jurisdictions with developing sustainability plans, including budget projections for continued program integration and ongoing activities across the participating jurisdictions after the funding period ends.

Criterion 5: RESOURCES/CAPABILITIES (20 points) – Corresponds to Section IV's Evaluation and Technical Assistance Capacity, Organizational Information, and Attachments

Strength and extent to which the applicant's proposed key project personnel (including any consultants and contractors) have the necessary knowledge, experience, training, and skills in:

- Conducting TA with state, city, and/or local health departments to improve health outcomes for people with HIV in the RWHAP.
- Developing data use/sharing agreements, tools to assist overcoming technical barriers such as data linkage and toolkits, specifically related to toolkits and web-based tools for state, city, and/or local health departments.
- Gathering data/information to determine the needs of state, city, and/or local health departments related to the development and implementation of surveillance system changes.
- Tailoring HCV and HIV intervention plans and strategies for specific organizations, and subsequent adaptations of established intervention plans.
- Working collaboratively with independent, outside evaluators to evaluate technical assistance provided on a project. and
- Monitoring subrecipients or partners on TA projects.

Extent to which the applicant provides:

- 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.
- 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.
- A staffing plan with job descriptions for key personnel (Attachment 2), including a description of any proposed consultants and/or contractors with roles and responsibilities on the project.
- Signed letters of agreement, memoranda of understanding, and brief descriptions of proposed and/or existing contracts related to the proposed project (Attachment 4).

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

The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives.

- 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 costs, as outlined in the budget, budget narrative, and the line item budgets for each year of the project period are reasonable and align

with the activities proposed in the Work Plan (Attachment 1) to accomplish the programmatic requirements described in this announcement.
- The extent to which key personnel have adequate time allocated to the project in percentages of full-time equivalents (FTEs) to achieve project objectives.
- The extent to which agreements for proposed contractors and consultants are clearly described in terms of contract purposes; how costs are derived; and that payment mechanisms and deliverables are reasonable and appropriate.
- Evidence that the budgets allocate sufficient support to meet the minimum costs of all proposed subawards; travel expenses to visit each jurisdiction at least annually; key personnel to host and attend the final in-person meeting at HRSA; attend the National Ryan White Conference on HIV Care & Treatment held in the Washington, DC area; and any travel relating to proposed staff training.

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.

Effective January 1, 2016, 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 any of 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 September 1, 2020. 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*.

Requirements of Subawards
The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards. See 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 federally supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's data rights.

Human Subjects Protection
Federal regulations (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 *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 an **annual** basis. HRSA will provide further information in the NOA.

2) **Final Project 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 project period. HRSA will provide further information in the NOA.

3) **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.

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 H. 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:

Adan Cajina, Chief
Demonstration and Evaluation Branch
Attn: Leveraging a Data to Care Approach to Cure Hepatitis C within the Ryan White HIV/AIDS Program (RWHAP)
Office of Training and Capacity Development
HIV/AIDS Bureau

Health Resources and Services Administration
5600 Fishers Lane, Room 09NWH04
Rockville, MD 20857
Telephone: (301) 443-3180
Email: ACajina@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 HRSA's EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

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

VIII. Other Information

Logic Models

You can find additional information on developing logic models at the following website: http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. You can find information on how to distinguish between a logic model and work plan at the following website: http://www.cdc.gov/healthyyouth/evaluation/pdf/brief5.pdf.

Technical Assistance

HRSA has scheduled following technical assistance:

Webinar
Day and Date: Tuesday, December 10, 2019
Time: 1:00 p.m. – 2:30 p.m. ET
Call-In Number: 1-888-455-9657
Participant Code: 2842784
Weblink: https://hrsa.connectsolutions.com/hrsa-20-077/
Playback Number: 1-888-277-9385
Passcode: 121019

Tips for Writing a Strong Application

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