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 - Evaluation and Technical Assistance Center

Announcement Type: New
Funding Opportunity Number: HRSA-16-188

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!
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may take up to one month to complete.

Release Date: May 16, 2016
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EXECUTIVE SUMMARY

Supported through funding from the Department of Health and Human Services (HHS) Secretary's Minority AIDS Initiative, the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) is accepting applications for (FY) 2016 *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Evaluation and Technical Assistance Center*. This three-year cooperative agreement program will support a single organization that will serve as an Evaluation and Technical Assistance Center (ETAC) working with up to four (4) Ryan White HIV/AIDS Program (RWHAP) Parts A and B cooperative agreement recipients (funded under HRSA-16-189) in the development of comprehensive jurisdiction-level hepatitis C (HCV) screening, care, and treatment systems for HIV/HCV coinfected people of color. The ETAC will provide technical assistance and capacity building to the RWHAP Parts A and B funded jurisdictions; collaborate with the AETC National Coordinating Resource Center (AETC/NCRC) to develop a National HCV Provider Competencies and Curriculum for HCV screening, care and treatment, with a focus on HIV/HCV coinfected people; design and implement a multisite evaluation to assess the implementation and impact of the four (or fewer) comprehensive HCV screening, care and treatment systems; and lead and coordinate the efforts for publication and dissemination of best practices, lessons learned and other findings from the initiative.

Funding Opportunity Title:	Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Evaluation and Technical Assistance Center
Funding Opportunity Number:	HRSA-16-188
Due Date for Applications:	July 14, 2016
Anticipated Total Annual Available Funding:	$550,000
Estimated Number and Type of Award(s):	Up to one (1) Cooperative Agreement
Estimated Award Amount:	Up to $550,000 per year
Cost Sharing/Match Required:	No
Project Period:	September 30, 2016 through September 29, 2019 (3 years)
Eligible Applicants:	Public and non-profit private organizations including health departments, state and local governments, tribal governments, community health centers, hospitals and medical centers, faith based and community based organizations, colleges and universities, for-profit companies and small businesses. [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 from 12:30 – 2:30 p m 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-16-188_ta/

Table of Contents

I. PROGRAM FUNDING OPPORTUNITY DESCRIPTION 1

1. PURPOSE 1
2. BACKGROUND 2

II. AWARD INFORMATION 4

1. TYPE OF APPLICATION AND AWARD 4
2. SUMMARY OF FUNDING 10

III. ELIGIBILITY INFORMATION 10

1. ELIGIBLE APPLICANTS 10
2. COST SHARING/MATCHING 10
3. OTHER 10

IV. APPLICATION AND SUBMISSION INFORMATION 11

1. ADDRESS TO REQUEST APPLICATION PACKAGE 11
2. CONTENT AND FORM OF APPLICATION SUBMISSION 11
i. Project Abstract 12
ii. Project Narrative 12
iii. Budget 18
iv. Budget Justification Narrative 18
v. Attachments 18
3. DUN AND BRADSTREET DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER AND SYSTEM FOR AWARD MANAGEMENT 20
4. SUBMISSION DATES AND TIMES 20
5. INTERGOVERNMENTAL REVIEW 20
6. FUNDING RESTRICTIONS 21

V. APPLICATION REVIEW INFORMATION 21

1. REVIEW CRITERIA 21
2. REVIEW AND SELECTION PROCESS 26
3. ASSESSMENT OF RISK 26
4. ANTICIPATED ANNOUNCEMENT AND AWARD DATES 27

VI. AWARD ADMINISTRATION INFORMATION 27

1. AWARD NOTICES 27
2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS 27
3. REPORTING 27

VII. AGENCY CONTACTS 28

VIII. OTHER INFORMATION 29

IX. TIPS FOR WRITING A STRONG APPLICATION 29

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 – Evaluation and Technical Assistance Center*. Funding will be provided in the form of a cooperative agreement to support one (1) organization for up to three years to coordinate the efforts of up to four (4) Ryan White HIV/AIDS Program (RWHAP) Parts A and B recipients funded under a separate announcement (HRSA-16-189). The purpose of the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Evaluation and Technical Assistance Center* initiative is to increase RWHAP Parts A and B jurisdiction-level capacity to provide comprehensive screening, care, and treatment for hepatitis C (HCV). These enhanced jurisdictional systems will increase the numbers of HIV/HCV coinfected people of color who are diagnosed, treated, and cured of HCV infection. Populations of interest include people of color living with HIV that have a high prevalence of coinfection with HCV, including Blacks/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.

The ETAC will assist RWHAP Parts A and B recipients funded under HRSA-16-189 in achieving their goal of a centrally coordinated, comprehensive system of HCV screening, care, and treatment among people living with HIV (PLWH). The ETAC will (1) provide technical assistance and capacity building assistance (TA/CBA) to the RWHAP Parts A and B funded jurisdictions; (2) design and implement a rigorous multisite evaluation to assess the implementation of the four comprehensive HCV screening, care, and treatment systems; and (3) lead and coordinate the efforts for publication and dissemination of best practices, lessons learned, and other findings from the initiative. The awarded RWHAP jurisdictions will be expected to cooperate with the ETAC in all phases of the project.

By the second month of Year 1, the ETAC will develop an assessment of coinfected patient knowledge regarding HCV treatment to be implemented by the four funded jurisdictions. Results of this Patient Knowledge Assessment will identify gaps to be addressed by implementing educational programs for consumers in their jurisdictions. Also by the second month of Year 1, the ETAC will develop an assessment of health care providers' knowledge of HCV screening and treatment among HIV/HCV coinfected people to be implemented by the four funded jurisdictions. Results of this Provider Assessment will identify knowledge gaps and training needs of health care providers to be addressed through training, TA/CBA. From these two assessments and a needs assessment conducted by each of the four funded jurisdictions, the ETAC will develop a TA/CBA Plan tailored to the needs of each jurisdiction, by the ninth month of Year 1. The TA/CBA Plan will include the implementation of a community of practice[1,2] of

[1] Introduction to communities of practice. http://wenger-trayner.com/introduction-to-communities-of-practice/. Accessed 4/25/16.

the project directors of the four jurisdictions, facilitated by the ETAC; the community of practice will provide a platform for the project directors to share challenges and lessons learned while implementing this project. Finally, in the first half of Year 1, the ETAC will be expected to develop a mixed-methods multisite evaluation plan (including quantitative and qualitative components) to assess the system and patient outcomes and the project implementation processes of the four jurisdictions.

Starting in the fourth quarter of Year 1, the ETAC will implement its TA/CBA Plan, providing individualized TA and CBA to the four jurisdictions and launching the Community of Practice. The ETAC will be expected to provide TA/CBA during regular teleconferences, through its website and webinars, during annual site visits, and at the annual national working meetings which will be coordinated by the ETAC and held in the Washington, DC area. Also starting in the second half of Year 1, the ETAC will implement its multisite evaluation, with the full cooperation of the four funded jurisdictions.

In Year 2, the ETAC will continue the TA/CBA activities and the multisite evaluation. The National HCV Provider Competencies and Curriculum will be implemented in Year 2 by the ETAC and the AIDS Education and Training Centers (AETCs). In Year 3, the ETAC will begin the analysis of its outcome and process data, and lead and coordinate publications and disseminations in collaboration with the HAB Special Projects of National Significance (SPNS) Program and the four funded jurisdictions.

Throughout the project, the ETAC will work in close coordination with the jurisdictional sites funded under HRSA-16-189, AETC program award recipients and other training and TA providers.

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 (HAB), Office of Training and Capacity Development, through the SPNS Program.

Although treatment outcomes continue to improve among PLWH,[3,4,5] HIV/HCV coinfection has emerged as a major concern, with approximately one quarter of PLWH also co-infected with

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[2] Wenger EC and Snyder WM. Communities of Practice: The Organizational Frontier. *Harvard Business Review* January-February 2000. https://hbr.org/2000/01/communities-of-practice-the-organizational-frontier. Accessed 4/25/16.

[3] 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

[4] Doshi RK, Milberg J, Isenberg D, Matthews T, Malitz F, Matosky M, Trent-Adams S, Hopson DP, & 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

[5] 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.

HCV.[6] People with HCV/ HIV co-infection have higher liver-related morbidity and mortality, even when their HIV infection is well controlled, and liver disease is one of the most common causes of non-AIDS deaths among PLWH.[7,8] 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.[9,10] In addition, MSM remain at risk for incident HCV infection.[11]

Several highly effective medications are available to treat and cure HCV in PLWH with minimal side effects.[12] 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 that are HIV/HCV co-infected, compared with HCV monoinfected individuals.[13] 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.[14,15,16,17,18,19,20] The HCV Care Continuum mirrors the HIV Care

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Published January 2016 and accessed 3-9-16 from: http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-hssr-mmp-2013.pdf.

[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] 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.

[8] 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

[9] 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

[10] 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.

[11] 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.

[12] 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

[13] 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

[14] 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

[15] 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

[16] 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,

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, as well as the number who have been treated and cured. Identified barriers to increased HCV treatment prescribing 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.

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 coinfected with HIV/HCV. For example, HRSA supported the Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV,[21] Technical Report (2011),[22] and implemented the SPNS Hepatitis C Treatment Expansion Initiative (2010 - 2014).[23] However, given the changes in the health care environment and advances in treatment, additional work is needed to expand treatment of HCV among individuals who are coinfected with HIV/HCV.

II. Award Information

1. Type of Application and Award

Type of applications sought: New

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

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

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

[17] 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/

[18] North CS, Hong BA, Adewuyi SA, Pollio DE, Jain MK, Devereaux R, Quartey NA, Ashitey S, Lee WM, & Lisker-Melman M. Hepatitis C treatment and SVR: the gap between clinical trials and real-world treatment aspirations. *General Hospital Psychiatry*. 2013; 35 (2): 122-128. Abstract available from: http://www.ncbi.nlm.nih.gov/pubmed/23219917

[19] 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. Accessed 3-14-16 from: http://www.nejm.org.ezproxyhhs.nihlibrary.nih.gov/doi/full/10.1056/NEJMp1302973

[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. Accessed 3-14-16 from: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101554

[21] 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.

[22] HRSA. Integrating Hepatitis C into Ryan White Clinics: Models and Tools. http://hab.hrsa.gov/files/hepatitiscmodelstools.pdf. Accessed 3/12/16.

[23] HRSA. Hepatitis C Treatment Expansion Initiative. http://hab.hrsa.gov/abouthab/special/spnshepatitisc.html. Accessed 4/25/16.

- 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;
- 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) Provision of technical assistance and capacity building assistance (TA/CBA)

The ETAC will provide TA/CBA to up to four funded jurisdictions under HRSA-16-189 for a range of needs over the course of the three-year initiative. The ETAC will conduct both initial and post-implementation routine assessments of the TA and CBA needs of the funded jurisdictions, to include a formatted, regular report to HAB SPNS staff. The ETAC will be expected to provide TA and CBA during regular teleconferences, through its website and webinars, during annual site visits, and at the annual national working meetings across the following domains:

a) TA/CBA: Comprehensive Jurisdiction-level HCV Screening, Care and Treatment System Planning, Implementation and Sustainability

The ETAC will develop an assessment of health care providers' knowledge of HCV screening and treatment, by the second month of Year 1. The Provider Assessment will be implemented by the four funded jurisdictions and submitted to the ETAC for analysis, with its results used to identify knowledge gaps and training needs of health care providers to be addressed through training, TA and CBA. The ETAC will develop an assessment of coinfected patient knowledge regarding HCV treatment, by the end of the second month of Year 1. The Patient Knowledge Assessment will be implemented by the four funded jurisdictions and results will be submitted to the ETAC for analysis by the end of the sixth month of Year 1, with its results used to identify gaps to be addressed by implementing educational programs for consumers in their jurisdictions.

The ETAC will analyze the Patient Knowledge Assessments, Provider Assessments; needs assessments conducted by the four funded jurisdictions; and their draft Project Implementation Plans, and develop a TA/CBA Plan tailored to the needs of each jurisdiction. The TA/CBA Plan will include assisting the funded jurisdictions and Regional AIDS

Education and Training Centers (AETCs) in their implementation of Communities of Practice and Learning among the providers of the four jurisdictions, using a Project ECHO (Extension of Community Healthcare Outcomes) approach.[24,25] The ETAC will assist the AETC Center, National Coordinating Resource Center (NCRC) and Regional AETCs to disseminate the National HCV Provider Competencies and Curriculum among providers in the funded jurisdictions.

The TA/CBA plan must be completed by the end of month 8 of Year 1, and submitted to the HAB SPNS Program for review and approval. During month 9 of year 1, the ETAC shall finalize the TA/CBA plan, utilizing HAB SPNS Program input.

The ETAC will implement its own Community of Practice[26,27] among the Project Directors/Managers of the funded jurisdictions to discuss challenges, emerging best practices and share TA/CBA resources, beginning in early Year 1.

The ETAC will implement the TA/CBA Plan beginning in month 10 of year 1, providing individualized TA and CBA to the four jurisdictions. The ETAC will assist the funded jurisdictions in the development of their plans to sustain their comprehensive HCV screening, care and treatment systems.

The ETAC is responsible for the planning and facilitation of recipient meetings, site visits, and conference calls. This will include, at a minimum, one annual site visit with each jurisdictional site, and one working meeting each year involving all of the jurisdictional sites. Annual working meetings will be held in the Washington, DC metropolitan area.

b) TA/CBA: Human Research Subjects Protection and Institutional Review Boards

Collection of any client-level data for the evaluation of this initiative will require diligent efforts to assure the privacy and confidentiality of the clients of funded jurisdictions and their medical records. The ETAC will be expected to lead these efforts and guide the funded jurisdictions in their compliance with human-subjects research protection set forth in the Code of Federal Regulations.[28] This will include review of the funded jurisdictions' required plans to safeguard client privacy and confidentiality and their documentation of procedures for electronic and physical protection of project information and data, in accordance with human

[24] Project ECHO. http://echo.unm.edu/ . Accessed 4/25/16.
[25] Arora S, Kalishman S, Thornton K, Dion D, Murata G, Deming P, Parish B, Brown J, Komaromy M, Colleran K, Bankhurst A, Katzman J, Harkins M, Curet L, Cosgrove E, & Pak W. Expanding access to hepatitis C virus treatment--Extension for Community Healthcare Outcomes (ECHO) project: disruptive innovation in specialty care. *Hepatology*, September 2010; 52 (3): 1124-33.
[26] Introduction to communities of practice. http://wenger-trayner.com/introduction-to-communities-of-practice/. Accessed 4/25/16.
[27] Wenger EC and Snyder WM. Communities of Practice: The Organizational Frontier. *Harvard Business Review* January-February 2000. https://hbr.org/2000/01/communities-of-practice-the-organizational-frontier. Accessed 4/25/16.
[28] See Code of Federal Regulations, Title 45, Part 46 Protection of Human Subjects, Revised January 15, 2009 Effective July 14, 2009, at: http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl

subjects research protections. Any deficits identified must be remedied by the funded jurisdictions, with the assistance of the ETAC.

The ETAC will be required to submit its data collection protocol and instruments for Institutional Review Board (IRB) review. Should the ETAC's IRB determine that its multisite evaluation plan and focused studies of interest are not exempt, the ETAC is also expected to serve as a resource for the funded jurisdictions regarding their own IRB review, approval and renewals of client-level data collection instruments, informed consents and any other pertinent evaluation documentation. The ETAC will also be responsible for tracking the IRB submissions, approvals and renewals of the funded jurisdictions and reporting them to the HAB SPNS program on a regular basis.

c) TA/CBA: *Multisite Evaluation and Local Evaluations*

The ETAC will be expected to assist the funded jurisdictions in implementing its multisite evaluation of the implementation and outcomes of their comprehensive HCV screening, care and treatment systems. This TA will include but is not limited to training funded jurisdiction staff in the use of the data collection instruments and web-based data entry portal; regular monitoring of data collection and reporting efforts by the funded jurisdictions; and remedial action when necessary to assure data collection is of the highest quality. Additionally, the funded jurisdictions will be expected to conduct their own local evaluations of their comprehensive HCV screening, care and treatment systems. The ETAC will serve as a resource to help the funded jurisdictions in the development, refinement, and implementation of their local evaluations to assure quality and validity.

2) Development and implementation of the Multisite Evaluation

The ETAC will be expected to develop and implement a mixed-methods multisite evaluation plan (including quantitative and qualitative approaches) to assess the system and patient outcomes and the project implementation processes of the comprehensive HCV screening, care and treatment systems implemented by the four jurisdictions, by the end of Year 1. The ETAC will begin the analysis of its outcome and process data early in Year 3. System and patient outcomes must include, at a minimum, the following data points to develop a multisite HCV Care Continuum, by race/ethnicity:

1) Number of PLWH in the jurisdiction
2) Screened for HCV: Number of PLWH in the jurisdiction screened for HCV since diagnosis of HIV
3) Chronic HCV: Number of PLWH in the jurisdiction who have chronic HCV infection (HCV RNA positive)
4) Linkage to HCV care: Number of HIV/HCV coinfected people in the jurisdiction who have been linked to a HCV provider (attended initial visit with HCV medication prescriber)
5) HCV treatment: Number of HIV/HCV coinfected people in the jurisdiction who have been prescribed HCV treatment

6) HCV cure: 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[29]).

The ETAC should be prepared to analyze the following data points as well, which shall be optional for the funded jurisdictions:

- 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)

Project implementation processes must include, at a minimum, best practices and lessons learned. The ETAC will implement its multisite evaluation, with the full cooperation of the four funded jurisdictions. The ETAC will design and implement focused studies of interest regarding HCV screening, care, and treatment systems, in collaboration with the funded jurisdictions and the HAB SPNS program.

3) Development and Implementation of Project Website and Data Portal

The ETAC will construct and maintain a secure website for the project that will include as a data portal for the reporting of multisite evaluation data by the funded jurisdictions. The website will also serve as a key component for the ETAC's TA/CBA delivery and as a communications nexus for the initiative, with both public access for promotion of the initiative and private password-protected access for funded jurisdictions, ETAC, and SPNS staff. The website shall contain a calendar of upcoming initiative events and national conferences with abstract submission deadlines, virtual resource library including recent findings of interest from outside the initiative, and registration system for the annual national working meetings of the initiative.

4) Publication and dissemination of best practices, lessons learned and other findings

Beginning in Year 2 and continuing throughout Year 3, the ETAC will lead and coordinate the publications and disseminations committee, made up of the ETAC, the four funded jurisdictions, AETCs, and HAB SPNS Program staff. This will include the identification of audiences and venues for the dissemination of findings, best practices and lessons learned, to include but limited to HRSA and HHS staff, peer-reviewed literature, and relevant scientific conferences. These activities must also include adherence to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds.

[29] 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

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 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 $550,000 is expected to be available annually to fund one (1) recipient. Applicants may apply for a ceiling amount of up to $550,000 per year. The project period is three (3) years. Funding beyond the first year is dependent on the availability of appropriated funds for *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Evaluation and Technical Assistance Center* 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

Entities that are eligible to apply include public and non-profit private organizations including health departments, state and local governments, tribal governments, community health centers, hospitals and medical centers, faith based and community based organizations, colleges and universities, for-profit companies and small businesses.

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.

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 of the roles and activities of the ETAC. Specifically, how the ETAC will provide leadership in its three primary functions: provision of TA/CBA to the funded jurisdictions, design and implementation of the multisite evaluation, and publication and dissemination efforts for the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color* initiative. Briefly describe the multisite evaluation and TA services that the ETAC will provide. Briefly describe the applicant organization and any collaborating organizations.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion 1 (Need)*
  Provide a brief summary, no more than four pages, of the literature that demonstrates a comprehensive understanding of issues regarding the provision of HCV screening, care and treatment to HIV/HCV coinfected people of color. Discuss the factors driving incidence and prevalence rates of HIV/HCV coinfection among the initiative's target populations, including Blacks/African Americans, Latinos/as, American Indians/Alaska Natives, as well as PWID and MSM, using the most recent available data. Data sources may include HCV testing data for PLWH from electronic health record systems, surveillance and epidemiology reports, profiles of state and local public health departments, needs assessment surveys, risk behavioral surveys, and other programmatic data.

  Discuss technical and programmatic issues in HCV screening, with particular attention to those at high risk of HCV infection, identifying salient challenges and possible strategies to address those challenges. Discuss clinical issues in HCV treatment of those coinfected with HIV, identifying salient challenges and possible strategies to address them. Discuss

barriers to access to and completion of HCV treatment encountered by HIV/HCV coinfected people of color and the role of ancillary services in facilitating their access. Provide a summary of the policy, financial, and structural issues that impact the provision of HCV screening, care and treatment services for HIV/HCV coinfected people of color.

- *METHODOLOGY -- Corresponds to Section V's Review Criteria 2 (Response), 3 (Evaluative Measures), and 4 (Impact)*
  Discuss how the National HCV Provider Competencies and Curriculum, developed by a work group led by the AETC National Coordinating Resource Center (NCRC) and including the AETC National Clinicians' Consultation Center, other AETC representatives and national experts, will be used in the initiative and disseminated among HCV providers in the funded jurisdictions.

  Describe a plan for the provision of TA/CBA to up to four funded jurisdictions over the course of the initiative. Include the process for both initial pre-implementation and post-implementation routine assessments of the TA and CBA needs of the funded jurisdictions under HRSA-16-189, to include a formatted, regular report to HAB SPNS staff. Describe the ETAC's methodology and any theory basis for the design and analysis of the required assessment of knowledge of HIV/HCV coinfected patients of color regarding HCV treatment, as well as the required assessment of health care providers' knowledge, skills and behaviors of HCV screening and treatment of HIV/HCV coinfected people, which will both be implemented by the jurisdictions funded under HRSA-16-189. Include samples of both assessment tools as **Attachment 8**. Discuss how the findings from the Patient Knowledge Assessment and the Provider Assessment, and the ETAC's analysis of the Needs Assessments and draft Project Implementation Plans submitted by the funded jurisdictions, will inform the ETAC's TA/CBA plan, to be tailored to the needs of each funded jurisdiction. Describe what kinds of TA/CBA needs are anticipated, and by what means/venues they will be addressed, such as regular teleconferences, through the ETAC's website and webinars, during annual site visits, and at the annual national working meetings to be coordinated by the ETAC and held in the Washington, DC, area. Describe the approach to supporting the funded jurisdictions, their affiliated training and TA providers and regional AETCs to develop their own jurisdiction-level Communities of Practice and Learning for HCV providers (which will utilize Project ECHO methodology).[30] Describe the elements of a site visit protocol for the annual site visits to the funded jurisdictions.

  Describe the approach to the formation and facilitation of a Community of Practice among the project directors of the four jurisdictions, to be facilitated by the ETAC. Describe the approach to assisting the funded jurisdictions in the development of their plans to sustain their comprehensive HCV screening, and care and treatment systems of HIV/HCV coinfected people of color, including realistic funding and programmatic strategies.

[30] Arora S, Kalishman S, Thornton K, Dion D, Murata G, Deming P, Parish B, Brown J, Komaromy M, Colleran K, Bankhurst A, Katzman J, Harkins M, Curet L, Cosgrove E, & Pak W. Expanding access to hepatitis C virus treatment--Extension for Community Healthcare Outcomes (ECHO) project: disruptive innovation in specialty care. *Hepatology*, September 2010; 52 (3): 1124-33.

Describe the plans to assist the funded jurisdictions in implementing the ETAC's multisite evaluation of the implementation and outcomes of their comprehensive HCV care and treatment systems for HIV/HCV coinfected people of color. This TA should include but is not limited to special studies, training funded jurisdiction staff in the use of the data collection instruments and web-based data entry portal, regular monitoring of data collection and reporting efforts by the funded jurisdictions, and remedial action when necessary to assure data collection is of the highest quality. Describe the approach to assisting the funded jurisdictions in the development, refinement and implementation of their own local evaluations of their comprehensive HCV care and treatment systems for HIV/HCV coinfected people of color, to assure quality and validity.

If applicable, describe a plan for review of the funded jurisdictions' plans to safeguard the privacy and confidentiality of study participants and their documented procedures for the electronic and physical protection of study participant information and data, in accordance with human subjects research protections. Include a means of assisting the funded jurisdictions to remedy those deficits.

Should the ETAC's IRB determine that its multisite evaluation plan and focused studies of interest (see below) are not exempt, describe the approach to serving as a resource for the funded jurisdictions regarding their own IRB review, approval and renewals of client-level data collection instruments, informed consents and any other pertinent evaluation documentation. Describe the means of tracking the IRB submissions, approvals and renewals of the funded jurisdictions and reporting them to the HAB SPNS program on a regular basis.

Describe a plan for a rigorous, mixed-methods national multisite evaluation (including quantitative and qualitative approaches) across the funded jurisdictions that will have maximum impact on practice and policy affecting HCV screening, care and treatment among people of color coinfected with HIV/HCV. Discuss anticipated evaluation questions for assessing the effectiveness of the comprehensive HCV systems of funded jurisdictions. Describe the methodology that will be used to conduct the multisite evaluation and provide the rationale for its selection. Outline the system and client-level outcome and project implementation elements of the multisite evaluation, and propose possible measures for them. System and patient outcomes must include, at a minimum, the following outcomes to develop a multisite HCV Care Continuum, by race/ethnicity (to ensure appropriate focus on target populations for this funding opportunity announcement):

1) Number of PLWH in the jurisdiction
2) Screened for HCV: Number of PLWH in the jurisdiction screened for HCV since diagnosis of HIV
3) Chronic HCV: Number of PLWH in the jurisdiction who have chronic HCV infection (HCV RNA positive)
4) Linkage to HCV care: Number of HIV/HCV coinfected people in the jurisdiction who have been linked to a HCV provider (attended initial visit with HCV medication prescriber)

5) HCV treatment: Number of HIV/HCV coinfected people in the jurisdiction who have been prescribed HCV treatment
6) HCV cure: 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[31]).

Describe a plan to analyze the following data points, which shall be optional for the funded jurisdictions:

- 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)

Project implementation processes must include, at a minimum, best practices and lessons learned. Propose any additional focused studies of interest relating to HCV screening, care and treatment, describing their rationale and possible impact. State the commitment to submit multisite data collection protocol and instruments for IRB review, and identify the IRB. State the agreement to submit IRB approval and renewal letters to the HAB SPNS program.

Describe the plans to construct and maintain a secure website for the initiative to serve as a data portal for the reporting of multisite evaluation data by the funded jurisdictions. Describe the documented procedures for the electronic and physical protection of participant information and data. Describe the capabilities of the website as a communications nexus for the initiative, with both public access for promotion of the initiative and private password-protected access for funded jurisdictions, ETAC, HCV providers, AETC and HAB SPNS staff. Discuss how the website will be used to provide TA and resources for funded jurisdictions, and include ongoing documentation of presentation, publication and dissemination efforts for the initiative; a calendar of upcoming initiative events and national conferences with abstract submission deadlines; a registration system for the annual national working meetings of the initiative; recent findings of interest from outside the initiative; and access/links to relevant resources.

Describe the approach in leading publication and dissemination efforts for the initiative's findings, best practices and lessons learned. Provide a brief discussion of how a publications and disseminations committee, composed of ETAC, funded jurisdictions, AETC and HAB SPNS staff would operate. Provide a dissemination plan identifying appropriate venues and target audiences, including but not limited to policy makers and national conferences geared toward HCV care and treatment providers. The dissemination plan should include best practices and lessons learned, and help facilitate the replication of HCV screening and access to treatment strategies proven effective by the multisite evaluation.

[31] 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

- *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-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, realistic and measurable; (3) action steps; (4) staff responsible for each action step; and (5) anticipated dates of completion. Among key activities that may be addressed in the time line 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 type of challenges (organizational, administrative, regulatory, technological and human-related) that are likely to be encountered in implementing the proposed project. Discuss approaches that will be used to resolve such challenges.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion 5 (Resources/Capabilities)*
  Describe how the proposed key project personnel (including any consultants and contractors, if applicable) have the necessary knowledge, experience, training and skills to provide TA/CBA across the domains listed earlier in this announcement. Describe the experience of project personnel in logistical planning for meetings that involve scientific and public health partners from across the United States.

  Describe the organization's capacity to conduct a comprehensive multisite evaluation of the proposed project. Describe the knowledge and expertise of proposed staff (including any consultants and contractors to be funded under this cooperative agreement , if applicable) in designing and conducting evaluations of public health programs for HCV screening among PLWH and care and treatment systems for HIV/HCV coinfected people. Provide evidence of their experience, skills, training and knowledge in achieving scientific excellence and evaluation integrity. Discuss any examples of previous projects that reflect the expertise of proposed staff, as well as proficiency in working collaboratively with large demonstration projects. Describe the Human Subjects Research Protections training of proposed staff. Describe the experience of proposed key project staff (including any consultants and contractors, if applicable) in collaborative writing and publishing study findings in peer-reviewed journals, making presentations at scientific conferences, and preparing materials for the dissemination of findings and implementation in other jurisdictions in the United States.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion 5 (Resources/Capabilities)*
  Describe the organization's mission and structure, scope of current activities, the quality and availability of facilities, and the scope of its current activities. Describe how these all contribute to the organization's ability to successfully carry out a project of this magnitude and meet the goals and objectives of this initiative. Describe the organization's capacity to conduct the multisite evaluation and TA/CBA activities described earlier in this announcement. Provide information on the organization's ability to lead and coordinate the publication and dissemination of best practices, lessons learned and other findings from the multisite evaluation. Describe the capacity of the organization's management information systems to support a comprehensive multisite evaluation in the collection, reporting and secure storage of client-level data. Describe the capacity of the organization to build and maintain the project website as described earlier. 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 who will 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, (3) Evaluative Measures and (4) Impact
Work Plan	(2) Response
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Justification 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 – Evaluation and Technical Assistance Center* program 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**.

In the budgets, include the logistical and coordination costs for annual working meetings to be held in Washington, DC, and costs to cover long distance travel and lodging costs for the required annual site visits to the funded jurisdictions.

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, time-framed, realistic 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, consultants, 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 deliverables. 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 and 5. Each biographical sketch should not 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 8: Tools for Patient Knowledge Assessment and Provider Assessment (required)

Include tools to be used in the patient knowledge assessment regarding the benefits of HCV treatment for HIV/HCV coinfected people and the provider assessment regarding knowledge, skills and behavior related to screening, care and treatment of HIV/HCV coinfected people of color.

***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

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 – Evaluation and Technical Assistance Center 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

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

1) Any charges that are billable to third party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare, HUD, other RWHAP funding including the AIDS Drug Assistance Program;
2) To directly provide medical or support services (e.g., HIV care, counseling and testing) that supplant existing services;
3) Cash payments to intended recipients of RWHAP services;
4) Purchase, construction of new facilities or capital improvements to existing facilities;
5) Purchase or improvement to land;
6) Purchase vehicles;
7) Fundraising expenses;
8) Lobbying activities and expenses;
9) Reimbursement of pre-award costs; and/or
10) 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 – Evaluation and Technical*

Assistance Center program has six (6) review criteria:

Criterion 1: Need	10 points
Criterion 2: Response	30 points
Criterion 3: Evaluative Measures	20 points
Criterion 4: Impact	10 points
Criterion 5: Resources/Capabilities	20 points
Criterion 6: Support Requested	10 points

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

- Strength and clarity of the applicant's description of how the ETAC will provide leadership in its three primary functions (provision of TA/CBA to the funded jurisdictions; design and implementation of the multisite evaluation; and publication and dissemination).
- Extent to which applicant's summary of the literature demonstrates a comprehensive understanding of issues regarding the provision of HCV screening, care and treatment to HIV/HCV coinfected people of color.
- Strength and clarity of the applicant's discussion of the factors driving incidence and prevalence rates of HIV/HCV coinfection among the initiative's target populations of Blacks/African Americans, Latinos/as, American Indians/Alaska Natives, as well as PWID and MSM, using the most recent available data, including HCV testing data for PLWH; surveillance and epidemiology reports; profiles of state and local public health departments; needs assessment surveys; risk behavioral surveys; and other programmatic data.
- Strength and clarity of the applicant's discussion of the clinical, programmatic, policy, financial and structural issues in HCV screening, care and treatment for HIV/HCV coinfected people of color, identifying salient challenges and possible strategies to address those challenges.

Criterion 2: RESPONSE (30 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 (20 points)

- Strength and clarity of the proposed methodology, theory basis and survey tool for the design and analysis of the required assessment of HIV/HCV coinfected patient of color knowledge regarding HCV treatment, and the required assessment of health care providers' knowledge of HCV screening, care and treatment for HIV/HCV coinfected people of color to be implemented by the funded jurisdictions.

- Strength and clarity of the applicant's discussion of how the findings from the Patient Knowledge Assessment and the Provider Assessment, and the ETAC's analysis of the Needs Assessments and draft Project Implementation Plans submitted by the funded jurisdictions will inform the ETAC's TA/CBA plan.
- Strength and clarity of the applicant's description of what kinds of TA/CBA needs are anticipated, and by what means/venues they will be addressed, such as regular teleconferences, through the ETAC's website and webinars, during annual site visits, at the annual national working meetings to be coordinated by the ETAC and held in the Washington, DC, area, and through assistance of the Regional AETCs and jurisdictions to develop their own Communities of Practice and Learning for HCV providers using Project ECHO methodology,[32] and through facilitation of Community of Practice among the project directors of the four jurisdictions, which will provide a forum for funded jurisdictions to share successes and challenges.
- Strength and clarity of the applicant's approach to collaborating with the AETC program recipients and other training and TA providers, to meet the training needs identified in this project.
- Strength and clarity of the applicant's proposed site visit protocol for the annual site visits to the funded jurisdictions.
- Strength and feasibility of the applicant's approach to assisting the funded jurisdictions in the development of their plans to sustain their comprehensive HCV screening care and treatment systems for HIV/HCV coinfected people of color, including realistic funding and programmatic strategies at the jurisdictional level.
- Strength and feasibility of the applicant's approach to assisting the funded jurisdictions in the development, refinement and implementation of their own local evaluations of their comprehensive HCV systems, to assure quality and validity.
- Strength and feasibility of the applicant's plans to assist the funded jurisdictions in implementing the multisite evaluation of the comprehensive HCV systems.
- Strength and clarity of the applicant's plan for review and remedial action for the funded jurisdictions' plans to safeguard the privacy and confidentiality of study participants, and their documented procedures for the electronic and physical protection of study participant information and data, in accordance with human subjects research protections.
- Strength and clarity of the applicant's approach to serving as a resource for the funded jurisdictions regarding their own IRB review, approval and renewals of client-level data collection instruments, informed consent forms and any other pertinent evaluation documentation.
- Strength and feasibility of the proposed means of tracking the IRB submissions, approvals and renewals of the funded jurisdictions and reporting them to the HAB SPNS program on a regular basis.
- Strength and clarity of the applicant's description of the capabilities of its website as a communications nexus for the initiative including a calendar of upcoming initiative events and national conferences with abstract submission deadlines, virtual resource library,

[32] Arora S, Kalishman S, Thornton K, Dion D, Murata G, Deming P, Parish B, Brown J, Komaromy M, Colleran K, Bankhurst A, Katzman J, Harkins M, Curet L, Cosgrove E, & Pak W. Expanding access to hepatitis C virus treatment--Extension for Community Healthcare Outcomes (ECHO) project: disruptive innovation in specialty care. *Hepatology*, September 2010; 52 (3): 1124-33.

registration system for the annual national working meetings of the initiative, recent findings of interest from outside the initiative; with a public access area for promotion of the initiative, and a private password-protected access area for funded jurisdictions, ETAC, HCV providers, AETC and HAB SPNS staff, for a data portal and internal communication.

ii. Work Plan (7 points)

- Strength, clarity and feasibility of the applicant's work plan and its goals for the three year project period (**Attachment 1**), including each planning, implementation and evaluation activity; the staff responsible to accomplish each step; and anticipated dates of completion.
- Extent to which the applicant's work plan addresses the program requirements the applicant described in the Methodology section of the Narrative.
- Evidence the applicant's objectives for the three year project period are specific to each goal, time-framed, realistic and measurable.

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 in a timely manner.

Criterion 3: EVALUATIVE MEASURES (20 points) – *Corresponds to Section IV's Methodology*

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

- Strength and rigor of the applicant's methodology (including evaluation questions) for a mixed-methods national multisite evaluation (including quantitative and qualitative approaches) across the funded jurisdictions that will have maximum impact on practice and policy affecting HCV screening, care and treatment among HIV/HCV coinfected people of color.
- Strength, rationale and possible impact of the proposed additional focused studies of interest relating to HCV screening, care and treatment for HIV/HCV coinfected people of color.
- Strength and appropriateness for the proposed system-level and client-level outcome and project implementation elements and measures for the multisite evaluation. At a minimum, system and patient outcomes must include the following measures, by race/ethnicity:
    1) Number of PLWH in the jurisdiction
    2) Screened for HCV: Number of PLWH in the jurisdiction screened for HCV since diagnosis of HIV
    3) Chronic HCV: Number of PLWH in the jurisdiction who have chronic HCV infection (HCV RNA positive)

4) Linkage to HCV care: Number of HIV/HCV coinfected people in the jurisdiction who have been linked to a HCV provider (attended initial visit with HCV medication prescriber)
5) HCV treatment: Number of HIV/HCV coinfected people in the jurisdiction who have been prescribed HCV treatment
6) HCV cure: 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[33]).

- Strength and clarity of the applicant's plans to analyze the following data points, which shall be optional for the funded jurisdictions:
  - 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)
- Strength and clarity of the applicant's plans to construct and maintain a secure website for the initiative to serve as a data portal for the reporting of multisite evaluation data by the funded jurisdictions.
- Strength and clarity of the applicant's documented procedures for the electronic and physical protection of participant information and data.

Criterion 4: IMPACT (10 points) – *Corresponds to Section IV's Methodology*
The feasibility and effectiveness of plans for dissemination of project results, and the degree to which the project activities are replicable.

- Strength and feasibility of the applicant's approach in leading publication and dissemination efforts for the initiative's findings, best practices and lessons learned.
- Strength and clarity of the applicant's brief discussion of how a publications and disseminations committee, composed of ETAC, funded jurisdictions, AETC and HRSA staff would operate.
- Strength and appropriateness of the proposed dissemination plan, to include the identification of appropriate venues and target audiences, including but not limited to other RWHAP-funded jurisdictions funded under Part A and Part B, policymakers, and national conferences geared toward HCV care and treatment providers. The dissemination plan should include best practices and lessons learned, and help facilitate the replication of HCV screening and access to treatment strategies proven to be effective by the multisite evaluation.

Criterion 5: RESOURCES/CAPABILITIES (20 points) – *Corresponds to Section IV's Evaluation and Technical Support 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.

[33] 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

- Strength and extent to which the proposed project personnel (including any consultants and contractors, if applicable) have the necessary knowledge, experience, training and skills to provide TA/CBA for jurisdictional planning related to hepatitis C screening, care and treatment, human subjects research protections and institutional review boards, and multisite evaluation.
- Extent of the proposed key project staff's (including any consultants and contractors, if applicable) training, experience, knowledge and skills in designing and implementing public health program evaluations, achieving scientific excellence, maintaining evaluation integrity, writing collaboratively and publishing study findings in peer reviewed journals, making presentations at conferences, and disseminating study findings to public health practitioners.
- Strength and extent of the proposed project personnel's (including any consultants and contractors, if applicable) training, experience, knowledge and skills in logistical planning for national scientific and/or public health meetings.

Criterion 6: SUPPORT REQUESTED (10 points) – *Corresponds to Section IV's Budget and Budget Justification Narrative*
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 project personnel have adequate time devoted to the project to achieve stated objectives.
- 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 logistical and coordination costs of the annual working meetings held each project year in the Washington, DC, area.
- Evidence that the budgets allocate sufficient support to meet the long distance travel expenses associated with the annual site visits and annual working meetings held each project year in the Washington, DC, area.

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, preferences or special considerations.

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 the entire budget year. Further information will be provided in the award notice.

2) **Final Project Report**: The recipient must submit a final project report to HRSA that covers activities for the entire performance period. Further information will be provided in the award notice.

3) The recipient must submit the final **Patient Knowledge Assessment** and **Provider Assessment** tools by the end of month 2 in Year 1.

4) The recipient must submit the **final multisite evaluation**, including conference abstracts, manuscripts for peer-reviewed journals and other dissemination materials by the end of Year 3.

5) The recipient must submit all **TA and CBA resources** by the end of Year 3.

6) **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
Health Resources and Services Administration
5600 Fishers Lane, Room 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
Health Resources and Services Administration
HIV/AIDS Bureau
Office of Training and Capacity Development
5600 Fishers Lane, 09NWH04

Rockville, Maryland 20857
Telephone: (301) 443-5313
FAX: (301) 443-2697
Email: rdoshi@hrsa.gov

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

Technical Assistance Webinar:
All interested 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, from 12:30 – 2:30 p m 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-16-188_ta/

IX. Tips for Writing a Strong Application

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