U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HRSA
Health Resources & Services Administration

HIV/AIDS Bureau
Office of Training and Capacity Development

Curing Hepatitis C among People of Color Living with HIV

Funding Opportunity Number: HRSA-17-047
Announcement Type: New Competition

Catalog of Federal Domestic Assistance (CFDA) No. 93.928

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2017

Letter of Intent Due Date: June 28, 2017

Application Due Date: July 28, 2017

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately!
Deadline extensions are not granted for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to one month to complete.

Issuance Date: June 14, 2017

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Authority: The Consolidated Appropriations Act, 2017 (P.L. 115-31), Division H, Title II.

EXECUTIVE SUMMARY

Supported through funding from the Department of Health and Human Services Secretary's Minority AIDS Initiative, the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) is accepting applications for the fiscal year (FY) 2017 *Curing Hepatitis C among People of Color Living with HIV* program. The purpose of this three (3) year demonstration project is to reduce hepatitis C virus (HCV) morbidity and mortality among low-income, underinsured, or uninsured racial and ethnic minorities living with HIV in the United States. The program will fund up to two (2) recipients to support the expansion of HCV prevention (including education), testing, care (including preventive health care), and treatment capacity. To accomplish these aims, recipients will subaward and work with Ryan White HIV/AIDS Program (RWHAP) funded clinics, Federally Qualified Health Centers (FQHCs), and Substance Abuse and Mental Health Services Administration (SAMHSA)-funded community-based substance use disorder (SUD) and behavioral health treatment providers that serve people living with both HIV and HCV. Recipients will work with subrecipients and partners to improve coordination of linkage to and retention in HCV care and treatment for people living with both HIV and HCV; improve coordination with SAMHSA-funded SUD treatment providers to deliver behavioral health and SUD treatment support to achieve treatment completion and prevent HCV infection and re-infection; and enhance state, local, and tribal health department surveillance systems to increase their capacity to monitor acute and chronic coinfections of HIV and HCV in areas of high populations of low-income, underinsured, or uninsured racial and ethnic minorities.

Funding Opportunity Title:	Curing Hepatitis C among People of Color Living with HIV
Funding Opportunity Number:	HRSA-17-047
Due Date for Applications:	July 28, 2017
Anticipated Total Annual Available Funding:	$5,000,000
Estimated Number and Type of Award(s):	Up to two (2) cooperative agreements
Estimated Award Amount:	Up to $2,500,000 per year
Cost Sharing/Match Required:	No
Project Period/Period of Performance:	September 30, 2017 through September 29, 2020 (3 years)
Eligible Applicants:	Eligible applicants include RWHAP Parts A, B, C and D funded recipients of record; state, local, and tribal governments, including health departments; institutions of higher education; and non-profit organizations, including community-based, faith-based, and tribal organizations, involved in addressing HIV/AIDS related issues at the state, regional, or national level. See Section III-1 of this notice of funding opportunity (NOFO), formerly known as the funding opportunity announcement (FOA) 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. A short video explaining the *Application Guide* is available at http://www.hrsa.gov/grants/apply/applicationguide/.

Technical Assistance

All interested applicants are encouraged to participate in a technical assistance (TA) webinar for this funding opportunity. The TA webinar is scheduled for July 6, 2017 from 12:30 – 2:30 pm Eastern Time. The purpose of this webinar is to assist potential applicants in preparing applications that address the requirements of this funding announcement. Participation in a pre-application TA webinar is optional.

Dial-in Phone Number: 888-469-2188
Passcode: 4237790

To access the webinar online, go to the Adobe Connect URL:
https://hrsa.connectsolutions.com/hrsa-17-047/

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I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for the Secretary's Minority AIDS Initiative Fund (SMAIF) fiscal year (FY) 2017 *Curing Hepatitis C among People of Color Living with HIV* program. This multi-pronged initiative will support up to two (2) recipients to improve the prevention, care, treatment, and cure of hepatitis C (HCV) in areas affected by HIV/HCV coinfection among low-income, underinsured, or uninsured racial and ethnic minority populations.

Components of the initiative will include:

- Expansion of HCV prevention (including education), testing, care (including preventive health care), and treatment capacity among RWHAP-funded clinics, HRSA and Medicare-certified Federally Qualified Health Centers (FQHCs),[1] and SAMHSA-funded community-based substance use disorder (SUD) and behavioral health treatment providers that predominantly serve people of color living with both HIV and HCV;
- Improved coordination of linkage to and retention in care and treatment for people who are co-infected with HIV/HCV;
- Improved coordination with SAMHSA-funded SUD treatment providers to expand the delivery of behavioral health and substance use treatment support to achieve treatment completion and to prevent HCV infection and re-infection; and
- Enhancement of health department surveillance systems to increase their capacity to monitor acute and chronic coinfections of HIV and HCV in areas affected by HIV/HCV coinfection among low-income, underinsured, or uninsured racial and ethnic minority populations, and to enable an HCV Data to Care capacity.[2]

You must provide evidence of HIV/HCV coinfection among low-income, underinsured, or uninsured racial/ethnic minority populations and demonstrate your ability to access people living with HIV (PLWH) who are also living with or at risk for acquiring HCV infection. Populations of interest include racial and ethnic minorities living with HIV who have demonstrated a high prevalence of HCV, including, but not limited to, people who use drugs (PWUD), especially people who inject drugs (PWID); men who have sex with men (MSM); high-risk heterosexuals; and transgender persons.

During the first year of the initiative, recipients will develop a plan that, based on local needs, will coordinate the implementation of multiple strategies to increase the number of people living with HIV and HCV in their service area who are screened, diagnosed, linked to care, treated, and cured of HCV. This project planning and development phase will be followed by two (2) years of implementation.

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[1] See https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/fqhcfactsheet.pdf

[2] See https://effectiveinterventions.cdc.gov/en/highimpactprevention/publichealthstrategies/DatatoCare.aspx

Recipients will be expected to partner with and provide annual subawards to clinical sites seeking to improve their capacity to treat HIV/HCV coinfection among low-income, underinsured, or uninsured racial/ethnic minority populations. Applicants should propose how they will work with subrecipients to increase capacity in the following areas:

- Provision of HIV/HCV coinfection care and treatment according to the HHS guidelines;
- Provision of HIV/HCV medication adherence support;
- Performance of necessary lab testing, referrals for liver biopsy and other staging procedures; and
- Provision of prevention education about HCV infection and re-infection.

Subrecipient clinics will be expected to conduct targeted outreach to include low-income, underinsured, or uninsured out of care (OOC) people living with both HIV and HCV; contact tracing; and development of their own HCV/HIV multidisciplinary teams. Strategies for collaboration between recipients and clinics may include case conferences, sharing OOC lists, and shared training events.

Please note that you may not use funds for the purchase of medications to treat HCV. Therefore, participating providers must have adequate access to direct acting antivirals (DAA) medications through other existing funding mechanisms and/or payor sources.

Recipients will also be expected to partner (which may include providing subawards) with SUD and mental health treatment provider(s) in the service communities of each of the clinical sites, if these services are not available at the clinical sites. You should propose how you will accomplish the following activities:

- Formation of partnerships (which may include providing subawards) with local SUD and mental health treatment provider(s) to build their capacity to provide integrated care and to enable bidirectional client referrals for appropriate HIV/HCV and SUD treatment;
- Linkage of clients of clinical sites who screen positive for SUDs into SUD treatment, either at the clinical site or at the partnering agency;
- Linkage of clients in SUD and mental health treatment who test or are identified as living with HIV and HCV and who are out of care to the clinical site for treatment;
- Provision of interventions by clinical sites working with SUD and mental health treatment providers to clients living with HIV and HCV with SUDs to prevent overdose and re-infection (including referrals to syringe services programs, or SSPs); and
- Provision of referrals to community education programs, including those which address the benefits of access to medication-assisted treatment (MAT) and SSPs.

Please note that funds from this initiative may be used by recipients to make subawards to accomplish any or all of the activities outlined above. Partnership agreements and/or subawards with either clinical sites or SUD providers should be established expeditiously in order to accomplish the goals of the project in the time period.

Recipients will also be expected to deliver training to HCV care providers at the clinical sites. You should propose how you will accomplish the following activities:

- Training of providers through the use of a curriculum and provider competencies developed by the AIDS Education Training Center (AETC) National Coordinating Resource Center;
- Collaboration (which may include subawards) with their Regional AETC;
- Collaboration (which may include subawards) with their Local Performance Site (LPS), if applicable, and;
- Support of practice transformation and other HIV/HCV – specific workforce development activities for all entities within the formal partnership of the recipient and all of their subrecipients/subawardees.

Please note that recipients will also be expected to partner (which may include subawards) with their state, local, or tribal health department to improve surveillance of HCV coinfection among PLWH in areas of high populations of racial/ethnic minorities, including people of color. Similar to HIV Data to Care efforts, the enhanced surveillance data systems will enable the use of HCV surveillance data to identify HCV-diagnosed PLWH in areas of high populations of racial/ethnic minorities, including people of color, who are not in care, and link them directly to care. Health departments will also play a critical role in facilitating the collection of HCV-related data required by the initiative.

Recipients will also be expected to work closely with a technical assistance and evaluation team (funded separately by HRSA/HAB) to demonstrate outcomes and disseminate findings, best practices and lessons learned. Recipients will be required to collect and report data on the extent of knowledge among HIV and HCV coinfected patients regarding HCV treatment; and of health care providers regarding HCV screening and treatment. Applicants who have previously collected these data should indicate such and provide the results. Applicants that have not previously collected these data will be required to conduct rapid assessments using existing instruments previously developed by the evaluation team. With the assistance of the technical assistance and evaluation team, recipients must submit these instruments to their Institutional Review Board (IRB) for review and approval within two months of award. The two knowledge assessments must be completed in the first nine months of year one, and will be used to identify gaps among consumers to be addressed by implementing educational programs; and to address provider training needs in their areas. During the first year of the initiative, recipients will be expected to develop a detailed project implementation plan to enhance their service area's public health infrastructure that will result in increased prevention, screening, care, treatment, and cure of HCV in people living with HIV, targeted to people of color. Subsequently, recipients shall implement their plans to expand their area's capacity to provide HCV screening, care, and treatment to people who are living with HIV and HCV, targeted to people of color. In year three, recipients will also be expected to work collaboratively with the evaluation team in the production of a project monograph and other publication and dissemination activities to document the findings, best practices, and lessons learned from this demonstration project initiative.

At the end of the three-year project period, recipients will have implemented effective, comprehensive, area-wide HCV screening, care, and treatment systems leading to demonstrable improvements in HCV care outcomes among people living with HIV and

HCV, including people of color. Recipients also will be expected to work with their partners and/or subrecipients to fully integrate their HCV screening, care, and treatment systems into their ongoing program efforts, clinical practice, and fiscal and administrative planning for their continuous operation and maintenance beyond the three-year funded project period.

2. Background

This initiative is funded through the Secretary's Minority AIDS Initiative Fund (SMAIF) as authorized under the Consolidated Appropriations Act, 2017 (P.L. 115-31), Division H, Title II. This initiative is administered by HRSA/HAB Office of Training and Capacity Development. This funding opportunity initiative represents a collaborative effort between HRSA/HAB, HRSA/Bureau of Primary Health Care, SAMSHA, Indian Health Service, and the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP). These federal partners will continue to collaborate and monitor the progress of this initiative.

Although HIV treatment outcomes continue to improve among PLWH including those of color,[3,4,5] HCV coinfection has emerged as a major concern, with approximately one quarter of PLWH also living with HCV.[6] PLWH who are coinfected with HCV have higher liver-related morbidity and mortality, even when their HIV infection is well controlled, and liver disease has become one of the most common causes of non-AIDS deaths among PLWH.[7,8] HCV monoinfection in the United States has been found to disproportionately affect racial and ethnic minorities, particularly African Americans, Latinos/as, and American Indians/Alaska Natives.[9,10] People of color who are most at risk for HIV and HCV coinfection include, but are not limited to, PWID, MSM; high-risk

[3] Doshi RK, Milberg J, Jumento T, Matthews T, Dempsey A, & Cheever LW. For Many Served By The Ryan White HIV/AIDS Program, Disparities In Viral Suppression Decreased, 2010-14. *Health Affairs*, January 1, 2017; 36 (1): 116-123.
[4] Bradley H, Viall AH, Wortley PM, Dempsey A, Hauck H, & Skarbinski J. Ryan White HIV/AIDS Program Assistance and HIV Treatment Outcomes. *Clinical Infectious Diseases*, January 1, 2016; 62 (1): 90-8.
[5] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2015. HIV/AIDS Bureau, HRSA, December 2016. Accessed 1-23-17 from: http://hab.hrsa.gov/sites/default/files/hab/data/datareports/2015rwhapdatareport.pdf
[6] CDC. HIV and Viral Hepatitis. Factsheet, June 2016. Accessed 1-23-16 from: http://www.cdc.gov/hiv/pdf/library/factsheets/hiv-viral-hepatitis.pdf
[7] Ragni MV and Belle SH. Impact of human immunodeficiency virus infection on progression to end-stage liver disease in individuals with hemophilia and hepatitis C virus infection. *Journal of Infectious Diseases, April 1, 2001; 183 (7): 1112-1115.*
[8] Weber R, Sabin CA, Friis-Møller N, et al. Liver-related deaths in persons infected with the human immunodeficiency virus: the D:A:D study. *Archives of Internal Medicine,* August 2006; 166 (15): 1632-1641.
[9] CDC. HIV and Viral Hepatitis. Factsheet, June 2016. Accessed 9-7-16 from: http://www.cdc.gov/hiv/pdf/library/factsheets/hiv-viral-hepatitis.pdf
[10] Liu G, Holmberg SD, Kamili S, & Xu F. Racial disparities in the proportion of current, unresolved hepatitis C virus infections in the United States, 2003-2010. *Digestive Diseases and Sciences*, August 2014; 59 (8): 1950-1957.

heterosexuals and transgender persons.[11,12,13]

Several highly effective medications are available to treat and cure HCV in PLWH with minimal side effects.[14,15] Unlike previous treatments, which were less effective in PLWH who were also living with HCV compared with HCV monoinfected persons, the newer medications have been shown to be equally effective in curing HCV in both HIV co-infected and HCV monoinfected persons. However, despite these advances in treatment, only a small percentage of HCV-infected patients have received treatment.[16] Structural barriers to increased treatment uptake include the high cost of these newer treatments, a lack of providers trained and willing to treat HCV, and health care systems that do not support treatment and follow-up of HCV.[17] Patient-level barriers have included continuing substance use, mental health disorders, and unstable housing.[18] Like the HIV care continuum, HCV care continuum models provide a framework to understand a public health and health care systems approach by quantifying the numbers of persons living with HCV, diagnosed, referred for treatment, treated, and cured.[19,20,21,22]

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[11] Spradling PR, Richardson JT, Buchacz K, Moorman AC, Finelli L, Bell BP, Brooks JT and the HIV Outpatient Study Investigators. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996-2007. *Journal of Acquired Immune Deficiency Syndromes*, March 1, 2010; 53 (3): 388-396.

[12] CDC. Viral Hepatitis Surveillance – United States, 2014. Accessed 9-8-16 from: http://www.cdc.gov/hepatitis/statistics/2014surveillance/pdfs/2014hepsurveillancerpt.pdf

[13] Nuttbrock L, Hwahng S, Bockting W, Rosenblum A, Mason M, Macri M, & Becker J. Lifetime Risk Factors for HIV/Sexually Transmitted Infections Among Male-to-Female Transgender Persons. *Journal of Acquired Immune Deficiency Syndromes*, November 1, 2009; 52 (3): 417-421.

[14] Zopf S, Kremer AE, Neurath MF, & Siebler J. Advances in hepatitis C therapy: What is the current state - what come's next? *World Journal of Hepatology*, January 28, 2016; 8 (3): 139-147.

[15] HHS Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents. Department of Health and Human Services. Updated July 14, 2016, and accessed 1-24-17 from: https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.

[16] Cope R, Glowa T, Faulds S, McMahon D, Prasad R. Treating Hepatitis C in a Ryan White-Funded HIV Clinic: Has the Treatment Uptake Improved in the Interferon-Free Directly Active Antiviral Era? *AIDS Patient Care and STDs*, February 2016; 30 (2): 51-55.

[17] Grebely J, Oser M, Taylor LE, Dore GJ. Breaking down the barriers to hepatitis C virus (HCV) treatment among individuals with HCV/HIV coinfection: action required at the system, provider, and patient levels. *Journal of Infectious Diseases*, March 2013; 207 (Supplement 1): S19-S25.

[18] Cachay ER, Wyles D, Hill L, Ballard C, Torriani F, Colwell B, Kuo A, Schooley R, & Mathews CW. The Impact of Direct-Acting Antivirals in the Hepatitis C-Sustained Viral Response in Human Immunodeficiency Virus-Infected Patients With Ongoing Barriers to Care. *Open Forum Infectious Diseases*, e-published Nov 12, 2015; 2 (4): ofv168.

[19] Cachay ER, Hill L, Wyles D, Colwell B, Ballard C, Torriani F, & Mathews WC. The hepatitis C cascade of care among HIV infected patients: a call to address ongoing barriers to care. *PloS One*, e-published July 18, 2014.

[20] Yehia BR, Schranz AJ, Umscheid CA, Lo Re V, 3rd. The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and meta-analysis. *PloS One*, July 2, 2014; 9 (7): e101554.

[21] Holmberg SD, Spradling PR, Moorman AC, Denniston MM. Hepatitis C in the United States. *The New England Journal of Medicine*, May 16, 2013; 368 (20): 1859-1861.

[22] North CS, Hong BA, Adewuyi SA, et al. Hepatitis C treatment and SVR: the gap between clinical trials and real-world treatment aspirations. *General Hospital Psychiatry*, March-April 2013; 35 (2): 122-128.

This initiative is informed by and supports the goals of the National Viral Hepatitis Action Plan.[23] Further, this SMAIF initiative aligns with the national goals to end the HIV epidemic by increasing access to care and optimizing health outcomes for PLWH.

Goals to End the HIV Epidemic

To the extent possible, program activities should strive to support four goals to end the HIV epidemic:

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

To achieve these goals, recipients should take action to align their organization's efforts, within the parameters of the RWHAP statute and program guidance around the following areas of critical focus:

- Widespread testing and linkage to care, enabling PLWH to access treatment early;
- Broad support for PLWH to remain engaged in comprehensive care, including support for treatment adherence; and
- Universal viral suppression among PLWH.

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 substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

HRSA programmatic involvement will include:

- Provision of experienced HRSA/HAB personnel as participants in the planning, development, management, and technical performance of all phases of the project;
- Provision of ongoing review of documents, activities, and procedures to be developed and implemented for accomplishing the goals of the cooperative agreement, including project information prior to its dissemination;
- Participation in relevant conference calls, meetings, and site visits to be conducted during the period of the cooperative agreement;

[23] Office of HIV/AIDS and Infectious Disease Policy. U.S. National Viral Hepatitis Action Plan for 2017-2020. OHAIDP, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services. Accessed 3-21-17 from: https://www.hhs.gov/sites/default/files/National%20Viral%20Hepatitis%20Action%20Plan%202017-2020.pdf?language=en

- Provision of information resources and facilitation of partnerships and communication with subrecipients, the evaluation and technical assistance provider, Regional AETC/LPS, state, local, and tribal health departments, and other stakeholders; and
- Participation in the dissemination of project findings, best practices, and lessons learned.

In collaboration with HRSA, the cooperative agreement recipient's responsibilities will include:

- Lead and coordinate all project-related activities including those performed by subrecipients and partners (described later in the announcement);
- Select and fund subrecipient HIV/HCV clinical sites to improve their capacity to treat HIV/HCV coinfection in areas of high populations of racial/ethnic minorities, including people of color;
- Work with the subrecipient HIV/HCV clinical sites in the development of sustainable approaches to increase access to HCV care and treatment, including medications, for people living with HIV and HCV, targeted to people of color;
- Employ collaborative strategies with the subrecipient HIV/HCV clinics to include case conferences, the sharing of OOC lists, and shared training events;
- Work collaboratively with the subrecipient Regional AETC/LPS to coordinate provider training, practice transformation and other HIV/HCV – specific workforce development activities for all entities within the formal partnership;
- If necessary, enter into agreements with local SUD and mental health treatment provider(s) in the service communities of the subrecipient clinical sites;
- Work collaboratively with the SUD and mental health treatment provider(s) to build the capacity of subrecipient clinical sites to provide integrated care and to develop bidirectional linkages into appropriate care and treatment for HIV/HCV, SUD and mental health issues, and to prevent overdose and re-infection due to SUD;
- Provide support through subawards, staffing support, or other agreements to their state, local, or tribal health department to improve the surveillance of acute and chronic coinfections of HIV and HCV in areas of high populations of low-income, underinsured, or uninsured racial and ethnic minorities in their jurisdiction;
- Work collaboratively with the state or local health department or tribal epidemiology center to enable the use of HCV surveillance data to identify HCV-diagnosed people living with HIV who are not in care, and link them directly to care;
- Work collaboratively with the state or local health department or tribal epidemiology center to collect and report relevant outcome data to the evaluation and technical assistance team funded separately. Surveillance systems should capture all acute and chronic HIV/HCV coinfections, but recipients will report on data regarding racial/ethnic minorities. Evaluation measures will include, at a minimum, the collection of data and reporting for these outcomes:
  - Number of people living with HIV in the area screened for HCV infection
  - Number of people living with HIV in the area who have chronic HCV infection

- Number of people living with HIV and HCV in the area who have been linked to an HCV provider (i.e., attended an initial visit with HCV medication prescriber)
- Number of people living with HIV and HCV in the area who have been prescribed HCV treatment (DAA medications). Please note that for the purposes of this announcement, eligible DAAs include DAAs that are approved by the U.S. Food and Drug Administration (FDA) for treatment of HCV.
- Number of people living with HIV and HCV in the area who have been cured of HCV (i.e., achieved sustained virologic response in accordance with HCV treatment guidelines)

Additional outcome data that may be included in the evaluation include but are not limited to:

- Number of people living with HIV and HCV in the area with positive HCV antibody tests who had HCV RNA checked (confirmatory test for chronic HCV infection)
- Number of people living with HIV and HCV in the area who have had appropriate disease staging done, in accordance with HCV treatment guidelines (i.e., fibrosis score check, genotype)

- Work closely with an evaluation and technical assistance team in the production of a project monograph, and participate in publication and dissemination efforts of the initiative's findings, best practices, and lessons learned;
- Attend annual meetings of the initiative to be held in the Washington, DC area;
- Work collaboratively with the HIV/HCV clinical sites in planning for program integration to assure the continuous operation and maintenance of the comprehensive HCV screening, care, and treatment system beyond the three year funded project period. For the purposes of this NOFO, program integration is defined as an explicit commitment to plan for the incorporation of HCV screening, and care and treatment system components into ongoing clinical practice, and fiscal and administrative planning for continuous operation and maintenance beyond the three-year funded project period; and
- Adherence to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds, per Section 2.2 of the Application Guide (**Acknowledgement of Federal Funding**).

2. Summary of Funding

Approximately $5,000,000 is expected to be available annually to fund up to two (2) recipients. You may apply for a ceiling amount of up to $2,500,000 total cost (includes both direct and indirect/facilities and administrative costs) per year. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds awarded in a timely manner.

Applicants should note that the annual award amount includes up to $1,825,000 to support:

- Subawards or agreements to subrecipient clinical sites to expand their capacity to provide HCV screening, laboratory testing, care and treatment, patient education, and other HCV-related services to areas with high populations of low-income, underinsured, or uninsured racial/ethnic minorities living with HIV and HCV;
- Subawards or agreements with local SUD and mental health treatment provider(s) in the service communities of the funded clinical sites;
- Subawards or agreements to the recipient's Regional AETC; and
- Subawards, staffing support, or other agreements to the recipient's state or local health department to improve surveillance of HCV status in areas of high populations of racial/ethnic minorities, including people of color living with HIV and HCV.

The project period is September 30, 2017 through September 29, 2020 (three (3) years). Funding beyond the first year is dependent on the availability of appropriated funds for the *Curing Hepatitis C among People of Color Living with HIV* 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 45 CFR part 75.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include RWHAP Parts A, B, C and D funded recipients of record; state, local, and tribal governments, including health departments; institutions of higher education; and domestic public or private, nonprofit organizations, including community-based, faith-based, and tribal organizations, involved in addressing HIV/AIDS-related issues among people of color at the state, regional, or national level.

Foreign entities are not eligible to apply.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

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

HRSA will consider any application that fails to satisfy the deadline requirements referenced in *Section IV.4* non-responsive and will not consider them for funding under this announcement.

NOTE: HRSA will not allow multiple applications from an organization.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates), you submit an application 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*** applicants for this NOFO to apply electronically through Grants.gov. You must download the SF-424 application package associated with this NOFO following the directions provided at https://www.grants.gov/applicants/apply-for-grants.html.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page, and when downloading the notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) or application package. This allows Grants.gov to email organizations that supply an email address in the event the NOFO is changed and/or republished on Grants.gov before its closing date. Responding to an earlier version of a modified announcement may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the Find Grant Opportunities 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. Applications must be submitted in the English language and must be 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 application package do not count in the page limitation. HRSA will not count in the page limitation your Indirect Cost Rate Agreement and proof of non-profit status (if applicable). **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 the announcement.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is 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 the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachment 9, Other Relevant Documents.

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

Program-Specific Instructions

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

i. Project Abstract

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

ii. Project Narrative

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

Use the following section headers for the Narrative:

- *INTRODUCTION – Corresponds to Section V's Review Criterion 1 (Need)*
  Provide a clear and succinct description and purpose of the proposed project. Briefly describe your organization and any collaborators, excluding potential subawardees.

- *NEEDS ASSESSMENT – Corresponds to Section V's Review Criterion 1 (Need)*
  Provide a description of the existing HCV epidemiological profile of your service area, using the most recent, available surveillance, screening, and treatment data. Provide an estimate of people of color who are living with HIV and HCV in your area, based upon local data (if available) or from national estimates, and clearly identify the data sources and methods used to calculate this estimate. Identify the target population(s) among people living with HIV and HCV for your project in your area.

Provide a description of the existing HCV screening, referral, and treatment systems for PLWH in your area. Identify relevant organizations and their roles in providing screening, referral, and treatment, and numerically estimate patient capacity of care and social service providers engaged in these activities. Identify any salient or previously identified service gaps and unmet needs with regard to HCV screening activities, referral procedures, treatment provision, patient education, provider education, and SUD and mental health treatment in the area. Briefly discuss the extent and depth of provider knowledge regarding HCV screening and treatment in your area. Describe state, local, and tribal laws and third-party payer policies such as insurance restrictions based upon provider type and HCV stage, that affect coverage of the costs of HCV screening and treatment in your area.

- *METHODOLOGY – Corresponds to Section V's Review Criteria 2 (Response) and 4 (Impact)*
  Describe your plan for the selection of an adequate number of clinical sites seeking to improve their capacity to treat HIV/HCV coinfection among low-income, underinsured, or uninsured racial/ethnic minority populations. Your plan should respond to the program expectations set forth in Section I of this NOFO and the following programmatic requirements:

  1) Conduct increased, targeted HCV screening among PLWH through education, outreach and in-reach to clinical settings to reach PLWH living with and at high risk of HCV infection;
  2) Perform necessary HCV laboratory testing, liver biopsy and other staging procedures for identified people living with HIV and HCV;
  3) Treat and cure HCV among people living with HIV and HCV through the enhanced provision of care and treatment; establishment of effective treatment referral models using case management and patient navigation; support for navigation of the payer systems in place in order to obtain HCV medications and treatment for patients, to include working with payers who may have restrictions on the type of provider who can treat HCV; and other approaches to address insurance restrictions and reauthorizations that limit access to HCV treatment;
  4) Provide enhanced HCV medication adherence support for people living with HIV and HCV. This may include, but is not limited to, directly observed therapy for those who are at risk of not completing HCV treatment.
  5) Provide patient education regarding the prevention of HCV infection and re-infection, and the benefits of access to care and treatment for HCV;
  6) Conduct targeted outreach to include people of color living with HIV and HCV who are OOC;
  7) Conduct partner notification;
  8) Screen and link appropriate clients with current SUDs or SUD histories to SUD and mental health treatment providers for prevention of overdose and re-infection interventions, including referrals to medication-assisted treatment (MAT) and syringe services programs (SSPs);
  9) Provide education and appropriate resources to SUD and mental health treatment providers to help engage and re-engage people living with HIV and

HCV about HIV and HCV care and treatment (such outreach efforts may be targeted to people of color);
10) Work with the recipient and Regional AETCs to develop their own multidisciplinary teams to effectively manage and cure HCV infection;
11) Submit the evaluation protocol, other instruments, and informed consent to an IRB, in order to collect and report data as described later in this announcement to the recipient and the evaluation team; and
12) Collect and report relevant outcome data to the recipient.

The plan should also demonstrate your ability to issue subawards or establish agreements with all clinical sites during the last quarter of the first year of the project period.

Unless SUD and mental health treatment services are co-located at the funded clinical sites, describe your plan to engage provider(s) of these services in the communities of each of the funded clinical sites. Your plan should respond to the program expectations set forth in Section I of this NOFO, and the following required activities:

1) Build the capacity of the clinical sites to provide integrated care through the expansion of SUD and mental health treatment to people living with HIV and HCV with active SUDs, targeted to people of color, or provide SUD treatment and mental health care to clients who are referred by the clinical sites for MAT and other addiction therapy;
2) Link appropriate clients who test or are identified as people living with HIV and HCV and who are out of care to the HIV/HCV primary care subrecipient;
3) Provide prevention of overdose and re-infection interventions including MAT and referrals to SSPs; and
4) Conduct community education programs on the benefits of access to MAT and SSPs.

The plan should also demonstrate your ability to enter into agreements and/or subawards with SUD and mental health treatment provider(s) during the first year of the project period.

Describe your plan to issue annual subawards to either your Regional AETC or one of its LPSs. Your plan should respond to the program expectations set forth in Section I of this NOFO, and the following required activities:

1) Conduct provider training in HCV prevention, care, and treatment for people living with HIV and HCV, targeted to people of color, for the subawarded clinical sites. This will include the identification of HCV care and treatment providers (physicians, nurse practitioners, physician assistants, nurses, pharmacists, and behavioral health staff) who care for people living with HIV and HCV. The Regional AETC shall use a curriculum and provider competencies developed by the AETC National Coordinating Resource Center. This component will also include the implementation by the Regional AETC/LPS of an area-wide Community of Practice and Learning (CPL) for HCV care and treatment providers with distance-based videoconferencing capabilities to advance the knowledge of existing providers and expand the provider pool in the area. The

CPL will be a primary means of training and capacity building among providers of HCV screening, care and treatment;

2) Increase clinical site capacity and efficiency to treat HCV among people living with HIV and HCV, targeted to people of color. This includes providing a comprehensive longitudinal training approach incorporating clinical practice transformation strategies as needed, such as task shifting; staff restructuring; integration of community health workers and patient navigators into the medical team; inter-professional team-based practice coordination or co-management; and other strategies to optimize human resources, reduce costs, and improve health outcomes; and
3) Support the clinical sites in the development of their multidisciplinary teams through coaching, mentoring, and training.

Describe your plan to provide annual support through subawards, staffing support, or other agreements to your state or local health department to improve the surveillance of HCV status among PLWH in your jurisdiction. Your plan must be responsive to the program expectations included in Section I of this NOFO.

The plan should also demonstrate your ability to enter into agreements and/or subawards with your state or local health department by the end of the second quarter of year 1.

Describe your organizational process for the management of subawards to be issued under this cooperative agreement. Include a description of your subaward process from initiation to approval, with the corresponding criteria for selection of jurisdictions, types of interventions/models to be supported and subrecipient sites to be provided subawards, and your timeline for procurements. Describe the methodology for monitoring the performance sites including, among other items, the submission of invoices and reimbursement for services in a timely manner.

Describe a possible sampling frame for the rapid assessment of HCV patient knowledge regarding HCV treatment among people living with HIV and HCV, targeted to people of color, in your area, identifying participating clinics and/or target populations. Describe a possible sampling frame for the rapid assessment of knowledge gaps and training needs of health care providers regarding HCV screening and treatment in your area, identifying participating clinics and professional provider levels. If you have previously collected these data, indicate such and provide the results. If you have not previously collected these data, you will be required to conduct rapid assessments using existing instruments previously developed by the evaluation team. The instruments for these knowledge assessments are available online at https://careacttarget.org/library/hepatitis-c-knowledge-assessment-tools, and both assessments must be completed in the first nine months of year one. With the assistance of the technical assistance and evaluation team, funded separately by HRSA/HAB, recipients must submit these instruments to their IRB for review and approval within two months of award.

Provide a detailed outline of a project implementation plan specific to your area for a comprehensive project to expand HCV screening, care and treatment among

people living with HIV and HCV. The outline will form the basis for a complete project implementation plan and will address any gaps identified by the needs assessment of the program narrative. After completion of the patient and provider knowledge assessments, the project implementation plan may be revised based on the results." The aim of the plan is to achieve an effective, comprehensive, area-wide HCV screening, care and treatment system leading to demonstrable improvements in health outcomes among people living with HIV and HCV by the end of the three-year project period.

The plan should also demonstrate your ability to complete the project implementation plan during year one (1) and should include, at a minimum, the required components/activities performed by the respective agencies outlined above.

- *WORK PLAN – Corresponds to Section V's Review Criterion 2 (Response)*
  Provide a work plan describing the steps used to achieve each of the activities proposed during the project period in the methodology section. The work plan must adhere to key activity due dates as specified earlier in the program narrative instructions. The work plan should be time-framed with specific dates to actively manage the project by measuring progress and quantifying accomplishments. In chronological order, list the major tasks and activities to be performed during the project period. Identify proposed staff members (supported by the cooperative agreement and provided in-kind) responsible for each activity. The work plan should be presented in a table format and include (1) goals; (2) objectives that are specific, measurable, attainable, reasonable and time-framed; (3) action steps; (4) staff responsible for each action step; and (5) anticipated dates of completion.

  Please note that goals for the work plan are to be written for the entire three (3) year project period, but objectives and action steps are required only for the goals set for year one. The work plan must be included as **Attachment 1**.

- *RESOLUTION OF CHALLENGES – Corresponds to Section V's Review Criterion 2 (Response)*
  Discuss any challenges (organizational, administrative, financial, regulatory, legislative, technological and human-related) that you are likely to encounter in implementing the proposed project. Discuss the approaches that you will use to resolve such challenges.

- *EVALUATION AND TECHNICAL ASSISTANCE CAPACITY -- Corresponds to Section V's Review Criteria 3 (Evaluative Measures) and 5 (Resources/Capabilities)*
  Describe your capacity to collect and report to the evaluation team on a timely, regular basis the following outcomes within your area:
  1) Number of people living with HIV in the area screened for HCV infection
  2) Number of people living with HIV in the area who have chronic HCV infection
  3) Number of people living with HIV and HCV in the area who have been linked to an HCV provider (i.e., attended initial visit with HCV medication prescriber)
  4) Number of people living with HIV and HCV in the area who have been prescribed HCV treatment (DAA medications)

5) Number of people living with HIV and HCV in the area who have been cured of HCV (i.e., achieved sustained virologic response in accordance with HCV treatment guidelines).[24]
6) Number of people living with HIV in the area with positive HCV antibody tests who had HCV RNA checked (confirmation of chronic HCV infection)
7) Number of people living with HIV and HCV in the area who have had appropriate disease staging done, in accordance with HCV treatment guidelines (i.e., fibrosis score check, genotype)

Surveillance systems should capture all acute and chronic HIV/HCV coinfections, but recipients for this project will report on data regarding racial/ethnic minorities.

Describe how the proposed key project personnel (including any consultants and contractors) have the necessary knowledge, experience, training and skills in designing, implementing, and evaluating public health programs. Describe the experience of proposed key project personnel (including any consultants and contractors) in writing and publishing study findings in peer-reviewed journals and in disseminating findings to local communities, national conferences and to policy makers. Describe any training in human subjects' research protection by proposed key project staff. Identify the Institutional Review Board that will review the evaluation protocol, client-level data collection instruments and consent forms to be used by the evaluation team. Please note that proof of IRB approvals and renewals for all client-level data collection instruments, informed consents, and evaluation materials must be submitted to the evaluation team on an annual basis. Describe your plan to safeguard the privacy and confidentiality of study participants, and the documented procedures for the electronic and physical protection of patient information and data, in accordance with Health Insurance Portability and Accountability Act (HIPAA) regulations and human subjects research protections. Describe how you will collaborate with the evaluation team in the production of a project monograph, and participate in publication and dissemination efforts of the initiative's findings.

ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion 5 (Resources/Capabilities)
Provide information on your organization's current structure and scope of current activities. Describe how these contribute to the ability of the organization to conduct the program requirements and meet program expectations. Describe how you will leverage your organization's existing agreements with HIV clinical and support service providers including outpatient ambulatory medical care, medical case management and other care coordination services for implementation of the proposed project for an area-wide, comprehensive, HCV screening, care and treatment project. Provide a one-page figure that depicts the organizational structure of the project, including collaborating organizations, subrecipients, contractors and other significant collaborators as **Attachment 6**. Do not provide a standard organization chart for the entire organization.

[24] See American Association for the Study of Liver Diseases- Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C at: www.hcvguidelines.org

If applicable, describe the roles and responsibilities of any consultants and/or contractors that will be used to implement the proposed project. Any current and/or proposed collaborating organizations, consultants and/or contractors must demonstrate their commitment to fulfill the goals and objectives of the project through signed and dated letters of support or memoranda of agreement or understanding. Include any such letters or memoranda, and descriptions of any existing or proposed contracts relating to the proposed project, as **Attachment 5**.

Reminder: you may not use funds for the purchase of medications to treat HCV. Therefore, you must indicate that participating providers have adequate access to the DAA medications listed previously in this announcement through the State AIDS Drug Assistance Program (ADAP)'s formulary or Local Pharmacy Assistance Program; third party payers including insurance plans; Medicaid or Medicare programs; or pharmaceutical company patient assistance programs.

NARRATIVE GUIDANCE

In order to ensure that the review criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

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

iii. Budget

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

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-

supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost-sharing requirement, as applicable.

In addition, the *Curing Hepatitis C among People of Color Living with HIV* program requires the following: separate line item budgets for each year of the three (3) year project period as a single spreadsheet table, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs as appropriate. See **Attachment 7**, below for additional information.

Your application budget should include any subawards, staff support, or other agreements during the project period to:

- Clinical sites;
- SUD and mental health treatment provider(s);
- Regional AETC or LPS over the three year initiative; and
- State and local health departments for improved surveillance of HCV status among PLWH in your area.

Also include travel costs for three (3) key project staff members to attend the annual working meetings, to be held in the Washington, DC area.

The Consolidated Appropriations Act, 2017 (P.L. 115-31), Division H, § 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." As of January 8, 2017, the Executive Level II salary limitation is now $187,000 (formerly $185,100). Please 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 will apply in FY 2018, as required by law.

iv. Budget Justification Narrative

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

v. Attachments

Please 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. **Each attachment must be clearly labeled**.

Attachment 1: Work Plan (required)

The work plan should include clearly written (1) goals; (2) objectives that are specific, measurable, attainable, reasonable, and time-framed; (3) action steps; (4) staff responsible for each action step (including consultants); and (5) anticipated dates of completion. Please note that goals for the work plan are to be written for the entire three-year project period, but objectives and action steps are required only for the goals set for year one.

Attachment 2: Staffing Plan *(see Section 4.1.vi of* HRSA's *SF-424 Application Guide) **(required)***

Attachment 3: Job Descriptions for Key Personnel (required)

Include succinct descriptions of the role, responsibilities, and qualifications of proposed project staff listed in in **Attachment 2**. Keep each job description to one paragraph in length as much as is possible.

Attachment 4: Biographical Sketches of Key Personnel (required)

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

Attachment 5: Project-specific Letters and Memoranda of Agreement/ Understanding and/or Description(s) of Proposed/Existing Contracts (required).

Provide any documents that describe working relationships between the applicant organization and other entities and programs cited in the proposal. Provide memorandum of agreement/understanding or letter of support from the Regional AETC with whom you will work for the provision of provider training and other workforce capacity development activities. If you are not a RWHAP Part A or B recipient, provide a memorandum of agreement/understanding or letter of support from the health department in your area with which you will work to improve surveillance of acute and chronic coinfections of HIV and HCV in areas of high populations of low-income, underinsured, or uninsured racial and ethnic minorities people living with HIV and HCV. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the contractors and any deliverables. Memoranda of agreement/understanding and letters of support agreement must be signed and dated.

Attachment 6: Project Organizational Chart (required)

Provide a one-page figure that depicts the organizational structure of the project, including collaborating organizations, subrecipients, contractors and other significant collaborators. Do <u>not</u> provide a standard organization chart for the entire organization.

Attachment 7: Line Item Budgets Spreadsheet for Years 1 through 3 (required)

Submit line item budgets for each year of the proposed project period, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs. Proposed budgets may not include the costs of medications used to treat HCV.

Attachment 8: indirect Cost Rate Agreement (Required, if applicable)

If indirect costs using a negotiated rate are included in the budget, please attach a copy of your organization's indirect cost rate agreement. Indirect cost rate agreements will not count toward the page limit.

Attachments 9 – 15: Other Relevant Documents (optional)

Include here any other documents that are relevant to the application.

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 (https://www.grants.gov/)

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

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 ***July 28, 2017 at 11:59 p.m. Eastern Time***.

See Section 8.2.5 – Summary of e-mails from Grants.gov of HRSA's *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

The *Curing Hepatitis C among People of Color Living with HIV* program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100. See Executive Order 12372 in the HHS Grants Policy Statement.

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

6. Funding Restrictions

You may request funding for a project period of up to three (3) years, at no more than $2,500,000 per year. Funding 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.

Funds under this announcement may not be used for the following purposes:

1) 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);
2) Purchase of HCV medications;
3) HIV testing;
4) Purchase or construction of new facilities or capital improvements to existing facilities;
5) Purchase or improvement to land;
6) Purchase of vehicles;
7) Syringe services programs (SSPs). Some aspects of SSPs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy;[25]
8) Fundraising expenses;
9) Lobbying activities and expenses; and/or
10) International travel

The General Provisions in Division H of the Consolidated Appropriations Act, 2017 (P.L. 115-31) apply to this program. "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." As of January 8, 2017, the Executive Level II salary limitation is now $187,000 (formerly $185,100). Please 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 will apply in FY 2018, as required by law.

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 the 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 under the program will be addition. Recipients are responsible for ensuring that subrecipients have systems in place to account for program income, and for monitoring to ensure that subrecipients are tracking and using program income consistent with RWHAP

[25] For more information, see https://www.aids.gov/federal-resources/policies/syringe-services-programs/

requirements. Please see 45 CFR §75.307 for post-award requirements for program income for additional information.

7. Other Submission Requirements

Notification 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.

This letter should be sent via e-mail by June 28, 2017, to:

HRSA Digital Services Operation (DSO): HRSADSO@hrsa.gov

Please use HRSA opportunity number as e-mail subject (HRSA-17-047)

Although Letters of Intent to apply are encouraged, 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

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. Critical indicators have been developed 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. Review criteria are outlined below with specific detail and scoring points.

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 *Curing Hepatitis C among People of Color Living with HIV* program has six (6) review criteria:

Criterion 1: Need	25 points
Criterion 2: Response	25 points
Criterion 3: Evaluative Measures	15 points
Criterion 4: Impact	10 points
Criterion 5: Resources/Capabilities	15 points
Criterion 6: Support Requested	10 points
TOTAL	100 points

Criterion 1: NEED (25 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 an enhanced, comprehensive, HCV screening, care, and treatment system in its area, with information on the number of people living with HIV and HCV who could benefit, including people of color.
- Strength and clarity of the applicant's description of the existing HCV epidemiological profile of its area.
- Strength and clarity of the applicant's description of its existing HCV screening, referral, and treatment systems, and its numerical estimate of the patient capacity of care and treatment, and social service providers in its area.
- Extent of the service gaps and unmet needs that are identified by the applicant with regard to HCV screening activities, referral procedures, treatment provision, patient education, provider education, and SUD and mental health treatment.
- Strength and clarity of the applicant's discussion of the extent and depth of provider knowledge regarding HCV screening and treatment in its area.
- Strength and clarity of the applicant's description of state, local, and tribal laws and third-party payer policies such as insurance restrictions based upon provider type and HCV stage, that affect coverage of costs of HCV screening and treatment in its area.

Criterion 2: RESPONSE (25 points) – *Corresponds to Section IV's Methodology and Attachment 5*

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 described in the application are capable of addressing the problem and attaining the project objectives.

i. Methodology (17 points)

- Feasibility of the proposed project implementation plan for a comprehensive program to expand HCV screening, care, and treatment among people living with HIV and HCV, targeted to people of color. This includes the extent to which an adequate number of clinical sites have been selected.
- Extent to which the proposed project implementation plan addresses any gaps described in the needs assessment of the program narrative.
- Extent to which the proposed project implementation plan includes project components for which it and its subawardees are responsible, as described earlier in the announcement.
- Strength and clarity of the applicant's proposed sampling frames for the patient and provider knowledge assessments.
- Evidence of intent to participate in the project in the form of memoranda of agreement/understanding or letters of support from the Regional AETC in the applicant's area, included in **Attachment 5**.
- If applicant is not a RWHAP Part A or B recipient, evidence of intent to participate in the project in the form of a memorandum of agreement/understanding or letter of support from the applicant's State or local health department, included in **Attachment 5**.
- Evidence that SUD and mental health treatment services are currently provided and readily available at the funded clinical sites, or the strength and feasibility of the applicant's plans for collaboration with these service provider(s) to build the

capacity of the clinical sites to provide integrated care through the expansion of mental health and SUD treatment to people living with HIV and HCV; develop bidirectional linkages into appropriate care and treatment for HIV, HCV, SUD and mental health issues; and to prevent overdose and HCV re-infection due to SUD.

ii. **Work Plan (5 points)**

- Strength, clarity and feasibility of the applicant's work plan and the goals for the three-year project period, including adherence to key activity due dates as specified earlier in the announcement (**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 (3 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*

- Extent of the applicant's current capacity to collect and report to the evaluation team on a timely, regular basis, the required HCV care outcomes and additional measures.
- Evidence the applicant has identified the IRB that will review the evaluation protocol, client-level data collection instruments and informed consents, and its agreement to submit proof of IRB approvals and renewals for these evaluation documents to the evaluation team on an annual basis.

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

- Strength of the proposed collaboration with the evaluation team in the production of a project monograph, and participation in publication and dissemination efforts of the initiative's findings, best practices, and lessons learned.
- Strength and feasibility of the applicant's program integration component in its draft project implementation plan to fully incorporate enhanced area-wide HCV screening, care, and treatment system components into ongoing clinical practice, and fiscal and administrative planning for continuous operation and maintenance beyond the three-year project period.

Criterion 5: RESOURCES/CAPABILITIES (15 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 designing and implementing public health program evaluations; in writing and publishing study findings in peer reviewed journals; and in disseminating findings to local communities, national conferences and to policy makers.
- Extent to which the applicant's existing agreements with HIV clinical and support service providers will be leveraged for implementation of the proposed comprehensive HCV screening, care, and treatment project.
- Strength and clarity of the applicant's one-page figure that depicts the organizational structure of the project, including collaborating organizations, contractors and other significant collaborators (**Attachment 6)**.
- Strength and clarity of the roles and responsibilities of any current and/or proposed collaborating organizations, consultants and/or contractors proposed to fulfill the goals and objectives of the project in the signed and dated letters of support or memoranda of agreement or understanding (**Attachment 5**).

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

- The extent to which costs, as outlined in the budget, budget narrative, and the line item budgets for each year of the project period (**Attachment 7**) 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 contracts 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; long distance travel expenses for three (3) key project staff to attend the annual working meetings held in the Washington, DC, area; and any travel relating to proposed staff training.

2. Review and Selection Process

The independent 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. In addition to the ranking based on merit criteria, HRSA approving officials may also apply geographical distribution in award selection. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below.

Please see Section 5.3 of HRSA's *SF-424 Application Guide* for more details.

This program does not have any funding priorities or preferences.

In making final award decisions, HRSA may take into consideration the geographic distribution of applicants, per 45 CFR 75 Appendix 1 (E)(2).

PLEASE NOTE: In order to achieve the distribution of awards as stated above, HRSA may need to fund out of rank order.

HRSA will consider past performance in managing contracts, grants and/or cooperative agreements of similar size, scope and complexity. Past performance includes timeliness and thoroughness of compliance with applicable programmatic and reporting requirements, conformance to the terms and conditions of previous awards, and if applicable, the extent to which any previously awarded federal funds will be expended prior to future awards.

3. Assessment of Risk and Other Pre-Award Activities

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).

Applications receiving a favorable objective review are reviewed 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. You may be asked 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 an award will be made. Following review of all applicable information, HRSA's approving and business management officials will determine whether an award can be made, 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 Federal Awarding Agency Review of Risk Posed by Applicants.

A determination that an applicant is not qualified will be reported by HRSA to FAPIIS (45 CFR § 75.212).

4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of September 30, 2017.

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award prior to the start date of September 30, 2017. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 2.2 of HRSA's *SF-424 Application Guide*.

Human Research 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 research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR part 46), available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

3. Reporting

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

1) **Progress Reports**. The recipient must submit a progress report to HRSA on a semiannual basis. Submission and HRSA approval of awardee Progress Report(s) triggers the budget period renewal and release of subsequent year funds. This report has two parts. The first part demonstrates awardee progress on program-specific goals. The second part collects core performance measurement data including performance measurement data to measure the progress and impact of the project. Further information will be provided in the NoA.

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

VII. Agency Contacts

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

Beverly Smith
Grants Management Specialist
Health Resources and Services Administration
Division of Grants Management Operations, OFAM
5600 Fishers Lane, Mailstop 10SWH04
Rockville, Maryland 20857
Telephone: (301) 443-7065
E-mail: 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: *Curing Hepatitis C among People of Color Living with HIV*
Office of Training and Capacity Development
Health Resources and Services Administration
HIV/AIDS Bureau
5600 Fishers Lane, Mail Stop: 09NWH04
Email: ACajina@hrsa.gov
Telephone (301) 443-3180
Fax: (301) 594-2511

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, seven days a week, excluding federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
E-mail: 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

TA Webinar:
All applicants are encouraged to participate in a TA webinar for this funding opportunity. The purpose of this webinar is to assist potential applicants in preparing applications that address the requirements of this funding announcement. The TA webinar is scheduled for July 6, 2017, at 12:30 – 2:30 pm Eastern Time. The purpose of this webinar is to assist potential applicants in preparing applications that address the requirements of this funding announcement. Participation in a pre-application TA webinar is optional.

Dial-in Phone Number: 888-469-2188
Passcode: 4237790
To access the webinar online, go to the Adobe Connect URL:
https://hrsa.connectsolutions.com/hrsa-17-047/

IX. Tips for Writing a Strong Application

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