U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

HIV/AIDS Bureau
Office of Training and Capacity Development

Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites

Announcement Type: New/Limited Competition
Funding Opportunity Number: HRSA-16-189

Catalog of Federal Domestic Assistance (CFDA) No. 93.928

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2016

Application Due Date: July 14, 2016

Ensure 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.

Release Date: May 16, 2016
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Authority: The Consolidated Appropriations Act, 2016 (P.L. 114-113), Division H, Title II

EXECUTIVE SUMMARY

Supported through funding from the Department of Health and Human Services (HHS) Secretary's Minority AIDS Initiative Fund, the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) is accepting applications for fiscal year (FY) 2016 *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites.* This three-year program is expected to fund cooperative agreements for up to two (2) Ryan White HIV/AIDS Program (RWHAP) Part A current award recipients and up to two (2) RWHAP Part B current award recipients in the development of comprehensive jurisdiction-level hepatitis C (HCV) screening, care, and treatment systems for HIV/HCV coinfected people of color. Cooperative agreement recipients will work in close collaboration with the recipient awarded under *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Evaluation and Technical Assistance Center*, to be funded under HRSA-16-188.

Funding Opportunity Title:	Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites
Funding Opportunity Number:	HRSA-16-189
Due Date for Applications:	July 14, 2016
Anticipated Total Annual Available Funding:	$2,600,000
Estimated Number and Type of Award(s):	Up to four (4) cooperative agreements: up to two (2) to current RWHAP Part A recipients and up to two (2) to current RWHAP Part B recipients
Estimated Award Amount:	Up to $650,000 per year See Section II Award Information for details.
Cost Sharing/Match Required:	No
Project Period:	September 30, 2016 through September 29, 2019 (3 years)
Eligible Applicants:	Eligible applicants are limited to current recipients under RWHAP Part A and current recipients under RWHAP Part B. Applicants must have a high prevalence of HIV/HCV coinfected people of color in their jurisdiction. For the purposes of this FOA, high prevalence means at least 20% of people of color living with HIV are coinfected with HCV, *and* there are at least 750 HIV/HCV coinfected people of color in the jurisdiction. This number is based on the number of people living with HIV in the jurisdiction as reported in the Centers for Disease Control and Prevention's (CDC) HIV Surveillance Report, Supplemental Report Provided for RWHAP, for fiscal year 2015. [See Section III-1 of this funding opportunity announcement (FOA) for complete eligibility information.]

Application Guide

All applicants 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 FOA to do otherwise. A short video for applicants 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 cooperative agreement funding opportunity. The TA webinar is scheduled for June 6, 2016, 2:30 – 4:30 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: 888-455-9645
Passcode: 6232824

To access the webinar online, go to the Adobe Connect URL:
https://hrsa.connectsolutions.com/hrsa-16-189/

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I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for Fiscal Year 2016 *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites.* This program will support up to two (2) Ryan White HIV/AIDS Program (RWHAP) Part A current grant recipients and up to two (2) RWHAP Part B current grant recipients to increase jurisdiction-level capacity to provide comprehensive screening, care, and treatment for hepatitis C (HCV) among HIV/HCV coinfected RWHAP clients and thus, increase numbers of HIV/HCV coinfected people who are diagnosed, treated, and cured of HCV infection. Recipients must demonstrate a high prevalence of HIV/HCV coinfection and will be selected based on their demonstrated ability to access HIV-infected populations that are also living with or at high risk for acquiring HCV infection, as described in Section III. Eligibility Information. Cooperative agreement recipients will work in close collaboration with the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Evaluation and Technical Assistance Center* (ETAC) to be funded under HRSA-16-188.

During the initial six months of Year One (1), recipients shall complete a needs assessment to: understand gaps and barriers in their existing HCV screening, care, and treatment systems of HIV/HCV coinfected persons of color, to include a thorough review of the jurisdiction's HCV surveillance and epidemiology profile, as well as other available data for their jurisdiction; identify structural, financial, and client-level barriers to access of HCV-related services encountered by coinfected patients of color; and review State and local laws and policies, as well as third-party payer policies, regarding their coverage of the costs of HCV screening, treatment, and medication. Populations of interest include people of color living with HIV and high prevalence of HCV, including Black/African Americans, Latinos/as, American Indians/Alaska Natives, as well as people who inject drugs (PWID). In addition, men who have sex with men (MSM) remain at risk for incident HCV infection.

Using tools developed by the ETAC, recipients will conduct an assessment of HIV/HCV coinfected patient knowledge regarding HCV treatment to identify gaps to be addressed by implementing educational programs for consumers in their jurisdictions. Recipients will also conduct an assessment to identify knowledge gaps and training needs of health care providers regarding HCV screening and treatment in their jurisdictions to be addressed through training, technical assistance and capacity building. The surveillance and data assessment, patient knowledge assessment, and provider assessment must be completed in the first six months of the award.

By the end of the ninth month of Year 1, recipients will have developed a project implementation plan to enhance the jurisdiction's public health infrastructure to rapidly expand HCV screening and treatment. The plan should clearly identify a comprehensive, jurisdiction-wide, centrally coordinated program that will result in increased screening, care, and treatment of HIV/HCV coinfected people of color. At a minimum, this plan shall include the following components: (1) increased HCV screening among people of color living with HIV; (2) provider training on HCV prevention, care, and treatment for people of color living with HIV; (3) patient education on HCV prevention, care, and treatment; 4) clinical practice transformation to treat HCV among people of color living with HIV; (5) increased access for people of color living with HIV to care

and treatment, including medications, for HCV; and (6) enhanced medication adherence support for HCV among HIV/HCV coinfected people of color.

In Year Two (2) and Year Three (3), recipients shall continue implementation of the plans to enhance the jurisdiction's public health infrastructure to expand HCV screening, and care and treatment of the HIV/HCV coinfected patient. At the end of the three-year project period, recipients are expected to have implemented effective, comprehensive jurisdiction-level HCV screening, care and treatment systems leading to demonstrable improvements in HCV care outcomes among HIV coinfected people.

Throughout the period of performance, recipients from this program announcement will work closely with the Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Evaluation and Technical Assistance Center, funded under HRSA-16-188, which is being announced concurrently with this FOA, as well as with recipients from the Regional AIDS Education and Training Centers (AETC) program in their jurisdiction and the National AIDS Clinician Resource Center (NCRC).[1]

2. Background

This initiative is funded through the Secretary's Minority AIDS Initiative Fund (SMAIF) as authorized under The Consolidated Appropriations Act, 2016 (P.L. 114-113), Division H, Title II. This initiative is administered by the HRSA HIV/AIDS Bureau Office of Training and Capacity Development, through the Special Projects of National Significance (SPNS) Program.

Although HIV treatment outcomes continue to improve among people living with HIV (PLWH),[2,3,4] HCV coinfection has emerged as a major concern, with approximately one quarter of PLWH also coinfected with HCV.[5,6] HCV in the United States also disproportionately affects racial and ethnic minorities, particularly Blacks / African Americans, Latinos/as, and American Indians/Alaska Natives.[7] People with HCV/ HIV coinfection have higher liver-related morbidity and mortality, even when their HIV infection is well controlled, and liver disease has become

[1] AIDS Education and Training Centers. http://hab.hrsa.gov/abouthab/partfeducation.html. Accessed 3/23/16.
[2] 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. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/26324390
[3] Doshi RK, Milberg J, Isenberg D, Matthews T, Malitz F, Matosky M, Trent-Adams S, Parham Hopson D, & Cheever LW. High Rates of Retention and Viral Suppression in United States HIV Safety Net System: HIV Care Continuum in the Ryan White HIV/AIDS Program, 2011. Clinical Infectious Diseases, January 1, 2015; 60 (1): 117-125 Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/25225233
[4] CDC. Behavioral and Clinical Characteristics of Persons Receiving Medical Care for HIV Infection – Medical Monitoring Project, United States, 2013 Cycle (June 2013–May 2014). HIV Surveillance Special Report 16. Published January 2016 and accessed 3-9-16 from: http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-hssr-mmp-2013.pdf.
[5] 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. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/11237838
[6] Spradling PR, Richardson JT, Buchacz K, et al. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996-2007. *Journal of acquired immune deficiency syndromes (1999).* 2010;53(3):388-396.
[7] 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. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/24573716

one of the most common causes of non-AIDS deaths among PLWH.[8,9] HIV/HCV coinfection in the United States disproportionately affects racial and ethnic minorities, particularly Blacks /African Americans, Latinos/as, and American Indians/Alaska Natives, as well as PWID.[10,11] In addition, MSM remain at risk for incident HCV infection.[12]

Several highly effective medications are available to treat and cure HCV in PLWH with minimal side effects.[13,14] Unlike previous treatments, which were less effective in HIV/HCV coinfected persons compared with HCV monoinfected persons, the newer medications have been shown to be equally effective in curing HCV in those individuals who are co-infected with HIV/HCV, compared with HCV monoinfected individuals. These new medications represent the culmination of major breakthroughs in drug development. Despite advances in treatment, only a small percentage of HCV-infected patients have received treatment, as identified by multiple authors, including from the Centers for Disease Control and Prevention (CDC) who have published the Hepatitis C Care Continuum.[15,16,17,18,19,20,21] The HCV Care Continuum mirrors

[8] Klein MB, Althoff KN, Jing Y, et al. Has Modern ART Reduced Endstage Liver Disease in HIV-Hepatitis Coinfection? Paper presented at Conference on Retroviruses and Opportunistic Infections, February 2015, Seattle, WA.

[9] Weber R, Sabin CA, Friis-Møller N, Reiss P, El-Sadr WM, Kirk O, Dabis F, Law MG, Pradier C, De Wit S, Akerlund B, Calvo G, Monforte Ad, Rickenbach M, Ledergerber B, Phillips AN, & Lundgren JD.. 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. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/16908797

[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. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/24573716

[11] Spradling PR, Richardson JT, Buchacz K, et al. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996-2007. *Journal of acquired immune deficiency syndromes (1999).* 2010;53(3):388-396.

[12] Vanhommerig JW, Lambers FA, Schinkel J, et al. Risk Factors for Sexual Transmission of Hepatitis C Virus Among Human Immunodeficiency Virus-Infected Men Who Have Sex With Men: A Case-Control Study. *Open forum infectious diseases.* 2015;2(3):ofv115.

[13] 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. 2016;8(3):139-147. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/26839638

[14] 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 January 28, 2016; accessed 2-1-16 from: https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.

[15] 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):S19-25. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/23390301

[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. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/26744994

[17] 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. Cachay ER, Hill L, Wyles D, Colwell B, Ballard C, Torriani F, Mathews WC. *PloS One*, e-published July 18, 2014. Accessed 3-8-16 from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0102883

[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. Accessed 3-8-16 from: http://www-ncbi-nlm-nih-gov.ezproxyhhs.nihlibrary.nih.gov/pmc/articles/PMC4683297/

[19] 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.* 2013;35(2):122-128.

the HIV Care Continuum, in that it provides a framework to understand public health and health care systems' approach to quantifying the number of persons living with hepatitis C, number who have been treated and the number who have been cured. Some barriers to increased treatment uptake are: 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.

The RWHAP (authorized by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87)) has been at the forefront of HCV treatment among individuals who are co-infected with HIV/HCV. In the past, HRSA has designed the Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV,[22] technical report (2011),[23] and implementation of the SPNS Hepatitis C Treatment Expansion Initiative (2010-2014).[24] However, due to changes in the health care environment and major advances in HCV treatment, additional work is needed to rapidly expand treatment of HCV among individuals who are co-infected with HIV/HCV.

II. Award Information

1. Type of Application and Award

Type of applications sought: New/Limited Competition

Funding will be provided in the form of a cooperative agreement. A cooperative agreement, as opposed to a grant, is an award instrument of financial assistance where substantial involvement is anticipated between HRSA and the recipient during performance of the contemplated project.

As a cooperative agreement, **HRSA Program involvement will include**:

- Provision of the services of experienced HRSA HAB personnel as participants in the planning, development, management and technical performance of all phases of the project;
- Coordination of the partnership and communication with other federal agencies' personnel and other funded capacity building entities;
- Provision of ongoing review of curriculum, documents, activities, procedures, evaluative measures and tools to be established and implemented for accomplishing the goals of the cooperative agreement, including project information prior to dissemination;
- Participation in conference calls, meetings, and site visits to be conducted during the period of the cooperative agreement;

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[20] Holmberg SD, Spradling PR, Moorman AC, Denniston MM. Hepatitis C in the United States. *The New England journal of medicine.* 2013;368(20):1859-1861.
[21] 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.* 2014;9(7):e101554.
[22] HRSA. A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV. http://hab.hrsa.gov/deliverhivaidscare/files/hepccoinfectguide2011.pdf. Accessed 3/12/16.
[23] HRSA. Integrating Hepatitis C into Ryan White Clinics: Models and Tools. http://hab.hrsa.gov/files/hepatitiscmodelstools.pdf. Accessed 3/12/16.
[24] HRSA. Hepatitis C Treatment Expansion Initiative. http://hab.hrsa.gov/abouthab/special/spnshepatitisc.html. Accessed 4/25/16.

- Provision of information resources and facilitating partnerships with other RWHAP recipients and 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:

1) Project Pre-implementation Activities

The cooperative agreement recipient will complete all of the following activities within the first six (6) months of the award:

- Conduct a needs assessment identifying gaps in RWHAP service provision in the existing HCV screening, care and treatment system of the jurisdiction. The needs assessment should include surveillance and other epidemiology data; identification of structural, financial and client-level barriers to access of HCV-related services encountered by HIV/HCV coinfected patients; and a review of State and local laws and policies and third-party payer policies regarding the costs of HCV screening and treatment.
- Prepare and submit the needs assessment to the ETAC, identifying which gaps and barriers may be addressed by the jurisdiction without assistance and those requiring technical assistance and capacity building by the ETAC, HRSA and/or external entities.
- Conduct a Patient Knowledge Assessment regarding HCV care and treatment among HIV/HCV coinfected people in the jurisdiction served by RWHAP to identify gaps to be addressed by implementing educational programs for consumers in their jurisdictions. The Patient Knowledge Assessment tool will be developed by the ETAC for implementation by the funded jurisdictions, and results will be submitted to the ETAC for review.
- Conduct a Provider Assessment to identify gaps in knowledge, skills and behaviors of health care providers regarding HCV prevention, screening and treatment to be addressed through training, technical assistance and capacity building. The Provider Assessment tool will be developed by the ETAC for implementation by the funded jurisdictions, and results will be submitted to the ETAC for review.
- Develop the Project Implementation Plan for a comprehensive, jurisdiction-level, centrally coordinated HCV screening, care and treatment system, with support from the ETAC, the Regional AETCS and the NCRC. The Project Implementation Plan must describe all system components, which at a minimum, must include:
    - *Provider Training*: to include identification of HCV providers (physicians, nurse practitioners, physician assistants, nurses, pharmacists, and behavioral health staff) who care for HIV/HCV co-infected persons; planned training activities implemented with the assistance of the ETAC and regional AETCs; and planned implementation of a jurisdiction-wide Community of Practice and Learning for clinical providers with distance-based videoconferencing to advance the knowledge of existing providers and expand the provider pool in the jurisdiction.
    - *Patient Education:* to inform HIV/HCV co-infected patients of the benefits of and access to treatment for HCV.
    - *Practice Transformation*: activities to increase the capacity of health care organizations in the jurisdiction to treat HCV among HIV/ HCV coinfected people. Resources to support this component include, but are not limited to, best practices from other HRSA-funded programs, such as the SPNS Hepatitis C

Treatment Expansion Initiative,[25,26] AETCs program,[27] SPNS System-level Workforce Capacity Building for Integrating HIV Primary Care in Community Health Care Settings,[28] and National Center for Interprofessional Practice and Education.[29]
    - *Enhanced HCV Screening:* increased targeted HCV testing through education, outreach/in-reach to clinical settings where HIV/HCV coinfected people seek care, including RWHAP-funded clinical settings, to reach PLWH at high risk of HCV infection;
    - *Improved Access to HCV Care and Treatment*: to include the provision of care and treatment; the establishment of effective treatment referral models using case management, care coordination and patient navigation; and support for navigation of the payer systems in place in order to obtain HCV medications and treatment for patients (i.e., working with payers who may have restrictions on the type of provider who can treat HCV);
    - *Medication Adherence Support*: to include directly observed therapy for coinfected persons at risk of therapy non-completion.
- Completion of all of the following activities within the sixth to ninth months of the award:
    - Preparation and submission of draft and final Project Implementation Plans to the ETAC for review, comment and approval.
    - Design of a local evaluation plan, with assistance from the ETAC.

2) Project Implementation Activities

The cooperative agreement will begin all of the following activities in the last third of Year 1 into Year 2:

- Implementation of the provider training component, working with the ETAC and AETCs to provide appropriate training support to novice and experienced providers.
- Implementation of the patient education component, working with the ETAC.
- Implementation of the practice transformation component.
- Implementation of the enhanced HCV screening component.
- Implementation of the Treatment Access Model.
- Implementation of the medication adherence support component.
- Implementation of the local evaluation plan.
- Participation in a collaborative Community of Practice designed to improve the quality of the jurisdiction-level HCV care and treatment system, coordinated by the ETAC.

[25] See HRSA/SPNS Hepatitis C Treatment Expansion Initiative at: http://hab.hrsa.gov/abouthab/special/spnshepatitisc.html

[26] Wills T, Friedrich M, Beal J, Somboonwit C, Mcintosh S, Bork A, Tinsley M, Cajina A, Belton P, Xavier J, Doshi R, Boyd R, & Solomon N. Implementing Hepatitis C treatment programs in comprehensive clinics: The Health Resources and Services Administration (HRSA) Special Projects of National Significance Hepatitis C treatment expansion initiative. Presented at IDWeek Conference, Philadelphia, PA, October 2014. Accessed 3-14-16 from: https://idsa.confex.com/idsa/2014/webprogram/Paper46140.html

[27] AIDS Education and Training Centers Program. http://aidsetc.org/. Accessed 3/12/16.

[28] HRSA. System-level Workforce Capacity Building for Integrating HIV Primary Care in Community Health Care Settings. http://hab.hrsa.gov/abouthab/special/spns_workforce.html. Accessed 3/12/16.

[29] National Center for Interprofessional Practice and Education. https://nexusipe.org/. Accessed 3/12/16.

- Collect and report system, patient outcome and project implementation process data to the ETAC, including the following required data points:

  1) Number of PLWH in the jurisdiction
  2) Number of PLWH in the jurisdiction screened for HCV since diagnosis
  3) Number of PLWH in the jurisdiction who have chronic HCV infection
  4) Number of HIV/HCV coinfected people in the jurisdiction who have been linked to an HCV provider (attended initial visit with HCV medication prescriber)
  5) Number of HIV/HCV coinfected people in the jurisdiction who have been prescribed HCV treatment
  6) Number of HIV/HCV coinfected people in the jurisdiction who have been cured of HCV (achieved sustained virologic response in accordance with HCV treatment guidelines[30]).

  The following data points are optional:
  - Confirmation of chronic HCV infection: Number of PLWH in the jurisdiction with positive HCV antibody who had HCV RNA checked
  - Number of HIV/HCV coinfected people in the jurisdiction who have had appropriate disease staging done, in accordance with HCV treatment guidelines (i.e. fibrosis score check, genotype)

3) Project Documentation, Publication and Dissemination Activities

The cooperative agreement will begin all of the following activities in Year 3:

- Development of the sustainability plan for the project.
- Completion of system and patient outcome and project implementation process data submissions to the ETAC.
- Completion of the local evaluation plan and associated project documentation activities.
- Participation in publication and dissemination activities to disseminate findings, best practices and lessons learned, as coordinated by the ETAC, to include adherence to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds.

Overall project timeline for ETAC (HRSA-16-188) and Jurisdictions (HRSA-16-189)

Project Date	ETAC (HRSA-16-188)	Jurisdictions (HRSA-16-189)
Year 1, Month 1	• Begin IRB approval process for Patient Knowledge Assessment tool and Provider Assessment tool • Begin multisite evaluation plan • Begin to plan year 1 scientific meeting for funded jurisdictions	• Begin project needs assessment
Year 1, Month 2	• Submit Patient Knowledge	

[30] 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

	Assessment tool to HRSA • Submit Provider Assessment tool to HRSA	
Year 1, Month 4	• Provide IRB-approved Patient Knowledge Assessment tool to funded jurisdictions • Provide IRB-approved Provider Assessment tool to funded jurisdictions	• Begin to use IRB-approved Patient Knowledge Assessment tool when available • Begin to use IRB-approved Provider Assessment tool when available
Year 1, Month 6		• Complete project needs assessment and submit to ETAC • Submit results of Patient Knowledge Assessment and Provider Assessment tools to ETAC
Year 1, Month 7		• Begin to develop jurisdictional project implementation plan
Year 1, Month 8	• Submit TA/CBA plan to HRSA	
Year 1, Month 9	• Finalize TA/CBA plan with HRSA's input	• Submit jurisdictional project implementation plan to ETAC
Year 1, Month 10	• Begin TA/CBA implementation	• Begin project implementation • Begin project evaluation
Year 1, Month 12	• Submit Multisite Evaluation Plan to HRSA	• Attend year 1 scientific meeting for funded jurisdictions by the end of year 1
Year 2	• Begin Publication and Dissemination Committee work • Begin implementation of multisite evaluation plan • Plan and implement year 2 scientific meeting for funded jurisdictions	• Participate in Publication and Dissemination Committee • Continue project implementation • Continue local evaluation • Continue jurisdictional responsibilities for multisite evaluation • Attend year 2 scientific meeting for funded jurisdictions
Year 3	• Complete implementation of multisite evaluation plan • Complete publication and dissemination work • Plan and implement year 3 scientific meeting for funded jurisdictions	• Complete project implementation • Complete local evaluation • Complete jurisdictional responsibilities for multisite evaluation • Attend year 3 scientific meeting for funded jurisdictions

2. Summary of Funding

This program expects to provide funding during federal fiscal years 2016 – 2018. Approximately $2,600,000 is expected to be available annually to fund up to four (4) cooperative agreement recipients. HRSA intends to fund up to two (2) current recipients under RWHAP Part A and up to two (2) current recipients under RWHAP Part B. Applicants may apply for a ceiling amount of up to $650,000 per year. Funding beyond the first year is dependent on the availability of appropriated funds for the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites* in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern federal monies associated with this award are subject to the Uniform Guidance 2 CFR 200 as codified by HHS at 45 CFR 75, which supersede the previous administrative and audit requirements and cost principles that govern federal monies.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants are limited to current recipients under RWHAP Part A and current recipients under RWHAP Part B. Applicants must have a high prevalence of HIV/HCV coinfected people of color in their jurisdiction as demonstrated by surveillance and/or clinical data. For the purposes of this FOA, high prevalence means at least 20% of people of color living with HIV are coinfected with HCV, *and* there are at least 750 HIV/HCV coinfected people of color in the jurisdiction. Applicants should use the CDC HIV Surveillance Report, Supplemental Report, HIV/AIDS Data through December 2013, Provided for RWHAP, for Fiscal Year 2015, to determine the number of PLWH (HIV and AIDS) living in the jurisdiction.[31] Estimates of HIV/HCV coinfection among PLWH of color may be based on national or local estimates.[32,33,34]

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

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[31] CDC. HIV/AIDS data through December 2013 provided for the Ryan White HIV/AIDS Program, for fiscal year 2015. *HIV Surveillance Supplemental Report* 2015; 20(3). http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillancereport-vol20-no3.pdf. Accessed 5/9/16.
[32] CDC. HIV Surveillance Report, 2014. http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf. Accessed 5/9/16.
[33] CDC. U.S. 2013 Surveillance Data for Viral Hepatitis. http://www.cdc.gov/hepatitis/statistics/2013surveillance/index.htm#tabs-801919-1. Accessed 5/9/16.
[34] Spradling PR, Richardson JT, Buchacz K, et al. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996-2007. *Journal of acquired immune deficiency syndromes (1999).* 2010;53(3):388-396.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.4* will be considered non-responsive and will not be considered for funding under this announcement.

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 the applicant's **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 FOA to apply electronically through Grants.gov. Applicants must download the SF-424 application package associated with this FOA following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 Application Guide* provides instructions for the budget, budget justification, 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. All applicants are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide* except where instructed in the FOA to do otherwise.

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 FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge applicants to take appropriate measures to ensure the 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) Where the prospective recipient is unable to attest to any of the statements in this certification, such prospective recipient shall attach an explanation to this proposal.

See Section 4.1 viii of HRSA's *SF-424 Application Guide* for additional information on this and other 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 the applicant organization and any collaborators.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion 1 (Need)*
  Provide a description of the existing HCV surveillance and epidemiological profile of the jurisdiction. Provide the estimated number of PLWH of color in the jurisdiction and of those, how many, and what percent, are coinfected with HCV. Applicants should use the CDC HIV Surveillance Report, Supplemental Report, HIV/AIDS Data through December 2013, Provided for RWHAP, for Fiscal Year 2015, to determine the number of PLWH (HIV and AIDS) living in the jurisdiction.[35] Estimates of HIV/HCV coinfection among PLWH of color may be based on national or local estimates.[36,37,38] Applicants should clearly state the sources of data used for eligibility determination. Provide a description of the existing HCV screening, referral and treatment systems for HIV/HCV coinfected persons in the jurisdiction. List relevant organizations and their jurisdictional roles in providing screening, referral and treatment, and numerically estimate patient/client capacity of care and social service providers engaged in these activities. Identify any

[35] CDC. HIV/AIDS data through December 2013 provided for the Ryan White HIV/AIDS Program, for fiscal year 2015. *HIV Surveillance Supplemental Report* 2015; 20(3). http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillancereport-vol20-no3.pdf. Accessed 5/9/16.
[36] CDC. HIV Surveillance Report, 2014. http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf. Accessed 5/9/16.
[37] CDC. U.S. 2013 Surveillance Data for Viral Hepatitis. http://www.cdc.gov/hepatitis/statistics/2013surveillance/index.htm#tabs-801919-1. Accessed 5/9/16.
[38] Spradling PR, Richardson JT, Buchacz K, et al. Trends in hepatitis C virus infection among patients in the HIV Outpatient Study, 1996-2007. *Journal of acquired immune deficiency syndromes (1999).* 2010;53(3):388-396.

salient and/or previously identified service gaps and unmet needs with regard to HCV screening activities, referral procedures, treatment provision, patient education, and provider education. Briefly describe the coinfected target populations of color for the project, using the most recent available surveillance, screening and treatment data. Briefly discuss the extent of HIV/HCV coinfected patient knowledge regarding HCV treatment in the jurisdiction. Discuss the extent and depth of provider knowledge regarding HCV screening and treatment in the jurisdiction.

As the funds from this project are not to be used for the purchase of medications to treat HCV, adequate access to Direct-Acting Antiretroviral (DAA) medications must be demonstrated. Identify which eligible DAA medications are currently, or will be added within one month of award start date, in the pharmacy benefit programs in the jurisdiction, including State ADAP's formulary or Local Pharmacy Assistance Program; third party payers including marketplace insurance plans; Medicaid or Medicare programs; or pharmaceutical company patient assistance programs. For the purposes of this announcement, eligible DAAs include daclatasvir (Daklinza); dasabuvir plus fixed dose combination ombitasvir/paritaprevir/ritonavir (Viekira Pak); fixed-dose combination elbasvir-grazoprevir (Zepatier); fixed dose combination ledipasvir/sofosbuvir (Harvoni); simeprevir (Olysio); and sofosbuvir (Sovaldi), fixed-dose combination ombitasvir/paritaprevir/ritonavir (Technivie); and any other DAAs that are approved by the U.S. Food and Drug Administration (FDA) for treatment of HCV.

- *METHODOLOGY -- Corresponds to Section V's Review Criteria 2 (Response) and 4 (Impact)*
  Describe proposed methods to respond to the findings of the needs assessment to identify gaps and barriers in the existing HCV screening, care, and treatment systems for HIV/HCV coinfected persons of color in the jurisdiction.

  Identify data sources to be used, including but not limited to surveillance, screening and treatment systems and any prior needs assessment, risk behavior or other evaluation and research studies. Briefly describe proposed methods to review State and local laws and policies, as well as third-party payer policies, regarding their coverage of the costs of HCV screening and treatment, as part of the needs assessment. The needs assessment, along with the ETAC-developed patient knowledge assessment and provider assessment, must be completed within the first six months of the initial award.

  Describe a detailed project implementation plan for the enhancement of existing HCV screening, referral and treatment system for HIV/HCV co-infected persons of color in the jurisdiction. The plan must address any gaps described earlier, with the aim of achieving an effective, comprehensive, centrally coordinated jurisdiction-level HCV screening, care and treatment system leading to demonstrable improvements among HIV/HCV coinfected people of color by the end of the three year project period. The project implementation plan must describe all system components, which at a minimum must include:

  - *Provider Training*: to include identification of HCV care and treatment providers (physicians, nurse practitioners, physician assistants, nurses, pharmacists, and behavioral health staff) who care for HIV/HCV coinfected persons; training activities implemented with the assistance of the ETAC and AETCs; and implementation of a jurisdiction-wide Community of Practice and Learning 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 jurisdiction.

- *Patient Education:* to inform HIV/HCV coinfected people of color of the benefits of and access to treatment for HCV.
- *Practice Transformation*: efforts to increase the capacity of health care organizations in the jurisdiction to treat HCV among coinfected people of color served by the RWHAP. Resources to support this component include, but are not limited to, best practices from other HRSA-funded programs, such as the SPNS Hepatitis C Treatment Expansion Initiative,[39,40] AETCs program,[41] SPNS System-level Workforce Capacity Building for Integrating HIV Primary Care in Community Health Care Settings,[42] and National Center for Interprofessional Practice and Education.[43]
- *Enhanced HCV Screening:* increased targeted HCV testing through education, outreach/in-reach to all RWHAP-funded clinical settings to reach people of color living with HIV at high risk of HCV infection;
- *Improved Access to HCV Care and Treatment*: to include the provision of care and treatment, including medications; the establishment of effective treatment referral models using case management and patient navigation; and support for navigation of the payer systems in place in order to obtain HCV medications and treatment for patients (i.e., working with payers who may have restrictions on the type of provider who can treat HCV).
- *Medication Adherence Support*: to include but not be limited to directly observed therapy for HIV/HCV coinfected people of color at risk of HCV therapy non-completion.

State the commitment to work with the ETAC, the regional AETC in your jurisdiction, and National AETCs to provide appropriate training support to novice and experienced providers. State the commitment to participate in a collaborative community of practice designed to improve the quality of HCV care and treatment systems with other funded jurisdictions and coordinated by the ETAC. Describe a detailed plan for the sustainability of the proposed comprehensive jurisdiction-level HCV screening, care and treatment systems, and the continuous operation and maintenance beyond the three year funded project period.

- *WORK PLAN -- Corresponds to Section V's Review Criterion 2 (Response)*
  Develop a work plan to describe the steps used to achieve each of the activities proposed during the project period in the methodology section. The work plan should be time-

[39] See HRSA/SPNS Hepatitis C Treatment Expansion Initiative at: http://hab.hrsa.gov/abouthab/special/spnshepatitisc.html

[40] Wills T, Friedrich M, Beal J, Somboonwit C, Mcintosh S, Bork A, Tinsley M, Cajina A, Belton P, Xavier J, Doshi R, Boyd R, & Solomon N. Implementing Hepatitis C treatment programs in comprehensive clinics: The Health Resources and Services Administration (HRSA) Special Projects of National Significance Hepatitis C treatment expansion initiative. Presented at IDWeek Conference, Philadelphia, PA, October 2014. Accessed 3-14-16 from: https://idsa.confex.com/idsa/2014/webprogram/Paper46140.html

[41] AIDS Education and Training Centers Program. http://aidsetc.org/. Accessed 3/12/16.

[42] HRSA. System-level Workforce Capacity Building for Integrating HIV Primary Care in Community Health Care Settings. http://hab.hrsa.gov/abouthab/special/spns_workforce.html. Accessed 3/12/16.

[43] National Center for Interprofessional Practice and Education. https://nexusipe.org/. Accessed 3/12/16.

framed with specific dates to actively manage the project by measuring progress and quantifying accomplishments. In chronological order, list the major elements/tasks/ activities to be performed during the project period. Identify proposed staff members (in-kind and cooperative agreement-supported) responsible for each activity. The work plan should be presented in a table format and include (1) goals; (2) objectives that are specific, time-framed, and measurable; (3) action steps; and (4) staff responsible for each action step, and; (5) anticipated dates of completion. Among key activities that may be addressed in the timeline include, but are not limited to, start-up activities, assessments, implementation of system components, training activities, development and implementation of the local evaluation, and documentation of the comprehensive screening and treatment system. The work plan should be included as **Attachment 1**.

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

- *EVALUATION CAPACITY -- Corresponds to Section V's Review Criterion 3 (Evaluative Measures), 4 (Impact) and 5 (Resources/Capabilities)*
  Provide a detailed proposal for a rigorous local evaluation plan to assess the effectiveness of the comprehensive HCV screening, care and treatment system in improving the numbers of HIV/HCV coinfected people of color who are diagnosed, treated, and cured of HCV infection in the jurisdiction. Discuss proposed evaluation questions to be explored and the quantitative and/or qualitative methodology to be used to assess the effectiveness of the comprehensive HCV screening, care and treatment system.

  Describe the capacity of the jurisdiction to measure and report to the ETAC on a timely, regular basis the following outcomes along the HCV Care Continuum, by race/ethnicity:

  1) Number of PLWH in the jurisdiction
  2) Number of PLWH in the jurisdiction screened for HCV since diagnosis
  3) Number of PLWH in the jurisdiction who have chronic HCV infection
  4) Number of HIV/HCV coinfected people in the jurisdiction who have been linked to an HCV provider (attended initial visit with HCV medication prescriber)
  5) Number of HIV/HCV coinfected people in the jurisdiction who have been prescribed HCV treatment
  6) Number of HIV/HCV coinfected people in the jurisdiction who have been cured of HCV (achieved sustained virologic response in accordance with HCV treatment guidelines)[44].

  Describe the capacity of the jurisdiction to collect and analyze the following optional data points:
  - Confirmation of chronic HCV infection: Number of PLWH in the jurisdiction with positive HCV antibody who had HCV RNA checked

[44] 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

- Number of HIV/HCV coinfected people in the jurisdiction who have had appropriate disease staging done, in accordance with HCV treatment guidelines (i.e., fibrosis score check, genotype)

Describe how the 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. Describe any prior experience of proposed key project personnel (including any consultants and contractors) in participating in a multisite evaluation of national scope. 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. If applicable, detail any published materials, presentations and previous work of a similar nature. Describe any training in human subjects' research protection by proposed key project staff. Describe the 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 HIPAA regulations and human subjects research protections.

State the commitment to fully cooperate and work collaboratively with the ETAC throughout the initiative. This collaboration includes, but is not limited to, data collection and reporting of system and patient outcome and project implementation process data for the multisite evaluation and additional focused evaluation studies; attendance at the annual working meetings of the initiative, to be held in the Washington, DC area and coordinated by the ETAC; and publication and dissemination efforts of the initiative's findings, best practices and lessons learned at the national, State and local levels.

Identify the Institutional Review Board (IRB) which will review the local evaluation plan and the multisite evaluation plan. State the agreement to submit to the ETAC on an annual basis proof of IRB approvals and renewals for all client-level data collection instruments, informed consents, and evaluation materials. State the agreement to cooperate with the ETAC and SPNS Program staff regarding the privacy and confidentiality of study participant medical records.

- *ORGANIZATIONAL INFORMATION* -- Corresponds to Section V's Review Criterion 5 ((Resources/Capabilities)
  Provide information on the applicant organization's current structure and scope of current activities. Describe how these all contribute to the ability of the organization to conduct the program requirements and meet program expectations. Describe how the applicant organization's existing agreements with clinical and support service providers for the provision of HIV care and treatment including outpatient ambulatory medical care, medical case management and other care coordination service categories will be leveraged for implementation of the jurisdiction-wide, comprehensive, centrally coordinated hepatitis C screening, care and treatment project. Describe how the applicant will work with entities covering the jurisdiction that are funded under RWHAP Part A, B, C and F (AETC) towards the goals of this project. If contractors will be used to implement the project, describe their proposed roles and responsibilities. Provide a one-page figure that depicts the organizational structure of the project, including collaborating organizations, contractors and other significant collaborators as **Attachment 2**. Do not provide a standard organization chart for the entire organization.

If applicable, describe the roles and responsibilities of any consultants and/or contractors will be used to carry out aspects of 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 3**.

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 Capacity	(3) Evaluative Measures, (4) Impact 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.

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 *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites* requires the following:

Submit a separate line item budget spreadsheet for each year of the three year project period, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs as appropriate, as **Attachment 4.**

Applicants must include in their budgets the costs of distance-based videoconferencing capabilities to serve as the hub for the Community of Practice and Learning webinars in their jurisdiction. 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. As a reminder, the costs of medications cannot be paid with grant funds in this initiative.

The Consolidated Appropriations Act, 2016, Division H, § 202, (P.L. 114-113) 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." 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 may apply in FY 2016, 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, reasonable, time-framed, and measurable; (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 1.

Attachment 2: Project Organizational Chart (required)

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

Attachment 3: Project-specific Letters of Agreement and/or Description(s) of Proposed/Existing Contracts (required if applicable)

Provide any documents that describe working relationships between the applicant organization and other entities and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the contractors and any deliverable. Letters of agreement must be dated.

Attachment 4: Line Item Budgets Spreadsheet for Years 1 through 3 (required)

Submit line item budgets for each year of the proposed project period as a single spreadsheet table, using the Section B Budget Categories of the SF-424A and breaking down sub-categorical costs.

Attachment 5: Staffing Plan (see Section 4.1.vi of HRSA's *SF-424 Application Guide) (required)*

Attachment 6: Job Descriptions for Key Personnel (required)

Include the role, responsibilities, and qualifications of proposed project staff. Keep each job description to one page in length as much as is possible.

Attachment 7: 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.

Attachments 8 – 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

Applicant organizations must obtain a valid DUNS number and provide that number in their application. Each applicant 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 it has 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 an applicant/recipient organization has 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://fedgov.dnb.com/webform/pages/CCRSearch.jsp)
- 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*.

Applicants that fail to allow ample time to complete registration with SAM or Grants.gov 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 FOA is ***July 14, 2016 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 *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites* is 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

Applicants responding to this announcement may request funding for a project period of up to three (3) years, at no more than $650,000 per year. 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.

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

1) Costs of HCV treatments 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 medications;
3) Cash payments to intended recipients of RWHAP services;
4) Pre-Exposure (PrEP) or Post-Exposure Prophylaxis (nPEP);
5) Purchase, construction of new facilities or capital improvements to existing facilities;
6) Purchase or improvement to land;
7) Purchase vehicles;
8) Fundraising expenses;
9) Lobbying activities and expenses;
10) Reimbursement of pre-award costs; and/or
11) International travel

The General Provisions in Division H of the Consolidated Appropriations Act, 2016 (P.L. 114-113) apply to this program. Please see Section 4.1 of HRSA's *SF-424 Application Guide* for additional information. Note that these or other restrictions will apply in FY 2017, as required by law.

All program income generated as a result of awarded funds must be used in an "additive" manner for the purposes for which the award is made.

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 the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant 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 the application. The entire proposal will be considered during objective review.

Review Criteria are used to review and rank applications. The *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites* 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.

- Strength and clarity of the applicant's description of the HIV/HCV coinfected target populations of color for the project, using the most recent available surveillance, screening, and treatment data.
- The extent to which the applicant demonstrates the need for a comprehensive HCV screening, care and treatment system.
- Strength and clarity of the description of the applicant's existing HCV screening, referral, and treatment systems for HIV/HCV coinfected persons in the jurisdiction.
- Strength and clarity of the applicant's listing of all relevant organizations and their jurisdictional roles in providing screening, referral, and treatment, and estimate of the number and capacity of clinical care and social service providers engaged in these activities.
- Strength and clarity of the applicant's identification of any salient service gaps and unmet needs with regard to HCV screening activities, referral procedures, treatment provision, patient education, and provider education.
- Strength and clarity of the applicant's brief discussion of the extent of HIV/HCV coinfected patient knowledge regarding HCV treatment in the jurisdiction.

- Strength and clarity of the applicant's discussion of the extent and depth of provider knowledge regarding HCV screening and treatment for HIV/HCV coinfected people in the jurisdiction.

Criterion 2: RESPONSE (25 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 described in the application are capable of addressing the problem and attaining the project objectives.

i**. Methodology (18 points)**

- Strength and clarity of the applicant's proposed methods for the required needs assessment to identify gaps and barriers in the existing HCV screening, care and treatment systems in the jurisdiction.
- Strength and clarity of the applicant's identification of data sources to be used in the needs assessment, including but not limited to surveillance, screening, and treatment systems; and any prior needs assessment, risk behavior or other evaluation and research studies.
- Strength and clarity of the applicant's brief description of methods proposed to review State and local laws and policies, as well as third-party payer policies, regarding their coverage of the costs of HCV screening and treatment, as part of the needs assessment.
- Strength and clarity of the applicant's detailed plan for the enhancement of existing HCV screening, referral, and treatment system for HIV/HCV coinfected persons of color in the jurisdiction.
- Extent to which the applicant's detailed plan addressed any gaps described earlier, including how the applicant will work with the ETAC and AETCs.
- Feasibility of the applicant's detailed plan to achieve an effective, comprehensive jurisdiction-level HCV screening, care and treatment system leading to demonstrable improvements among coinfected people by the end of the three year project period.
- Extent to which the applicant's detailed plan includes enhanced HCV screening and treatment system components such as increased targeted HCV testing through education, outreach, and in-reach to all RWHAP-funded clinical settings to reach high-risk PLWH; identification and training of HCV care and treatment providers (physicians, nurse practitioners, physician assistants, nurses, pharmacists, and behavioral health staff) who care for HIV/HCV co-infected persons; medication adherence support, including directly observed therapy for persons at risk of therapy non-completion; improved access to HCV medications by the establishment of effective treatment referral models using case management and patient navigation; and education of HIV/HCV co-infected patients of color about the benefits of and access to treatment for HCV.

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 timeframes as stated in this announcement (**Attachment 1**).
- Extent to which the applicant's work plan addresses the program requirements the applicant described in the Methodology section of the Narrative.

- Evidence that the applicant's objectives for the three-year project period are specific to each goal, time-framed, and measurable.
- Evidence that 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 (2 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 Evaluation Capacity*

The strength and effectiveness of the methods proposed to monitor and evaluate the project. 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.

- Extent of the applicant jurisdiction's capacity to measure and report to the ETAC on a timely, regular basis, the following outcomes along the HCV Care Continuum, by race/ethnicity:
  1) Number of PLWH in the jurisdiction
  2) Number of PLWH in the jurisdiction screened for HCV since diagnosis
  3) Number of PLWH in the jurisdiction who have chronic HCV infection
  4) Number of HIV/HCV coinfected people in the jurisdiction who have been linked to an HCV provider (attended initial visit with HCV medication prescriber)
  5) Number of HIV/HCV coinfected people in the jurisdiction who have been prescribed HCV treatment
  6) Number of HIV/HCV coinfected people in the jurisdiction who have been cured of HCV (achieved sustained virologic response in accordance with HCV treatment guidelines)[45]
- Strength, feasibility and clarity of the applicant's detailed proposal for a rigorous local evaluation plan to assess the effectiveness of the comprehensive HCV screening, care, and treatment system in improving the numbers of HIV/HCV coinfected people of color who are diagnosed, treated, and cured of HCV infection in the jurisdiction.
- Strength and clarity of the applicant's proposed evaluation questions to be explored and the quantitative and/or qualitative methodology to be used to assess the effectiveness of the proposed comprehensive HCV system.

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

The feasibility and effectiveness of plans for dissemination of project results, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

[45] 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

- Evidence of the applicant's commitment to fully cooperate and work collaboratively with the ETAC including but not limited to data collection and reporting of system and patient outcomes, and project implementation process data for the multisite evaluation and additional local evaluation studies; attendance at the annual working meetings of the initiative, to be held in the Washington, DC area and organized and facilitated by the ETAC; and publication and dissemination efforts of the initiative's findings, best practices and lessons learned at the national, State and local levels.
- Strength and feasibility of the applicant's detailed plan for the sustainability of the proposed comprehensive jurisdiction-level HCV screening, care and treatment systems, and the continuous operation and maintenance beyond the three year funded project period.

Criterion 5: RESOURCES/CAPABILITIES (15 points) – *Corresponds to Section IV's Evaluation Capacity and Organizational Information*
The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project.

- Strength 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.
- Strength and extent to which applicant's proposed key project personnel (including any consultants and contractors) possess prior experience in participating in a multisite evaluation of national scope.
- Strength of the applicant organization's description of existing agreements with clinical and support service providers for the provision of HIV care and treatment including outpatient ambulatory medical care, medical case management and other care coordination service categories that will be leveraged for implementation of the jurisdiction-wide, comprehensive, centrally coordinated hepatitis C screening, care and treatment project.
- Strength of the applicants proposed work with entities covering the jurisdiction that are funded under RWHAP Part A, B, C and F (AETC) towards the goals of this project.
- Strength and extent of applicant's proposed key project personnel's (including any consultants and contractors) experience in writing and publishing study findings in peer-reviewed journals and in disseminating findings to local communities, national conferences and to policymakers.
- Extent to which the applicant organization's current structure and scope of current activities contribute to the ability of the organization to conduct the program requirements and meet program expectations.
- 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 2)**.
- If applicable, 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 3**).

- Evidence that applicant has identified eligible Direct-Acting Antiviral (DAA) medication(s) that are currently, or will be added within one month of the award start date, in the pharmacy benefit programs in the jurisdiction, including State ADAP's formulary or Local Pharmacy Assistance Program; third party payers including marketplace insurance plans; Medicaid or Medicare programs; or pharmaceutical company patient assistance programs. Please note that for the purposes of this announcement, eligible DAAs include daclatasvir (Daklinza); dasabuvir plus fixed dose combination ombitasvir/paritaprevir/ritonavir (Viekira Pak); fixed-dose combination elbasvir-grazoprevir (Zepatier); fixed dose combination ledipasvir/sofosbuvir (Harvoni); simeprevir (Olysio); and sofosbuvir (Sovaldi), fixed-dose combination ombitasvir/paritaprevir/ritonavir (Technivie); and other DAAs that are FDA-approved for treatment of HCV.

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 project period in relation to the objectives, the complexity of the activities, and the anticipated results.

- The extent to which key personnel have adequate time devoted to the project to achieve project objectives.
- Strength of the applicant's line item budgets for each year of the project period (**Attachment 4**) and their appropriateness to the proposed work plan
- Strength and clarity of the application's budget justification narrative's support for each line item.
- If applicable, 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 long distance travel expenses associated with the annual working meetings held each project year in the Washington, DC, area; and any travel relating to proposed staff training.

2. Review and Selection Process

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

This program does not have any funding priorities or preferences. HRSA may use factors other than merit criteria in selecting applications for this federal award. For this program, HRSA will use the special considerations specified below.

Funding Special Considerations
HRSA intends to fund, through the competitive review process, the following RWHAP categories:

- Up to two awards to Part A recipients; and
- Up to two awards to Part B recipients

3. Assessment of Risk

The Health Resources and Services Administration 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).

Effective January 1, 2016, HRSA is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). An applicant may review and comment on any information about itself that a federal awarding agency previously entered. HRSA will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants 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).

The decision not to make an award or to make an award at a particular funding level, is discretionary and is not subject to appeal to any HHS Operating Division or HHS official or board.

4. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of September 30, 2016.

VI. Award Administration Information

1. Award Notices

The Notice of Award will be sent prior to the start date of September 30, 2016. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

2. Administrative and National Policy Requirements

See Section 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, recipients 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

The successful applicant under this FOA must comply with Section 6 of HRSA's *SF-424 Application Guide* **and** the following reporting and review activities:

1) **Annual Progress Report**: The recipient must submit a progress report to HRSA that covers activities for each budget year. Further information will be provided in the Notice of Award.

2) **Final Project Report**: The recipient must submit a progress report to HRSA that covers activities for the entire project period. Further information will be provided in the Notice of Award.

3) **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

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this FOA by contacting:

Beverly Smith
Grants Management Specialist
Health Resources and Services Administration
Division of Grants Management Operations, OFAM
5600 Fishers Lane, 10NWH04
Rockville, Maryland 20857
Telephone: (301) 443-7065
E-mail: bsmith@hrsa.hhs.gov

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Rupali Doshi, M.D.
Medical Officer
Office of Training and Capacity Development
Health Resources and Services Administration
HIV/AIDS Bureau
5600 Fishers Lane, Mail Stop: 09NWH04
E-mail: rdoshi@hrsa.gov
Telephone: (301) 443-5313
FAX: (301) 443-2697

Applicants may need assistance when working online to submit their application forms electronically. Applicants should 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, 8:00 a.m. to 8:00 p.m. ET:

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 June 6, 2016, 2:30 – 4:40 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: 888-455-9645
Passcode: 6232824
To access the webinar online, go to the Adobe Connect URL:
https://hrsa.connectsolutions.com/hrsa-16-189/

IX. Tips for Writing a Strong Application

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