To: National Alliance of State and Territorial AIDS Directors (NASTAD)

From: U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB)

Subject: Request for Proposal to apply for a single source cooperative agreement award, the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – State Health Departments Coordinating Center (HRSA-16-195)*, in response to an urgent public health problem caused by HIV and Hepatitis C coinfection

I. Program Description - Background and Purpose

This request solicits your application for the *State Health Departments Coordinating Center* of the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color* demonstration project. This program has four goals: 1) Increase jurisdiction-level capacity to provide comprehensive screening, care and treatment for HCV among HIV/HCV co-infected people; 2) Increase the numbers of HIV/HCV co-infected people who are diagnosed with hepatitis C, treated, and cured; 3) Identify and provide technical assistance for jurisdictions to reach goals (1) and (2); and, 4) Develop a plan for evaluation of the program impact. NASTAD will work in close coordination with the *Evaluation and Technical Assistance Center* (ETAC) of the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color*, funded under Funding Opportunity Announcement HRSA-16-188.

NASTAD's role is to facilitate the participation of up to two (2) Ryan White HIV/AIDS Program (RWHAP) Part B recipients as subrecipients in this demonstration project outlined in HRSA-16-189 *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – Jurisdictional Sites*. Selection criteria for the RWHAP Part B participants shall focus on need, geographic location, and capabilities for successful participation in this project. Need is demonstrated by 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 program, 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. In consultation with HRSA, NASTAD will 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 people living with HIV (PLWH) and AIDS living in the jurisdiction. Estimates of HIV/HCV coinfection among PLWH of color may be based on national or local estimates.

NASTAD would assist participating RWHAP Part B subrecipients with the following:

During the initial six months of Year One (1), Part B subrecipients shall complete a needs assessment to: understand gaps and barriers in their existing HCV screening, care, and treatment systems of HIV/HCV coinfected people 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 the access of HCV-related services encountered by coinfected people 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, RWHAP Part B subrecipients 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. Subrecipients 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, RWHAP Part B subrecipients 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), RWHAP Part B subrecipients shall continue implementation of the plans to enhance the jurisdiction's public health infrastructure to expand screening, care, and treatment of HIV/HCV coinfected people of color. At the end of the three-year project period, subrecipients 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/HCV coinfected people of color.

Throughout the period of performance, NASTAD and RWHAP Part B subrecipients from this program announcement will work closely with the *Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color – ETAC* (the RAND Corporation funded under HRSA-16-188), as well as with the <u>Regional AIDS Education and Training Centers</u> (AETC) in their jurisdiction and the AETC <u>National Coordinating Resource Center</u> (NCRC).

This initiative is funded through the Secretary's Minority AIDS Initiative Fund (SMAIF) authorized under The Consolidated Appropriations Act, 2016 (P. L. 114-113), Division H, Title II. This initiative is administered by the HRSA HAB Office of Training and Capacity

Development, through the Special Projects of National Significance (SPNS) Program, and in collaboration with the Division of State HIV/AIDS Programs (DSHAP).

II. Federal Award Information - Summary of Funding

This program expects to provide funding during federal fiscal years (FFY) 2016 - 2018. The three-year project period will be September 30, 2016, to September 29, 2019. In FFY 2016, up to \$977,400 is available. In FFYs 2017 and 2018, up to \$750,000 is available each year. NASTAD will subaward up to \$265,000 annually to each RWHAP Part B recipient selected for this project. Funding beyond the first year is dependent on the availability of appropriated funds, NASTAD's satisfactory performance, and a decision that continued funding is in the best interest of the Federal government. This single source award does not require cost sharing/matching.

III. Cooperative agreement roles and responsibilities for HRSA and NASTAD

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.

For this cooperative agreement, **HRSA will**:

- In collaboration with NASTAD, participate in the development of the selection process to be used by NASTAD in NASTAD's selection of the RWHAP Part B recipients who are to be funded through the cooperative agreement;
- Provide the services of experienced HRSA HAB personnel as participants in the planning, development, management and technical performance of all phases of the project;
- Coordinate the partnership and communication with other federal agencies' personnel and other funded capacity building entities;
- Provide 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;
- Participate in conference calls, meetings, and site visits to be conducted during the period of the cooperative agreement;
- Provide information resources and facilitating partnerships with other RWHAP recipients and stakeholders; and
- Participate in the dissemination of project findings, best practices and lessons learned.

In collaboration with HRSA, NASTAD will:

1) Project Pre-implementation Activities (Year 1)

- Select and subaward up to two RWHAP Part B recipients through the cooperative agreement for participation in this demonstration project.
- Assist the selected RWHAP Part B recipients in completing a needs assessment that includes the following:

- O Description of the epidemiology of HIV/HCV coinfection among people of color in the jurisdiction using surveillance and other available data;
- o Identification of the gaps in RWHAP service provision in the existing HCV screening, care and treatment system of the jurisdiction;
- o Identification of the structural, financial and client-level barriers to the access of HCV-related services encountered by HIV/HCV coinfected patients; and
- o Review of State and local laws and policies and third-party payer policies regarding the costs of HCV screening and treatment.
- Review, revise and submit the selected RWHAP Part B recipients' needs assessments 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, AETC, HRSA and/or external entities.
- Assist selected RWHAP Part B recipients in conducting 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. NASTAD shall submit the results of the survey to the ETAC for review.
- Assist selected RWHAP Part B recipients in conducting 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.
- Assist selected RWHAP Part B recipients in developing 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, <u>must</u> include:
 - O Provider Training: to include identification of HCV providers (physicians, nurse practitioners, physician assistants, nurses, pharmacists, and behavioral health staff) who care for HIV/HCV coinfected people; 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.
 - o *Patient Education*: to inform HIV/HCV co-infected patients of the benefits of and access to treatment for HCV.
 - o *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, ^{1,2} AETCs program, ³ SPNS System-level

¹ See HRSA/SPNS Hepatitis C Treatment Expansion Initiative at: http://hab.hrsa.gov/abouthab/special/spnshepatitisc.html

² Wills T, Friedrich M, Beal J, Somboonwit C, Mcintosh S, Bork A, Tinsley M, Cajina A, Belton P, Xavier J, Doshi

- Workforce Capacity Building for Integrating HIV Primary Care in Community Health Care Settings,⁴ and National Center for Interprofessional Practice and Education.⁵
- 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:
- o 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);
- o *Medication Adherence Support*: to include directly observed therapy for coinfected people at risk of therapy non-completion.
- Assist selected RWHAP Part B recipients to prepare, revise and submit the Project Implementation Plans to the ETAC for review, comment and approval.
- Assist selected RWHAP Part B recipients to design a local evaluation plan, with assistance from the ETAC.

2) Project Implementation Activities (Year 2 and Year 3)

- Assist selected RWHAP Part B recipients to implement the projects, in accordance with their individual Project Implementation Plans. The required components include:
 - Implementation of the provider training component, working with the ETAC and AETCs to provide appropriate training support to novice and experienced providers.
 - o Implementation of the patient education component, working with the ETAC.
 - o Implementation of the practice transformation component.
 - o Implementation of the enhanced HCV screening component.
 - o Implementation of the treatment access component.
 - o Implementation of the medication adherence support component.
 - o 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.
- Assist selected RWHAP Part B recipients to collect and report system, patient outcome
 and project implementation process data to the ETAC, including the following required
 data points to be collected by race/ethnicity:

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

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

⁴ 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.

⁵ National Center for Interprofessional Practice and Education. https://nexusipe.org/. Accessed 3/12/16.

- 1) Number of PLWH in the jurisdiction
- 2) Number of PLWH in the jurisdiction screened for HCV since HIV 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).

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 (Year 2 and Year 3)

Participate in the following activities to support the selected RWHAP Part B recipients:

- 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.
- Publication and dissemination activities to disseminate findings, best practices and lessons learned, as coordinated by the ETAC.

IV. Application and Submission Information

HRSA *requires* NASTAD to apply electronically through Grants.gov. Please download the SF-424 application package associated with HRSA-16-195 following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

NASTAD must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which you have an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR § 25.110(b) or (c), or has an exception approved by the agency under 2 CFR § 25.110(d)).

The application package consists of the following:

Project Abstract

Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed project including the needs to be addressed, the proposed services, and the population group(s) to be served.

Please place the following at the top of the abstract:

- Project Title
- Organization Name
- Address
- Project Director Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable

The project abstract must be single-spaced and limited to one page in length.

Program Narrative (3 – 5 pages)

- 1) Please describe your history working with State Health Departments and RWHAP Part B recipients.
- 2) Please briefly describe any past and/or current work around enhancing access to HIV and HCV services.
- 3) Please describe your ability to work with HRSA/HAB to identify 2-3 RWHAP Part B recipients to take part in this project.
- 4) Please describe your past experience and ability to support State Health Departments to identify and overcome structural and institutional barriers to implementing HIV service programs.
- 5) Describe your ability to assist and support identified States to conduct a needs assessment to identify gaps in the existing HCV screening, care and treatment system.
- 6) Describe your ability to utilize your current agency infrastructure to rapidly ramp up and implement this program.

Instructions for Completing the SF-424

Application Face Page

Complete Application Form SF-424 provided with the application package. Prepare according to instructions provided in the form itself.

Important note regarding the SF-424:

• Enter the name of the **Project Director** in 8. f. "Name and contact information of person to be contacted on matters involving this application." If, for any reason, the PD will be out of

the office, please ensure the email Out of Office Assistant is set so HRSA will be aware if any issues arise with the application and a timely response is required.

• Enter the amount requested during the first budget period in item 18 a.

The CFDA Number (93.928) is prepopulated in box 11 of the form.

This program is not subject to E.O. 12372, "Intergovernmental Review of Federal Programs."

SF-424A Budget

See Section 4.1.iv of HRSA's <u>SF-424 Application Guide</u>. 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.

Funding Restrictions: 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 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 <u>SF-424 Application Guide</u> for additional information. Note that these or other salary limitations may apply in FY 2017, as required by law.

See section 2 of HRSA's <u>SF-424 Application Guide</u> for applicable National Policy and administrative requirements.

Budget Narrative

Provide a brief budget narrative that explains the amounts requested for each line of the budget in Section B. 6. Object Class Categories of the SF-424A Budget. The budget narrative should describe how each item will support the achievement of the proposed project. Be very careful about showing how each item in the "other" category is justified. For subsequent budget years, the narrative should highlight the changes from year one or clearly indicate that there are no

substantive budget changes during the project period. Do NOT use the budget narrative to expand the project narrative.

Assurances

Complete Application Form SF-424B Assurances – Non-Construction Programs. See section IV. vii. of the *SF-424 Application Guide*.

Certifications

Complete the required Certification Regarding Lobbying Form and, if applicable, the Disclosure of Lobbying Activities Form provided with the application package. See section IV. viii. of the *SF-424 Application Guide*.

V. Submission Deadline

The due date for the application is September 19, 2016 at 11:59 P.M. Eastern Time.

VI. Application Review Process

HRSA will review the application and will make a final award decision based on the following information:

- The feasibility and impact of the proposed plan in addressing the project goals.
- The feasibility and appropriateness of the budget provided to support the plan.

VII. 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.

VIII. Reporting Requirements

NASTAD must comply with Section 6 of HRSA's <u>SF-424 Application Guide</u> 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. Submission and HRSA approval of awardee Progress Report(s) triggers the budget period renewal and release of subsequent year funds. This report has two parts. The first part demonstrates awardee progress on program-specific goals. The second part collects core performance measurement data including performance measurement data to measure the progress and impact of the project. Further information will be provided in the Notice of Award.
- 2) **Integrity and Performance Reporting.** The Notice of Award will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR 75 Appendix XII.

IX. Agency Contacts

NASTAD may obtain technical assistance regarding this award by contacting:

Harold J. Phillips, MRP

Director, Office of HIV/AIDS Training and Capacity Development

E-mail: HPhillips@hrsa.gov Telephone: (301) 443-8109

Fax: (301) 443-2697

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

For assistance with submitting information in HRSA's Electronic Handbooks (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