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

HIV/AIDS Bureau Division of State HIV/AIDS Programs

# HIV Care Grant Program - Part B States/Territories Formula and AIDS Drug Assistance Program Formula and ADAP Supplemental Awards

Announcement Type: Competing Continuation Announcement Number: HRSA-17-036

Catalog of Federal Domestic Assistance (CFDA) No. 93.917

#### FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2017

# Application Due Date: November 21, 2016

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

#### Issuance Date: September 22, 2016

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Authority: Sections 2611-23 and 2693 of Title XXVI of the Public Health Service Act, 42 U.S.C. 300ff-21-300ff-31b and 300ff-121, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87)

# **EXECUTIVE SUMMARY**

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Division of State HIV/AIDS Programs (DSHAP) is accepting applications for the Ryan White HIV/AIDS Program Part B Base, AIDS Drug Assistance Program (ADAP) Base, Pacific Island Jurisdiction Part B/ADAP Base, ADAP Supplemental, Minority AIDS Initiative, and Emerging Communities program. The purpose of this program is to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality HIV care and treatment for low-income people living with HIV (PLWH). It supports the National HIV/AIDS Strategy (NHAS) goals of reducing HIV incidence, increasing access to care and optimizing health outcomes, and reducing HIV-related health disparities.

Funding Opportunity Title:	HIV Care Grant Program - Part B States/Territories Formula and AIDS Drug Assistance Program Formula and ADAP Supplemental Awards
Funding Opportunity Number:	HRSA-17-036
Due Date for Applications:	November 21, 2016
Anticipated Total Annual Available Funding:	\$1,500,000,000
Estimated Number and Type of Award(s):	Up to 59 Grants
Estimated Award Amount:	Varies- formula calculation
Cost Sharing/Match Required:	Yes for Part B Formula/Base, Emerging Communities and ADAP Supplemental when applicable to specific States
Project Period:	April 1, 2017 through March 31, 2018 (one (1) year)
Eligible Applicants:	All 50 States and Territories. For the purposes of this program, "States" include the District of Columbia and "Territories" include the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. [See <u>Section III. 1</u> of this funding opportunity announcement (FOA) for complete eligibility information.]

#### **Application Guide**

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at <u>http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf</u>, except where instructed in this FOA to do otherwise. A short video explaining the *Application Guide* is available at <u>http://www.hrsa.gov/grants/apply/apply/applicationguide/</u>.

#### **Technical Assistance**

An FOA webinar will be held on Wednesday, October 26, 2016 from 3:00 - 4:00 PM ET. To join the web portion, please use the following link:

https://hrsa.connectsolutions.com/pre-app\_ta\_fy17/

To join the audio portion, please Dial: 800-779-9011; and the participant passcode: 6765852.

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# I. Program Funding Opportunity Description

#### 1. Purpose

This announcement solicits applications for the Ryan White HIV/AIDS Program (RWHAP) Part B Base, AIDS Drug Assistance Program (ADAP) Base, Pacific Island Jurisdiction Part B/ADAP Base, ADAP Supplemental, Minority AIDS Initiative (MAI), and Emerging Communities (EC) program. The purpose of this program is to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality HIV care and treatment for low-income people living with HIV (PLWH). For the purposes of this program, "States" include the District of Columbia and "Territories" include the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. This program supports the National HIV/AIDS Strategy: Updated to 2020 (NHAS 2020) which is inclusive of the HIV continuum of care. The goals of NHAS 2020 are to reduce HIV incidence, increase access to care and optimize health outcomes, and reduce HIV-related health disparities.

A comprehensive system of HIV care includes the 13 core medical services specified in the Public Health Service (PHS) Act, Section 2612(b)(3) [42 U.S.C. 300ff-21(b)(3)], as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87). Comprehensive HIV care beyond these core services may include supportive services that meet the criteria of enabling individuals and families living with HIV to access and remain in primary medical care to improve their medical outcomes. These core and support services assist PLWH in accessing treatment for HIV infection that is consistent with the Department of Health and Human Services (HHS) Treatment Guidelines (see http://www.aidsinfo.nih.gov).

The RWHAP Part B ADAP recipients must use grant funds to support, develop and expand systems of care to meet the needs of PLWH. The Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) requires RWHAP Part B/ ADAP Programs to conduct needs assessments and use needs assessment data to make decisions on services needed to eliminate barriers faced by PLWH in accessing and remaining in medical care.

In June 2015, HRSA HAB and the Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP) released a joint guidance for the Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SCSN), a legislative requirement for RWHAP Part A and B recipients. This guidance was set forth for health departments and HIV planning groups funded by DHAP and HAB for the development of an Integrated HIV Prevention and Care Plan. This new guidance format allows jurisdictions to submit one Integrated HIV Prevention and Care Plan, including the SCSN, to CDC and HRSA by September 30, 2016, covering calendar years 2017 – 2021. Submission of the Integrated HIV Prevention and Care Plan not only meets the legislative and programmatic requirements of CDC and HRSA, but also serves as a jurisdictional HIV/AIDS Strategy or roadmap. Please see http://hab.hrsa.gov/manageyourgrant/hivpreventionplan062015.pdf.

#### Important Notes:

- The Unmet Need requirements in this funding opportunity announcement (FOA) have been updated. Please review carefully when preparing this section of your application.
- The Work Plan: You will only be required to submit an Implementation Plan Narrative with this funding announcement. The Implementation Plan Table will not be submitted with this application. You will provide the Implementation Plan Table with your Program Terms Report.
- Needs Assessment: The HIV/AIDS epidemiological data and narrative from the Integrated HIV Prevention and Care Plan which will be submitted by September 30, 2016 will be utilized for this application. More information about this document can be found at <u>Integrated HIV Prevention and Care Plan Guidance</u>. You will not be required to submit epidemiologic data in this application.
- You will be required to submit an updated Quality Management Plan as a reporting requirement.

The following information will assist you in understanding and completing this year's grant application:

- RWHAP Part B funds are subject to Section 2612(b)(1) of the PHS Act, which
  requires that not less than 75 percent of the award (minus amounts for
  administration, planning/evaluation and clinical quality management) be used to
  provide core medical services. Support services allowed under RWHAP Part B
  are limited to services that are needed for PLWH to achieve their medical
  outcomes. The service definitions can be found in Policy Clarification Notice
  (PCN) 16-02.
- Applicants seeking a waiver to the core medical services requirement must submit a waiver request either with this application, or up to four (4) months after the budget period start date. Submission should be in accordance with the HAB Policy Notice 13-07. HAB Policy Notice 13-07, and sample letters can all be found at <u>http://hab.hrsa.gov/manageyourgrant/policiesletters.html</u>. A core medical services waiver request should be included as <u>Attachment 8 if it is</u> <u>submitted with the application</u>.
- The Agreements and Compliance Assurances required for this FOA are found in **Appendix A**, and require the signature of the Chief Elected Official (CEO), or the CEO's designee. The Agreements and Compliance Assurances should be included as <u>Attachment 7</u>.

#### 2. Background

This program is authorized by the PHS Act, Sections 2611 - 23 and 2693 [42 U.S.C. 300ff-21-300ff-31b and 300ff-121], as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87). HHS administers the RWHAP Part B through the HRSA, HAB, Division of State HIV/AIDS Programs (DSHAP). All 59 States and Territories receive RWHAP Part B Base and ADAP Base funding through this program. For more information regarding the RWHAP, please visit the HRSA website: http://hab.hrsa.gov/.

#### National HIV/AIDS Strategy: Updated to 2020

The National HIV/AIDS Strategy for the United States: Updated to 2020 (NHAS 2020 or Strategy) is a five-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic. To the extent possible, program activities should strive to support the primary goals of <u>NHAS 2020</u>:

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

Updated in 2015, <u>NHAS 2020</u> has fully integrated the objectives and recommendations of the <u>HIV Care Continuum Initiative</u> (see below) and the Federal Interagency Working Group on the Intersection of HIV/AIDS, Violence against Women and Girls, and Gender-Related Health Disparities. The Strategy also allows opportunities to refocus and strengthen the ongoing work in HIV prevention, care, and research.

Within the parameters of the RWHAP legislation and programmatic guidance, you should take action to align your organization's efforts, over the next five years, around the Strategy's four areas of critical focus:

- Widespread testing and linkage to care, enabling PLWH to access treatment early;
- Broad support for PLWH to remain engaged in comprehensive care, including support for treatment adherence;
- Universal viral suppression among PLWH; and
- Full access to comprehensive pre-exposure prophylaxis (PrEP) services for those for whom it is appropriate and desired, and support for medication adherence for those using PrEP.

More information on how recipients can support <u>NHAS 2020</u>, including the <u>Community</u> <u>Action Plan Framework</u>, which is a tool to help recipients and other stakeholders in developing their own plans to implement <u>NHAS 2020</u>, can be found here: <u>https://aids.gov/federal-resources/national-hiv-aids-strategy/overview/</u>.

#### HIV Care Continuum

The HIV care continuum includes the diagnosis of HIV, linkage to HIV medical care, lifelong retention in HIV medical care, appropriate prescription of Antiretroviral Therapy (ART), and, ultimately, HIV viral suppression. The HIV care continuum performance measures align with the <u>HHS Common HIV Core Indicators</u>, approved by the HHS Secretary. RWHAP recipients and providers submit data through the Ryan White HIV/AIDS Program Services Report (RSR). HAB collects the data elements needed to produce the HHS Common HIV Core Indicators (Indicators); uses the data to calculate Indicators, across the entire RWHAP; and reports six of the seven Indicators to the HHS, Office of the Assistant Secretary for Health.

RWHAP recipients are encouraged to assess the outcomes of their programs along the HIV care continuum and work with their community and public health partners to improve outcomes, so that individuals diagnosed with HIV are linked to and engaged in

care and started on ART as early as possible. HAB requests that recipients use the RWHAP <u>performance measures</u>, at their local level, to assess the efficacy of their programs and to analyze and improve the gaps along the HIV care continuum.

#### Integrated Data Sharing and Use

The HRSA, HAB and the CDC, DHAP support integrated data sharing, analysis, and utilization for the purposes of program planning, needs assessments, unmet need estimates, reports, quality improvement, the development of the HIV care continuum, and public health action. HRSA HAB strongly encourages you tofollow the principles and standards in the *Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action.* HRSA HAB strongly encourages establishing data sharing agreements between surveillance and program to ensure clarity about the process and purpose of the data sharing and utilization. Integrated HIV data sharing and utilization approaches by State and Territorial Health Departments can help further progress in reaching the goals of the NHAS 2020 and improving outcomes on the HIV care continuum.

In order to fully benefit from integrated data sharing and utilization, HRSA HAB strongly encourages complete CD4/viral load (VL) reporting to the State and Territorial Health Departments' surveillance systems. CD4 and VL data can be used to identify cases, classify stage of disease at diagnosis, and monitor disease progression. These data can also be used to evaluate HIV testing and prevention efforts, determine entry into care and retention in care, measure viral suppression, and assess unmet health care needs. Analyses at the national level to monitor progress against HIV can only occur if all HIV-related CD4 and VL test results are reported by all jurisdictions. CDC recommends the reporting of all HIV-related CD4 results (counts and percentages) and all VL results (undetectable and specific values). Where laws, regulations, or policies are not aligned with these recommendations, States should propose strategies to best implement these recommendations within current parameters or consider steps to resolve conflicts with these recommendations. In addition, reporting of HIV-1 nucleotide sequences from genotypic resistance testing might also be considered to monitor prevalence of antiretroviral drug resistance, and HIV genetic diversity subtypes and transmission patterns.

# **II.** Award Information

# 1. Type of Application and Award

Type of applications sought: Competing Continuation.

Funding will be provided in the form of a formula grant.

# 2. Summary of Funding

Approximately \$1,500,000,000 is expected to be available to fund 59 recipients. The actual amount available will not be determined until enactment of the final fiscal year (FY) 2017 federal budget. This program announcement is subject to the appropriation

of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner. The project period is April 1, 2017 through March 31, 2018 (one (1) year). Future funding beyond this initial project period may be awarded through a modified non-competing continuation in order to reduce the administrative burden on recipients. Notification of awards will be sent to the CEO or to the delegated administrative agency responsible for dispersing RWHAP Part B funds.

RWHAP Part B Base, ADAP Base, and EC formula awards are based on the number of reported living cases of HIV in the State or Territory in the most recent calendar year as confirmed by CDC and submitted to HRSA. Similarly, for recipients applying for MAI formula funds, awards are based on the number of reported living minority HIV cases for the most recent calendar year as confirmed by CDC and submitted to HRSA. Supplemental ADAP grants are awarded by the same formula as ADAP Base to States which meet any of the criteria listed in that section of the FOA and choose to apply.

Please note that the Secretary may reduce the amounts of grants under the RWHAP Part B to a State/Territory or political subdivision of a State/Territory for a FY, if with respect to such grants for the second preceding FY, the State/Territory or subdivision fails to prepare audits in accordance with the procedures of Section 7502 of Title 31, United States Code. See Section 2682(a) of the PHS Act.

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 <u>Uniform Guidance 2 CFR part 200</u> as codified by HHS at <u>45 CFR part 75</u>, which supersede the previous administrative and audit requirements and cost principles that govern federal monies.

Please see <u>PCN #15–01</u> for information regarding the statutory 10 percent limitation on administrative costs.

# **III. Eligibility Information**

#### 1. Eligible Applicants

The following States and Territories are eligible to apply for RWHAP Part B Base, ADAP and MAI funding: all 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, and the following Pacific Island Jurisdictions: American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.

RWHAP Part B applicants must designate a lead State/Territory agency that will be responsible for administering all assistance received; conducting a needs assessment and preparing a State/Territory comprehensive plan; preparing all applications and reports; receiving notices regarding programs; and collecting and submitting to the Secretary every two years all audits from recipients within the State/Territory, including an audit regarding funds expended.

**ADAP Supplemental funding:** States and Territories are eligible to apply for ADAP Supplemental funding if they meet at least one of the following criteria, as reported by the State or Territory on the most recent ADAP Data Report (ADR):

- a) Financial requirement of Federal Poverty Level (FPL) = or <200 percent;
- b) Limited formulary compositions for all core classes of antiretroviral medications;
- c) Waiting list, capped enrollment, or capped expenditures;
- d) An unanticipated increase of eligible individuals with HIV.

Even if a State/Territory meets one of the eligibility criteria listed, it will be deemed **ineligible** for FY 2017 ADAP Supplemental funds if the State/Territory did not obligate 75 percent of its FY 2016 RWHAP Part B award within 120 days of the project/budget period start date, as reported on the FY 2016 Interim Federal Financial Report (FFR) within 150 days of the project/budget period start date.

Based on the eligibility criteria, the following States/Territories are eligible to apply for a FY 2017 ADAP Supplemental Grant:

Georgia	Mississippi
Idaho	Montana
Illinois	Puerto Rico
Indiana	Texas
Iowa	Utah

ADAP Supplemental funding is determined on an annual basis; receipt of funding in one year does not guarantee funding in any subsequent year.

**Eligibility for EC formula awards** depends in part on the number of confirmed AIDS cases within a statutorily specified "metropolitan area." The Secretary of HHS uses the Office of Management and Budget's (OMB's) census-based definitions of a Metropolitan Statistical Area (MSA) in determining the geographic boundaries of a RWHAP metropolitan area, including an EC. HHS relies on the OMB geographic boundaries that were in effect when a jurisdiction was initially funded as an EC. For all newly eligible areas, the boundaries are based on current OMB MSA boundary definitions. Receipt of EC funding in one year will not guarantee funding in any subsequent year.

An EC must have between 500-999 cumulative AIDS cases during the most recent five years. Cumulative AIDS cases are reported and confirmed by the Director of the CDC as of December 31 of the most recent calendar year. States with jurisdictions classified as an EC are eligible to apply for these funds. ECs continue their eligibility for these funds as long as the statutory incidence requirements during the most recent period of five calendar years and prevalence level for three consecutive years have been met. Areas are notified by letter when they are at risk of losing eligibility.

The following States are eligible to apply for EC formula awards and they are responsible for applying for the eligible MSAs below:

States	Emerging Communities*
Alabama	Birmingham-Hoover, AL MSA
California	Bakersfield, CA MSA
Delaware	Philadelphia-Camden - Wilmington, PA-NJ-DE-MD MSA
Florida	Lakeland-Winter Haven, FL MSA
	Port St. Lucie, FL MSA
	North Port-Bradenton-Sarasota, FL MSA
Georgia	Augusta-Richmond County, GA-SC MSA
Kentucky	Louisville/Jefferson County, KY-IN MSA
Mississippi	Jackson, MS MSA
New York	Albany-Schenectady-Troy, NY MSA
	Buffalo-Cheektowaga-Niagara Falls, NY MSA
	Rochester, NY MSA
North Carolina	Raleigh, NC MSA
Ohio	Cincinnati, OH-KY-IN MSA
Oklahoma	Oklahoma City, OK MSA
Pennsylvania	Pittsburgh, PA MSA
Rhode Island	Providence-Warwick, RI-MA MSA
South Carolina	Columbia, SC MSA
	Charleston-North Charleston, SC MSA
Virginia	Richmond, VA MSA
Wisconsin	Milwaukee-Waukesha-West Allis, WI MSA
Total: 16 States	Total: 21 Emerging Communities

\*The list of RWHAP Part B ECs uses the most recent MSA names pursuant to OMB Bulletin 15-01. Only the EC MSA names have been updated; the MSA codes and boundaries remain the same. Source:

<u>https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15-01.pdf</u>. The AIDS cases for determining eligibility have been reported to and confirmed by the Director of the CDC, based on the boundaries that were in effect when the EC first received funding.

# 2. Cost Sharing/Matching

Cost sharing/matching is required for this program as described below.

Section 2617(d)(3) of the PHS Act indicates that matching funds are required from States with more than one percent of the total HIV cases reported to the CDC during the previous two FYs (i.e., 2014 and 2015). The State match is listed on the Notice of Award (NoA). A State can meet its match requirement through non-federal cash or inkind resources, which can be provided either directly or through donations to the State from public or private entities, in proportion to the RWHAP Part B/ADAP funding. The same eligible funds can be used to meet both a recipient's State match requirement and the Maintenance of Effort (MOE) requirement. The match begins at \$1 in non-federal funds for every \$5 in federal funds and increases to \$1 in non-federal funds for every \$2 in federal funds in later years (Section 2617(d)(1) of the PHS Act).

State/Territory matching funds for ADAP Supplemental awards are required in an amount equal to \$1 for each \$4 of federal funds provided in the supplemental grant award (Section 2618(a)(2)(F)(ii)(III) of the PHS Act). A State/Territory is eligible for a

waiver from the match requirement for ADAP Supplemental funding if it also has a State match requirement for the RWHAP Part B Formula/ADAP Base funding.

The RWHAP Part B MAI awards are exempt from the matching requirements.

EC funds are not exempt from matching requirements.

#### 3. Other

Note: Multiple applications from a State or Territory 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.

#### Maintenance of Effort

The RWHAP Part B funds are not intended to be the sole source of support for HIV care and treatment services in the States and Territories. Grant funds shall not be used to take the place of current funding for activities described in the application. By signing the 2017 Agreements and Assurances (Appendix A) and the SF-424 application, the recipient agrees to maintain non-federal funding for HIV- related activities at a level which is not less than expenditures for such activities during the FY prior to receiving the award (as authorized by Section 2617(b)(7)(E) of the PHS Act). The MOE requirement is important in ensuring that RWHAP funds are used to supplement existing State expenditures for HIV-related care and treatment services and to prevent RWHAP Part B funds from being used to offset specific HIV-related budget reductions at the State level.

To demonstrate compliance with the MOE provision, States and Territories must maintain adequate systems for consistently tracking and reporting on HIV-related expenditure data from year to year. The system must define the methodology used, be written and auditable, and must ensure that federal funds do not supplant State spending, but instead expand and enrich HIV-related activities.

# **IV. Application and Submission Information**

#### 1. Address to Request Application Package

HRSA *requires* applicants for this FOA to apply electronically through Grants.gov. You must download the SF-424 application package associated with this FOA following the directions provided at <u>http://www.grants.gov/applicants/apply-for-grants.html</u>.

# 2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 Application Guide</u> provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications,

and abstract. You must submit the information outlined in the Application Guide in addition to the program specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 Application Guide</u> 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 **90 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 you 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

- 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.
- 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 <u>SF-424 Application Guide</u> for additional information on this and other certifications.

# **Program-Specific Instructions**

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u> (including the budget, budget narrative, 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.

In addition, the abstract should include the following information:

- A general overview of the HIV epidemiology in the State/Territory including demographics and the geography of the epidemic;
- A general description of the HIV service delivery system in the State/Territory, including what services are available, where those are located, and how clients access those services; and
- A general description of the ADAP, including number of clients served, medication and insurance assistance program models, and any program

limitations currently in place or anticipated in the upcoming project period.

As noted in the SF-424 Application Guide, the project abstract must be single-spaced and limited to one page.

#### *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:

- (A) FY 2017 Part B Base Grant Application
- (B) FY 2017 ADAP Base Grant Application
- (C) Pacific Island Jurisdictions' FY 2017 Part B Grant Application
- (D) FY 2017 ADAP Supplemental Grant Application
- (E) FY 2017 EC Grant Application.

For each header section listed above, use the following subheadings:

- Introduction
- Needs Assessment
- Methodology
- Work Plan
- Resolution of Challenges
- Evaluation
- Organization Information

#### (A) FY 2017 Part B Base Grant Application

# This Section is to be completed by the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands and Guam.

INTRODUCTION

This section should briefly describe how the State/Territory will utilize RWHAP Part B Base grant funds in support of a comprehensive continuum of high-quality care and treatment for PLWH.

- NEEDS ASSESSMENT
  - 1) HIV/AIDS Epidemiology: The HIV/AIDS epidemiological data and narrative from Section I. A. of the Integrated HIV Prevention and Care Plan will be utilized for this application. You are not required to submit epidemiological data in this application.
  - 2) Needs Assessment and Public Advisory Planning Process: The purpose of this section is to describe the Needs Assessment process and ensure that public health agencies receiving RWHAP Part B grants have established a public advisory planning process that includes public hearings, as required by Section 2617(b)(7)(A) of the PHS Act.

#### a) Needs Assessment

You are not required to submit a needs assessment as a part of this application. HRSA HAB will use the information provided in the Integrated HIV Prevention and Care Plan.

#### b) Public Advisory Planning Process

- i) Describe the State/Territory's HIV Public Advisory Planning process model (e.g., integrated care and prevention, statewide or regional, consortia). Please cross reference this section with your Integrated HIV Prevention and Care Plan section II (B) and indicate the number and affiliations of the participating parties, including PLWH, other RWHAP recipients, other HIV related programs, other general and local stakeholders, and community leaders.
- ii) If the RWHAP planning entity is not integrated with the CDC HIV Planning Group currently, please indicate what plans exist to integrate and/or what collaborative activities occur currently between the groups.
- **3) Unmet Need:** Unmet Need is defined as the number of individuals with HIV in a State/Territory who are **aware** of their HIV status but for which there is no evidence of at least one of the following three components of HIV primary medical care during a specified 12 month time frame: 1) VL testing, 2) CD4 count, or 3) provision of ART.

**Important Note:** For programs that plan on applying for FY 2017 RWHAP Part B Supplemental (X08) funds, the Unmet Need Framework and narrative provided in this application will be provided to the FY 2017 RWHAP Part B Supplemental Objective Review Committee (ORC) reviewers for the purpose of scoring the Unmet Need section of the Part B Supplemental application. The FY 2017 Part B Supplemental FOA will <u>not</u> request Unmet Need data.

For this FOA, the Unmet Need Section will require you to compute unmet need estimates in the following two ways (**Attachment 6**):

- Current methodology using the Unmet Need Framework to calculate Unmet Need for FY 2017, using CY 2015 data.
- New methodology using the HIV care continuum Framework to calculate an Unmet Need estimate for FY 2017 using CY 2015 data.

#### Current Methodology: Unmet Need Framework Estimate

Provide an Unmet Need Narrative description of the following:

- i) <u>Estimation methods</u>: The method used to develop the Unmet Need estimates and the reason for choosing this method, revisions or updates from the FY 2016 estimates, any limitations, and any cross program collaboration that occurred.
- ii) <u>Assessment of Unmet Need</u>: Summarize the findings or results of studies on the demographics of populations and special populations that comprise the Unmet Need estimate. The summary should include

the following:

- i) The demographics and geographic location of people who are aware of their HIV status but are not in care;
- ii) A description of the Unmet Need trends over the past five years; and
- iii) An assessment of service needs, gaps, and barriers to care for people not in care.

#### New Methodology: Unmet Need Estimate based on the HIV Care Continuum Framework

An estimate of Unmet Need can also be derived by using data from the HIV Care Continuum Framework. On the HIV care continuum, people who are HIV positive and know their status are referred to as *Diagnosed*, the known/reported cases of HIV infection, regardless of AIDS (stage 3 HIV infection) status. The number of people who are "in care" aligns with the third stage of the HIV care continuum, *Retained in Care*. Retained in Care is the number of diagnosed individuals who had two or more documented medical visits, VL or CD4 tests performed at least three months apart in the calendar year. The Unmet Need estimate is then calculated by subtracting the number of *Retained in Care* from the number of *Diagnosed*. Use this method to derive an estimate of unmet need for your area using the most current CY data.

#### Note: The definition of Retained in Care used in this estimate is taken from the CDC and most closely mirrors the number of people in care described in the previous Unmet Need Framework.

Based upon the need estimates derived from the Current Unmet Need Framework and the HIV Care Continuum Framework, please provide the following information:

- (1) Describe any variances in the Unmet Need Estimate for CY 2017 resulting from the HIV Care Continuum Framework methodology.
- (2) How does the estimate derived from the HIV Care Continuum Framework align with the estimates from the past three calendar years?
- (3) Explain how the estimate derived from the HIV Care Continuum Framework would impact your approach to Unmet Need, and whether it would require your State/Territory to revise or modify its strategy for identifying the unmet need populations and their characteristics; strategies to link these populations into care; and eliminate barriers to improving access to care.
- (4) What are the challenges of using the retention in care measure to calculate Unmet Need? What adjustments would you make/suggest to better reflect the true Unmet Need in your State/Territory?
- (5) Describe how the Unmet Need estimate is utilized in planning for services in the State/Territory.
- (6) Describe how efforts to impact the Unmet Need estimate are evaluated in the State/Territory.
- (7) Describe the data capabilities in your State/Territory in calculating Unmet Need. What are the data limitations in calculating Unmet Need?

4) Early Identification of Individuals with HIV/AIDS (EIIHA): The purpose of this section is to describe the strategy, plan, and data associated with ensuring that individuals who are unaware of their HIV status are identified, informed of their status, referred to supportive services, and linked to medical care if HIV positive. The goals of this initiative are to: 1) increase the number of individuals who are aware of their HIV status, 2) increase the number of HIV positive individuals who are in medical care, and 3) increase the number of HIV negative individuals referred to services that contribute to keeping them HIV negative.

Use the most current year's data presented for persons at higher risk for infection in Section I. A. Epidemiologic Overview of the Integrated HIV Prevention and Care Plan to respond to the EIIHA plan section of the FOA.

The CDC has published a series of statewide data sets reflecting the number of people unaware of their HIV status. Use this data set reflecting the number of people unaware of their HIV status to develop your plan.

#### CDC Unaware State Tables

Prevalence of Diagnosed and Undiagnosed HIV Infection — United States, 2008–2012

(http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6424a2.htm).

Describe the process for linking people identified in the EIIHA data to both prevention (for HIV negative clients) and care services (for HIV positive clients). Include a description of community partners and other resources utilized to provide these services and any major collaboration with other programs and agencies including HIV prevention and surveillance programs.

#### a) FY 2017 EIIHA Plan

The overarching goal of the EIIHA Plan is to reduce the number of undiagnosed and late diagnosed individuals and to ensure they are accessing HIV care and treatment.

- i) Describe the planned activities of the State/Territory EIIHA Plan for FY 2017. Include the following information:
  - (a) The primary activities that will be undertaken, including system level interventions (e.g., routine testing in clinical settings, and expanding partner services);
  - (b) Major collaborations with other programs and agencies, including HIV prevention and surveillance programs; and
  - (c) The planned outcomes of the program's overall EIIHA strategy.
- ii) Describe how the proposed FY 2017 EIIHA Plan contributes to the goals of the <u>NHAS 2020</u>
  - (a) List any innovative approaches that are used in the program's EIIHA plan to address barriers to assessing testing and treatment.
  - (b) List the collaborations being pursued within the program's EIIHA plan within the jurisdiction and with other public health stakeholders.

- (c) Describe how the EIIHA data are used to analyze or address any gaps.
- iii) Describe how the Unmet Need estimate and activities related to the Unmet Need population inform and relate to the EIIHA planned activities.
- iv) Describe how the EIIHA Plan for FY 2016 (e.g., process, activities and outcomes) influenced the development of the EIIHA Plan for FY 2017.
- v) Describe any planned efforts to remove legal barriers, including State laws and regulations, to routine HIV testing.
- vi) Select three (3) distinct target populations for the FY 2017 EIIHA Plan. For each selected target population describe:
  - (a) Why the target population was chosen and how the epidemiological data, Unmet Need estimate data, or other data supports that decision;
  - (b) Specific challenges with, or opportunities for, working with the targeted population;
  - (c) The specific activities that will be undertaken with the target population;
  - (d) Specific objectives for each component of EIIHA (identify, inform, refer, and link to care) for the target population (all objectives should be written as S.M.A.R.T. objectives Specific, Measurable, Achievable, Realistic, and Time phased);
  - (e) The responsible parties, including any coordination with other agencies and/or programs for ensuring each of the activities are implemented, and their respective roles; and
  - (f) Planned outcomes that will be achieved for the target population as a result of implementing the EIIHA Plan activities.
- vii) Describe how EIIHA data are utilized in planning for services in the State/ Territory.
- viii) Describe how efforts to impact the EIIHA population are evaluated in the State/Territory.
- ix) Describe how information related to planning and evaluation of the EIIHA data and plan is disseminated in the State/Territory.
- METHODOLOGY
  - 1) Third Party Reimbursement/Payer of Last Resort: The RWHAP is the payer of last resort, and you must vigorously pursue alternate sources of payments. HRSA expects you to certify client eligibility every 12 months/annually and recertify eligibility at least every six (6) months (please see HAB PCNs 13- 02, 13-03, 13-04, 13-05, 13-06 and 14-01 at

http://hab.hrsa.gov/manageyourgrant/policiesletters.html). You are required to use effective strategies to coordinate with third party payers that are ultimately responsible for covering the cost of services provided to eligible or covered persons. Third party sources include, Medicaid, Children's Health Insurance Programs (CHIP), Medicare, including Medicare Part D, basic health plans, and private insurance, including those purchased through the Health Insurance Marketplace. Subrecipients providing Medicaid eligible services must be Medicaid certified. Provide a narrative that describes the following:

- a) The eligibility criteria for PLWH who receive RWHAP Part B funded services. Indicate the process for determining client eligibility for RWHAP Part B at least every six months.
- b) How recipients/subrecipients document that PLWH have been screened for and enrolled in eligible programs such as Medicare, Medicaid, private health insurance, the Marketplace plans, or other programs to ensure that RWHAP Part B funds are the payer of last resort, as well as the frequency of this screening.

Please see HAB PCN 13-02 Clarifications on Ryan White Program Client Eligibility Determinations and Recertifications Requirements

- c) The process used by the State/Territory to ensure that all recipients/ subrecipients, including those funded through consortia or lead agencies, are accessing, receiving, tracking and documenting third party reimbursement. Also describe the contract language or other mechanism(s) to ensure compliance(please see HAB PCNs 13- 02, 13-03, 13-04, 13-05, 13-06 and 14-01 at http://hab.hrsa.gov/manageyourgrant/policiesletters.html).
- 2) Consortia: The RWHAP defines Consortia as an entity or group of entities (public or private for-profit if such is the only available provider of quality HIV care in the area) that the RWHAP Part B recipient funds to perform the following functions in a designated service area: development and delivery, through the direct provision of services or through entering into agreements with other entities for the provision of such services, of comprehensive outpatient health and support services for low-income PLWH. All such expenditures for or through Consortia are considered support services, not core medical services. Please see 2613(f) of the PHS Act.

If the consortia is administering the RWHAP Part B award on behalf of the recipient (conducting planning, resource allocation, contracting, program and fiscal monitoring and required reporting), these expenditures would count toward the recipient's 10 percent limit on administrative expenses.

For States with Consortia, please respond to the following:

- a) List the funded Consortia entities and the regional areas covered by the Consortia;
- b) Describe how the Consortia conducts planning, resource allocation and contracting, program and fiscal monitoring, and required reporting;
- c) Provide a summary of the benefits of utilizing the Consortia model for your State; and

- d) The State is fully accountable for activities within the consortia. Describe the policies in place to ensure that the State is fully providing fiscal and program monitoring.
- 3) Women, Infants, Children and Youth Proportionate Spending: You are required to use a proportionate amount of your grant to provide services to women, infants, children and youth (WICY) living with HIV, unless a waiver is obtained. You demonstrate compliance with the WICY expenditure requirement in your annual progress report and may request a waiver as part of the annual progress report.

Describe the method used by the State/Territory to document that it meets the legislative requirement for proportionate spending on services to WICY, or that it has obtained, or plans to obtain, a waiver.

WORK PLAN

Describe the proposed activities of the RWHAP Part B Program. This should be presented in the form of a work plan and a narrative.

The Work Plan: Applicants will only be required to submit an Implementation Plan Narrative with this funding announcement. The Implementation Plan Table will not be required. Applicants will provide the Implementation Plan Table with their Program Terms Report.

This work plan applies to Part B Base and ADAP supplemental so please include ADAP funded services including ADAP Supplemental in this work plan.

1) FY 2017 Implementation Plan Narrative: The FY 2017 Implementation Plan indicates the core medical and support service categories that are prioritized and funded by the jurisdiction's RWHAP Part B Program in order to impact progress on the HIV care continuum. The Implementation Plan contains objectives and outcomes which are related to the Stages of the HIV care continuum, and demonstrates how funded services are implemented to achieve positive health outcomes and to promote access to high quality HIV care.

Provide a narrative that describes the following:

- a) How the activities described in the plan will be used to address gaps/barriers and improve outcomes along the HIV care continuum;
- b) How the HIV care continuum is currently or may be in the future utilized in planning, prioritizing, targeting and monitoring available resources in response to needs of PLWH in the jurisdiction, and in improving engagement at each stage in the HIV care continuum;
- c) Any significant health disparities (related to race or ethnicity, gender, sexual identity, age, disability, socioeconomic status and geographic location)

among populations within your jurisdiction's HIV care continuum, and current or planned activities targeted to address these disparities;

- d) How the activities in the plan address Unmet Need and reduce the number of persons out of care;
- e) How the activities described in the plan will ensure geographic parity in access to HIV services throughout the State or Territory;
- f) How the activities described in the plan will address the needs of emerging populations;
- g) How proposed FY 2017 allocations address significant issues and core service needs identified in the Integrated HIV Prevention and Care Plan;
- h) How the resources of AIDS Education and Training Centers will be used in the development and implementation of RWHAP Part B Programs;
- i) How the services and their goals and objectives relate to the goals of the <u>Healthy People 2020</u> initiative, particularly the objectives related to the HIV listing under the Topics and Objectives tab; and
- j) Outreach and enrollment activities to enroll RWHAP clients into the Health Insurance Marketplace.
- 2) FY 2017 Minority AIDS Initiative (MAI) Planning and Implementation: The purpose of this section is to provide a narrative description of the State/Territory's planning for and implementation of an MAI program to increase racial and ethnic minority populations' participation in the ADAP through MAI-funded education and outreach services.
  - a) If eligible to receive MAI funds, does the recipient plan to accept MAI funds in FY 2017? (Respond yes or no)
     If the State/Territory is planning to decline MAI funds, please provide a brief explanation for the declination.
  - b) If the State/Territory plans to accept the MAI funding, please address the following:
    - i) Provide a description of the FY 2017 MAI planning process in terms of:
      - (a) How program results and data generated from previous MAI-funded outreach/education and/or other RWHAP Part B funded outreach activities informed the planning for the use of FY 2017 MAI funding; and
      - (b) How PLWH, particularly targeted minority individuals, provided input into the MAI planning process.
    - ii) Describe how the following have been taken into consideration and how they will be coordinated with RWHAP Part B MAI funds:

- (a) Education and outreach services provided by other RWHAP recipients within the State/Territory that are intended to increase access to ADAP; and
- (b) Education and outreach services funded by other federal, State, and local resources, such as CDC HIV Prevention Services, Medicaid, Medicare Part D, and Substance Abuse and Mental Health Services Administration substance abuse and mental health treatment services.
- iii) MAI Plan Narrative and ADAP Capacity: Please provide a narrative description of the State's FY 2017 MAI Plan to increase racial and ethnic minority populations' participation in the ADAP through MAI-funded education and outreach services. Include a description of how education and ADAP outreach services will be provided, in terms of:
  - (c) Targeted Audiences;
  - (d) Targeted Activities;
  - (e) Traceable Clients (i.e., how will the State know if a client provided MAI-funded outreach and education has been enrolled in ADAP or another medication assistance program);
  - (f) Geographic locations;
  - (g) Types of agencies and staff to provide services;
  - (h) Coordination with existing services and providers; and
  - (i) Involvement of targeted minority populations in implementation of plan.

# 3) AIDS Pharmaceutical Assistance (i.e., Local Pharmaceutical Assistance Program):

This section must be completed by all States/Territories that have included funding for a Local Pharmaceutical Assistance Program (LPAP) in the application. The purpose of this section is to describe the need for an LPAP, including a description of the systems and activities required to effectively operate an LPAP. When a jurisdiction determines there is a need for medication assistance and decides to allocate funds to the LPAP service category, it must demonstrate that the decision was based on information identified through a formal needs assessment process. The needs assessment must determine that the State's/Territory's ADAP does not adequately address the medication assistance needs of clients in the States/Territories (e.g., existence of an ADAP waiting list, restrictive ADAP financial eligibility criteria, or a limited ADAP formulary). The needs assessment must also demonstrate that other resources are inadequate to meet the medication needs of clients residing in the States/Territories.

In August 2013, HRSA HAB provided guidance on the LPAP requirements <u>https://careacttarget.org/sites/default/files/supporting-</u> <u>files/DCL%20LPAP%20August%202013%20Signed%208-29-13.pdf</u>. Implementation of an LPAP involves the development of a drug distribution system that includes, but is not limited to: client enrollment and eligibility determination process that includes screening for ADAP and LPAP eligibility with rescreening at minimum every six months; an LPAP advisory board; uniform benefits for all enrolled clients; compliance with RWHAP requirement of payer of last resort; and a drug formulary approved by the local advisory committee/board. An LPAP may not be used to provide short-term or emergency medication assistance. Please refer to the LPAP Update and Clarifications for more information <u>https://careacttarget.org/library/local-pharmaceutical-assistance-programs-lpaps-update-and-clarifications</u>.

If you are planning to use funds for an LPAP, describe the following:

- a) The need for an LPAP in detail; include how the ADAP, other RWHAP funded service categories, and other resources (e.g., pharmaceutical assistance programs, patient assistance programs, local/State funded medication assistance programs) are failing to meet the State's/Territory's medication needs;
- b) The component of the medication need that the LPAP will fill;
- c) How the LPAP will be coordinated with the ADAP;
- d) The client enrollment and eligibility process including how payer of last resort is ensured;
- e) The existing LPAP advisory board composition; if this is a new service category, describe the process and timeframe for development of the LPAP advisory board;
- f) How the recipient ensures that the LPAP follows the most recent HHS HIV/AIDS Treatment Guidelines; and
- g) The mechanism to ensure "best price" for medications (e.g., 340B Drug Pricing Program and/or Prime Vendor Program).
- RESOLUTION OF CHALLENGES

Please describe challenges you anticipate encountering for any applicable area below and describe what approaches you plan to use to resolve those challenges.

- 1) Needs Assessment and Public Advisory Planning Process
- 2) Unmet Need
- 3) Early Identification of Individuals with HIV/AIDS
- 4) Third Party Reimbursement/Payer of Last Resort
- 5) Women, Infants, Children, and Youth (WICY) Proportionate Spending
- 6) Clinical Quality Management
- 7) HIV Care Continuum

- 8) Other
- EVALUATION AND TECHNICAL SUPPORT CAPACITY
  - Clinical Quality Management: Title XXVI of the PHS Act RWHAP Parts A D (Sections 2604(h)(5), 2618(b)(3)(E), 2664(g)(5), and 2671(f)(2)) requires the establishment of a clinical quality management (CQM) program to:
    - Assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent PHS guidelines (otherwise known as the HHS Guidelines) for the treatment of HIV disease and related opportunistic infections; and
    - Develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV services.

The CQM requirement applies directly to Parts A – D recipients; it is the responsibility of the recipient to work directly with their subrecipients to implement, monitor and provide any needed data on the CQM program. A CQM program is the coordination of activities aimed at improving patient care, health outcomes, and patient satisfaction. To be effective, a CQM program requires:

- Specific aims based in health outcomes;
- Support by identified leadership;
- Accountability for CQM activities;
- Dedicated resources; and
- Use of data and measurable outcomes to determine progress and make improvements to achieve the aims cited above.

CQM activities should be continuous and fit within and support the framework of grant administration functions. The CQM program should be in relative size and scope of the grant award. You are strongly encouraged to use the <u>NHAS</u> <u>2020</u> to frame CQM activities and goals.

CQM programs have three main components:

- (1) **Infrastructure** is needed to plan, implement, and evaluate CQM program activities.
- (2) **Performance measurement** is the process of collecting, analyzing, and reporting data regarding patient care, health outcomes on an individual or population level, and patient satisfaction.
- (3) **Quality improvement** entails the development and implementation of activities to make changes to the program in response to the performance data results.

Quality Management Plan:

You will be required to submit an updated Quality Management Plan as a reporting requirement. A quality management plan describes all aspects of the

CQM program including infrastructure, priorities, performance measures, quality improvement activities, action plan with a timeline and responsible parties, and evaluation of the CQM program.

More information about the HRSA RWHAP expectations for CQM programs can be found in PCN 15-02 released in September 2015. Frequently asked questions were released in December 2015.

Resources:

PCN 15-02 Clinical Quality Management Policy Clarification Notice and Frequently Asked Questions

HIV/AIDS Bureau Performance Measures

Department of Health and Human Services HIV/AIDS Medical Practice Guidelines: https://aidsinfo.nih.gov/guidelines

HIV/AIDS Bureau Part B Monitoring Standards (Part B specific, Universal Monitoring Standards, and Frequently Asked Questions)

HIV/AIDS Bureau Part B Manual

HIV/AIDS Bureau ADAP Manual

The Ryan White HIV/AIDS Program Services Report (RSR)

- a) **Description of CQM Program Infrastructure**: Include the ADAP CQM in this description.
  - i) List the number of staff (Full Time Equivalents (FTEs)) assigned to CQM.
  - ii) Describe the CQM Program staff roles and responsibilities.
  - iii) Name the entity(s) under contract or to be contracted with for the CQM Program, if applicable, and activities that the recipient has provided/will provide.
  - iv) Describe efforts to coordinate CQM activities with other RWHAP recipients in the State/Territory.

#### b) Description of the CQM Program Performance Measures:

- i) List the performance measure(s) for the upcoming project period for each funded service category(s).
- ii) Describe how often performance measure data are collected for each funded service category, including from subrecipients (if applicable).
- iii) Summarize the performance measure data collected for ADAP, outpatient ambulatory health services and medical case management from the last project period or calendar year, including any trending data.
- iv) Describe how performance measure data are analyzed to evaluate for disparities in care, and actions taken in the last project period to eliminate disparities.

 v) Describe how stakeholders, including subrecipients, consumers, other RWHAP recipients in the State/Territory, and planning bodies contribute to the selection of performance measures and receive information about performance measure data.

#### c) Description of CQM Program Quality Improvement:

- i) Describe the quality improvement approach or methodology (e.g. model for improvement, Lean Six Sigma, etc.) you have implemented.
   Describe the processes for identifying priorities for quality improvement.
   Provide examples of specific quality improvement projects undertaken in the last project period. Describe the process to monitor and support subrecipient engagement in quality improvement projects.
- Describe quality improvement activities you implemented in the last project period aimed at improving HIV viral suppression within the State/Territory. Describe how subrecipients were involved in improving HIV viral suppression.
- iii) Discuss how the CQM data have been used to improve and/or change service delivery in the State/Territory, including strategic long-range service delivery planning.
- iv) Describe how stakeholders, including subrecipients, consumers, other RWHAP recipients in the State/Territory, and planning body contribute to the selection of quality improvement activities you undertake.

#### d) Data for Program Reporting:

- i) Name and describe the information/data system(s) used for data collection and reporting operations in the State/Territory.
- Describe your current capabilities of collecting client level data included in the RSR and ADAP Data Report (ADR). Include the percentage of subrecipients that were able to report CY 2015 client-level data. Describe efforts to increase data completeness and validity.

#### ORGANIZATIONAL INFORMATION

1) Recipient Administration and Accountability: The purpose of this section is to demonstrate the extent to which the CEO in the State/Territory has met the legislative requirements to disburse funds quickly, closely monitor their use, and ensure that the State/Territory has complied with the RWHAP legislative mandates for payer of last resort, MOE, and the minimum expenditure requirement to provide services to women, infants, children, and youth.

#### a) Program Organization

Provide a description of how RWHAP Part B funds are administered in the State/Territory. This should reference positions described in the budget narrative and organizational chart, including the fiscal staff that are located outside of the RWHAP Part B Program. Include an organizational chart in **Attachment 1**.

#### b) Fiscal and Program Monitoring

HRSA HAB holds recipients accountable for the expenditure of funds

awarded under the RWHAP Part B, and expects recipients to monitor fiscal and programmatic compliance with all contracts and other agreements for HIV services in the State/Territory, including contracts with consortias. You are also required to have on file a copy of each subrecipient's procurement documents (contracts), and fiscal and programmatic site visit reports. The HAB National Monitoring Standards can be found at:

http://hab.hrsa.gov/manageyourgrant/granteebasics.html.

Provide a narrative that describes the following:

- i) The roles and responsibilities of program and fiscal staff in ensuring adequate reporting, reconciliation, and tracking of program expenditures and program revenue (including program income and medication rebates). Describe the process and coordination methods used by program and fiscal staff to ensure adequate and accurate tracking, reporting, and reconciliation of program expenditures and program revenue (including program income and medication rebates);
- ii) The process used to separately track RWHAP Part B Base, ADAP Base, ADAP Supplemental (if applicable), EC (if applicable) and MAI (if applicable) grant funds; medication rebates (if applicable); program income (if applicable); and the unobligated and carryover funds for each of these grant fund categories as applicable. Include information about the data system(s) utilized to track funds;
- iii) Process and mechanisms used to ensure that providers funded through multiple RWHAP parts (i.e., Parts A, B, C, D, or F) are able to accurately track clients and expenditures and avoid duplication of services;
- iv) The process used for fiscal and program monitoring, including the type and frequency of required reports;
- v) The process and timeline for corrective actions when a fiscal or program-related concern is identified;
- vi) The process, including a timeline, for receiving vouchers or invoices from providers/subrecipients; the process, including a timeline, for issuing payments to providers/subrecipients, from receipt of voucher/invoice to reimbursement;
- vii) The ongoing progress by the recipient to implement the National Monitoring Standards (NMS);
- viii) If the State/Territory has an approved annual site visit exemption, describe the State/Territory's compliance with the terms of the exemption.
- ix) Provide the following information about the monitoring site visits performed:
  - (a) The total number of subrecipients, including consortia, funded in FY 2016;
  - (b) The total number and percentage of subrecipients that received a monitoring site visit in FY 2015;
  - (c) The total number of subrecipients expected to receive a monitoring site visit by the end of FY 2016;
  - (d) Whether each site visit included both fiscal and programmatic monitoring. If not, how the State/Territory will ensure that both fiscal and programmatic site visit monitoring occurs for each subrecipient;

- (e) The number of findings (including improper charges by subrecipients) identified in monitoring site visits in FY 2016. Identify the corrective actions planned or taken to resolve the findings identified;
- (f) The number of subrecipients that received technical assistance (TA) during FY 2016, including the types, scope, and timeline of the TA provided.
- (g) The number and percentage of eligible subrecipients compliant with audit requirements in 45 CFR Part 75, Subpart F. Indicate if there were any findings in subrecipients' single audit reports. Describe the measures taken by the recipient to ensure that subrecipients have taken appropriate corrective action.
- (h) For those applicants with consortia, describe the State's monitoring requirements for consortia in relation to their subrecipients, including how those requirements and processes are compliant with the NMS.

## (B) FY 2017 AIDS Drug Assistance Program (ADAP) Grant Application

This Section is to be completed by the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Republic of the Marshall Islands, and the Republic of Palau.

The purpose of this section is to describe the State/Territory's ADAP. ADAP pays for medications to treat HIV disease, health insurance coverage, and services that enhance access, adherence, and monitoring of medication treatment. ADAP eligibility is determined by the State or Territory and includes verification of HIV status, financial eligibility, and residency eligibility criteria. Financial eligibility is usually determined as a percentage of the FPL. You are required to determine client eligibility on an annual/12 month basis and to recertify eligibility at least every six months.

Steady growth in the number of eligible clients combined with rising costs of complex HIV sometimes results in States/Territories experiencing greater demand for ADAP services than available resources can cover. An ADAP waiting list is implemented when adequate funding is not available to provide medications to eligible persons requesting enrollment in that State's ADAP after that State has utilized all other feasible cost-containment strategies. ADAPs with waiting lists are required to verify eligibility for the program for all individuals on a waiting list, and prioritize individuals by pre-determined criteria. The ADAP manages the waiting list to bring clients into the program as funding becomes available.

Cost-containment can include "cost-cutting" and "cost-saving" measures. Examples of "cost-cutting" measures include: reductions in ADAP financial eligibility below 300 percent of the FPL; capped enrollment; formulary reductions with respect to antiretroviral and/or medications to treat opportunistic infections and complications of HIV disease; and/or restrictions with respect to ADAP insurance eligibility criteria.

Examples of "cost-saving" measures include: RWHAP Part B Program structural or operational changes such as expanding insurance assistance; improved systems

and procedures for back-billing Medicaid; improved client recertification processes; strategies to increase enrollment in insurance through State or federally funded Health Insurance Marketplaces; collection of rebates; and Medicare Part D Prescription Drug Plan data-sharing agreements.

ADAPs are eligible to participate as covered entities in the 340B Drug Pricing Program under Section 340B of the PHS Act. Funds received as a result of participating in the 340B Drug Pricing Program must be returned to the State/Territory RWHAP Part B Program, with priority given to ADAP. The applicant must ensure that rebates and program income are used consistently with RWHAP requirements. Please see the following Policy Clarification Notices:

- <u>PCN 15-03: Clarifications Regarding the Ryan White HIV/AIDS Program</u> and Program Income
- PCN 15-04: Utilization and Reporting of Pharmaceutical Rebates
- Frequently Asked Questions for Policy Clarification Notices 15-03 and 15-04

## INTRODUCTION

This section should briefly describe how the project will use grant funds to pay for ADAP-allowable services, including medication assistance, health insurance assistance, and services that enhance access, adherence, and monitoring of medication treatment.

## NEEDS ASSESSMENT

This section should provide a detailed description of the need for funding for ADAP services in the State/Territory, providing the information as requested below:

#### 1) ADAP Enrollment and Utilization

- a) Discuss the driving factors for any significant increases or decreases in the ADAP enrollment and/or utilization in the past year (e.g., MAI Outreach, EIIHA activities, CDC testing initiatives, Health Insurance Marketplace enrollment, Medicaid expansion), or any anticipated increases or decreases in FY 2017; and
- b) Provide a narrative that explains how ADAP services are equally and consistently available to all eligible enrolled individuals throughout the State/Territory, including clients in outlying or rural areas.

# 2) ADAP Funding Resources

Provide a table that lists all sources of funds for the ADAP Program (e.g., ADAP Base, State funds, other RWHAP funds, rebates) for FY 2016 and those anticipated for FY 2017. The table should be included as <u>Attachment 4</u>. Provide a brief narrative that describes any changes to the funding from FY 2016 to FY 2107; and, if there are anticipated funding shortfalls for ADAP in FY 2017, the amount of and reason for the shortfall.

#### METHODOLOGY

This section should describe the methods that you will use to address the need for ADAP medication and health insurance assistance in the State/Territory. Provide information as requested below:

#### 1) Eligibility Determination and Recertification

Provide a brief description of each of the following:

- a) How the State/Territory ensures that eligibility criteria are consistently applied across the State/Territory;
- b) How the State/Territory ensures the timeliness of eligibility determination, including the current timeframe from the receipt of a complete application to initial ADAP eligibility determination; and
- c) The State/Territory's process for annual certification and 6 month recertification, including the level of documentation required for each.

#### 2) Formulary

Provide a brief description of each of the following:

- a) Whether the State/Territory added or removed drugs from the formulary in the past year. If so, the reason for and the process followed for adding/ removing drugs; and
- b) If/how the State/Territory utilizes an advisory body to inform decisions on ADAP formulary and operations.

#### 3) Payer of Last Resort

Provide a description of each of the following:

- a) How the ADAP ensures it does not pay for any cost when there is another public or private payer available to cover the cost;
- b) How the ADAP ensures compliance with HRSA's mandate to vigorously pursue expeditious enrollment into health care coverage for which clients may be eligible, and how such efforts are documented;
- c) The process by which ADAP back-bills other payers (including Medicaid) when clients are determined to be eligible for other programs that provide prescription drugs; and
- d) Whether or not the ADAP has executed a data-sharing agreement with the Centers for Medicare & Medicaid Services (CMS). If yes, briefly describe any benefits and challenges of the data-sharing agreement. If no, explain why the ADAP has not executed a data-sharing agreement and any plans for executing an agreement.

#### 4) Medication Assistance

ADAPs are required to use every means at their disposal to secure the best price available for all products on the ADAP formularies in order to achieve maximum results with these funds. Provide answers to each of the questions below:

- a) Drug Pricing:
  - Does your ADAP participate in the 340B program?
    - o If yes:
      - How is the ADAP registered as a 340B covered entity status: Direct Purchase, Rebate, or both?
      - Does the program participate in the 340B Prime Vendor Program?
      - How does the ADAP ensure compliance (for itself and any contractors) with 340B program rules (e.g. prohibition on drug diversion, duplicate discounts and 'double dipping')?
    - If no, how does the ADAP ensure it is receiving the best price available for medications?
  - In addition to participation in the 340B program, describe the ADAP's current cost-saving practices, including participation with ADAP Crisis Task Force negotiated discounts.
- b) Drug Distribution System:

Provide a brief description of the drug distribution system used by the State/ Territory's ADAP. Include each of the following elements, as relevant:

- Provide the name of the wholesaler;
- Provide the name of the pharmacy benefits manager (PBM) and the services provided; and
- Describe the pharmacy/pharmacy network (e.g., national drug chain, mail order, State health department pharmacies, local pharmacies, university or disproportionate share hospital pharmacy), including the number of contract pharmacies.
- c) ADAP-generated revenue:

Provide a brief description of any revenue generated by the State/Territory's ADAP. Include each of the following elements, as relevant:

- If the ADAP generates rebates, describe the mechanisms and timelines used by the State/Territory to identify, request, track, and utilize rebates. Describe how the State/Territory ensures that manufacturers' rebates are utilized consistent with <u>PCN 15-04</u>.
- If the ADAP generates program income, describe how the program income is generated, and the process used by the State/Territory to track, utilize and report program income consistent with <u>PCN 15-03</u>: <u>Clarifications Regarding the Ryan White HIV/AIDS Program and</u> <u>Program Income</u>.

# 5) Health Insurance Assistance

The RWHAP allows State/Territory ADAPs to purchase health insurance and assist with medication co-payments, co-insurance and deductibles. Provide information as requested below:

a) Notification of Intent

Does the ADAP plan to utilize funds for health insurance assistance in FY 2017? Respond yes or no.

- If yes, please specify which of the following components of health insurance assistance will be provided: premium payment, medication co-payment assistance, medication co-insurance assistance, and/or medication deductible assistance.
- If no, please describe why the ADAP does not provide health insurance assistance, and whether the ADAP is planning to provide health insurance assistance in the future; then skip to item 6.
- b) Minimum Coverage Standards

Describe how the State/Territory ensures that the health insurance to be purchased includes at least one drug in each class of core antiretroviral therapeutics from the HHS Clinical Guidelines for the Treatment of HIV/AIDS as well as appropriate primary care services.

c) Cost-Effectiveness

Provide the methodology used to determine that the purchase of health insurance is cost effective compared to the cost of medications in the aggregate.

For more information please see the PCNs located at <a href="http://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>

# 6) Flexibility Policy as it Relates to Access, Adherence and Monitoring Services

The RWHAP legislation allows for a percentage of a recipient's ADAP award be used to "encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring." States may request to redirect up to five (5) percent of their ADAP base award for these services under this policy, and up to ten (10) percent in 'extraordinary circumstances.' The amount that a recipient can request to be redirected is in addition to the aggregate of 15 percent of ADAP funds allowed for administrative, planning and evaluation costs. In order to be eligible to utilize funds under the flexibility policy, the States/Territories cannot have any program restrictions. Address each of the issues below:

a) Notification of Intent

Do you plan to utilize part of the ADAP award for access, adherence and/or monitoring services in FY 2017? Respond yes or no.

- If yes, what percentage (up to 5 percent, or 10 percent in 'extraordinary circumstances') of the ADAP base award do you plan to redirect to pay for the proposed services?
- If no, please skip to the next section.
- b) Proposed Program

Provide a narrative description that includes:

• Proposed services to be funded (access, adherence, and/or monitoring) and the amount budgeted for each service area;

- The unit cost for each proposed service area (e.g., cost for billable hours for adherence and access services, lab services, etc.), and the methodology used to determine the cost; and
- The number of clients who will directly benefit from each of the proposed services.
- c) 'Extraordinary Circumstances' Clause
   If the recipient plans to redirect >five (5) percent and up to 10 percent of the
   ADAP base award under this policy, describe:
  - Why the additional amount is essential to addressing access, adherence and/or monitoring within the State/Territory's ADAP; and
  - How the program ensures the redirection of funds does not diminish the availability of medication assistance for ADAP-eligible clients.
- WORK PLAN

The intent of this section is to describe the activities proposed for ADAP in the Methodology section above. The Implementation Plan and CQM Plan information provided in Section (A) of this FY 2017 Part B Base Grant Application applies to this ADAP section (i.e., all ADAP-funded services should be included in the Implementation Plan). Therefore, **the submission of a separate ADAP work plan is not needed**.

RESOLUTION OF CHALLENGES

Provide answers to each of the issues below:

1) Potential Challenges and Proposed Solutions

Briefly discuss any challenges that may be encountered in the implementation of ADAP activities described above in the Work Plan and CQM Plan, and approaches that will be used to resolve such challenges.

#### 2) Waiting List

Does the State/Territory currently have a waiting list or anticipate implementing a waiting list in FY 2017? Respond yes or no. If no, skip to the following section. If yes, also respond to the following questions:

- a) Has the State/Territory established written policies and procedures for the establishment and monitoring of a waiting list?
- b) What factors (e.g., State general fund cuts, increased enrollment, increased costs of medications or insurance premiums, etc.) contributed/are contributing to the decision to implement/maintain an ADAP waiting list?
- c) Describe how stakeholders (e.g., ADAP Advisory Body, PLWH, providers) were/are involved in the decision to begin a waiting list. Describe the process employed to communicate the implementation of a waiting list to stakeholders, providers, PLWH case managers and eligibility specialists

- d) What preventative measures and cost containment measures were/are being implemented prior to implementing a waiting list (e.g., formulary reduction, reducing income eligibility, cutting support or core medical services funding)?
- e) Describe the process the program employed/will employ for training and informing PLWH, physicians, providers, eligibility specialists and case managers about the availability of medications through the Pharmaceutical Manufacturer Patient Assistance Programs (PAP). If applicable, address any challenges clients, case managers, physicians, eligibility specialists and/or providers are facing in enrolling clients on PAP; and any steps the program has taken to assist in meeting these challenges?
- EVALUATION AND TECHNICAL SUPPORT CAPACITY
   Describe the data and process that will be used to monitor the ADAP specific
   objectives listed in the FY 2017 RWHAP Part B (X07) Implementation Plan.

ORGANIZATIONAL INFORMATION

This section should describe the organizational structure and resources that contribute to the administration of the ADAP in compliance with legislative requirements and program expectations.

#### 1) Agency Oversight/Administration

Provide a narrative that identifies any changes in the management/ administration of the ADAP from FY 2016, and/or any proposed changes for FY 2017. Include an organizational chart if the ADAP is administered by a different agency. Place this chart in <u>Attachment 1</u>.

#### 2) Contract Oversight

Describe the State/Territory mechanisms for monitoring ADAP-related contracts or subcontracts to ensure compliance with legislative requirements and program expectations.

#### (C) Pacific Island Jurisdictions' FY 2017 Part B Grant Application

This Section should be completed only by eligible applicants listed:

- Republic of the Marshall Islands
- Federated States of Micronesia
- Republic of Palau
- American Samoa
- The Commonwealth of the Northern Mariana Islands

**Note:** For those territories that are eligible to apply for the ADAP Supplemental, please refer to and complete the FY 2017 ADAP Supplemental Grant Application Section.

Project Abstract

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

In addition, the abstract should include the following information:

- a) A general overview of the HIV epidemiology in the Territory including demographics and the geography of the epidemic;
- A general description of the HIV service delivery system in the Territory, including what services are available, where those are located, and how clients access those services; and
- c) A general description of the ADAP, including number of clients served, medication and insurance assistance program models, and any program limitations currently in place or anticipated in the upcoming project period.

As noted in the SF-424 Application Guide, the project abstract must be singlespaced and limited to one page.

INTRODUCTION

This section should briefly describe how the Territory will utilize RWHAP Part B Base grant funds in support of a comprehensive continuum of high-quality care and treatment for PLWH. Provide a narrative that describes the following:

- The proposed project including the needs to be addressed, the proposed services and the population groups to be served;
- The general demographics of the Territory;
- The organizational structure of the Territory;
- Demographics of the HIV populations in the Territory; and
- The geography of the Territory.

#### NEEDS ASSESSMENT

This section provides information about the needs of PLWH in the Pacific Island Territory.

 The Territory's HIV/AIDS Epidemiology: The HIV/AIDS epidemiological data and narrative from the Integrated HIV Prevention and Care Plan will be utilized for this application. You are not required to submit epidemiological data in this application.

#### 2) The Territory's Planning Mechanisms

- a) Identify the planning entity and mechanism the Territory uses to make decisions about RWHAP Part B funds. Discuss the participation of PLWH in the planning process, including what the Territory is doing to encourage and support their participation in this process.
- b) If the planning entity is not currently integrated with the CDC HIV Planning Group, please indicate if there are plans to integrate and/or what collaborative activities occur currently between the groups.
- c) Discuss how allocation decisions are made between geographically or politically separate areas, and who is involved in making these decisions.
- METHODOLOGY

Describe the HIV care continuum for PLWH, the strategy for identifying individuals

living with HIV, what HIV resources are available, disparities in access and/or services, and what outreach efforts the Territory plans for outreach and enrollment in care.

- 1) The Territory's HIV/AIDS Care System: Describe the Territory's HIV care continuum in 2017 (i.e., primary medical care, supportive services that enable individuals to access and remain in primary care, and other health and supportive services that promote health and enhance quality of life).
  - a) Outline the strategy for identifying individuals with HIV who do not know their status, making such individuals aware of their status, and enabling such individuals to access services. Focus the response using the below guidelines.
  - b) The strategy should include discrete goals. Describe how the strategy contributes to the goals of <u>NHAS 2020</u>.
  - c) Provide a timetable for achieving the goals and coordination with other community stakeholders.
  - d) Describe the current availability and capacity of HIV resources and services to provide HIV care.
  - e) Describe any plans to increase the availability or to build capacity in the Territory.
  - f) Discuss any disparities in access or services among affected subpopulations or communities.
  - g) Describe efforts to inform individuals living with HIV about services and to engage individuals in HIV care.
  - Specifically address how the Medicaid program, if applicable in the Territory, provides services to PLWH, including eligibility, and which HIV services are covered by Medicaid.
  - i) Describe how HIV counseling and testing services are designed to facilitate access to care for persons testing positive for HIV. In addition, describe any other linkages with early intervention services.
- WORK PLAN

Describe the proposed activities of the RWHAP Part B Program. This should be presented in the form of a work plan and a narrative. You will only be required to submit an Implementation Plan Narrative with this funding announcement. The Implementation Plan Table will not be submitted with this application. You will provide the Implementation Plan Table with the Program Terms Report.

**FY 2017 Implementation Plan Narrative**: The FY 2017 Implementation Plan indicates the core medical and support service categories that are prioritized and
funded by the Territory's RWHAP Part B Program in order to impact progress on the HIV care continuum. The Implementation Plan contains objectives and outcomes which are related to the Stages of the HIV care continuum, and demonstrate how funded services are implemented to achieve positive health outcomes and to promote access to high quality HIV care.

Provide a narrative that describes the following:

- 1) How the activities described in the plan will be used to address gaps/barriers and improve outcomes along the HIV care continuum;
- 2) How the HIV care continuum is currently or may be in the future utilized in planning, prioritizing, targeting and monitoring available resources in response to needs of PLWH in the Territory, and in improving engagement at each stage in the HIV care continuum;
- Any significant health disparities (related to race or ethnicity, gender, sexual identity, age, disability, socioeconomic status, and geographic location) among populations within your Territory's HIV care continuum, and current or planned activities targeted to address these disparities;
- 4) How the activities in the plan address Unmet Need and reduce the number of persons out of care;
- 5) How the activities described in the plan will ensure geographic parity in access to HIV services throughout the Territory;
- 6) How the activities described in the plan will address the needs of emerging populations;
- 7) How proposed FY 2017 allocations address significant issues and core service needs identified in the Integrated HIV Prevention and Care Plan;
- How the services and their goals and objectives relate to the goals of the <u>Healthy People 2020</u> initiative, particularly the objectives related to the HIV listing under the Topics and Objectives tab; and
- 9) Outreach and enrollment activities to enroll RWHAP clients into the Health Insurance Marketplace.
- RESOLUTION OF CHALLENGES
   The purpose of this section is to describe any challenges that may occur in
   implementing the proposed activities that are described in the Work Plan, and
   describe the approaches that will be used to address these challenges.
- EVALUATION AND TECHNICAL SUPPORT CAPACITY
  - 1) FY 2017 Implementation Plan: Describe the data and process that will be used to monitor the Implementation Plan.

- 2) The Territory's Clinical Quality Management Program: Title XXVI of the PHS Act RWHAP Parts A D (2604(h)(5), 2618(b)(3)(E), 2664(g)(5), and 2671(f)(2)) requires the establishment of a CQM program to:
  - Assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent PHS guidelines (otherwise known as the HHS Guidelines) for the treatment of HIV disease and related opportunistic infections; and
  - Develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV services.

The CQM requirement applies directly to Parts A – D recipients; it is the responsibility of the recipient to work directly with their subrecipients to implement, monitor and provide any needed data on the CQM program. A CQM program is the coordination of activities aimed at improving patient care, health outcomes, and patient satisfaction. To be effective, a CQM program requires:

- Specific aims based in health outcomes;
- Support by identified leadership;
- Accountability for CQM activities;
- Dedicated resources; and
- Use of data and measurable outcomes to determine progress and make improvements to achieve the aims cited above.

CQM activities should be continuous and fit within and support the framework of grant administration functions. The CQM program should be in relative size and scope of the grant award. You are strongly encouraged to use the <u>NHAS 2020</u> to frame CQM activities and goals.

CQM programs have three main components:

- (1) Infrastructure is needed to plan, implement, and evaluate CQM program activities.
- (2) Performance measurement is the process of collecting, analyzing, and reporting data regarding patient care, health outcomes on an individual or population level, and patient satisfaction.
- (3) Quality improvement entails the development and implementation of activities to make changes to the program in response to the performance data results.

Quality Management Plan:

You will be required to submit an updated Quality Management Plan as a reporting requirement. A quality management plan describes all aspects of the CQM program including infrastructure, priorities, performance measures, quality improvement activities, action plan with a timeline and responsible parties, and evaluation of the CQM program.

More information about the HRSA RWHAP expectations for CQM programs can

be found in PCN 15-02 released in September 2015. Frequently asked questions were released in December 2015.

Resources:

PCN 15-02 Clinical Quality Management Policy Clarification Notice and Frequently Asked Questions

HIV/AIDS Bureau Performance Measures

Department of Health and Human Services HIV/AIDS Medical Practice Guidelines:

HIV/AIDS Bureau Part B National Monitoring Standards (Part B specific, Universal Monitoring Standards, and Frequently Asked Questions)

HIV/AIDS Bureau Part B Manual

HIV/AIDS Bureau ADAP Manual

- a) Description of CQM Program Infrastructure: Include the ADAP CQM in this description.
  - i) List the number of staff FTEs assigned to CQM.
  - ii) Describe the CQM Program staff roles and responsibilities.
  - iii) Name the entity(s) under contract or to be contracted with for the CQM Program, if applicable, and activities that the recipient has provided/will provide.
  - iv) Describe efforts to coordinate CQM activities with other RWHAP recipients in the Territory.
- b) Description of the CQM Program Performance Measures.
  - i) List the performance measure(s) for the upcoming project period for all funded service category(s).
  - ii) Describe how often performance measure data are collected for each funded service category, including from subrecipients (if applicable).
  - iii) Summarize the performance measure data collected for ADAP, outpatient ambulatory health services and medical case management from the last project period or calendar year, including any trending data.
  - iv) Describe how performance measure data are analyzed to evaluate for disparities in care, and actions taken in the last project period to eliminate disparities.
  - v) Describe how stakeholders, including subrecipients, consumers, other RWHAP recipients in the Territory, and planning bodies contribute to the selection of performance measures and receive information about performance measure data.
- c) Description of CQM Program Quality Improvement:
  - i) Describe the quality improvement approach or methodology (e.g. model for improvement, Lean Six Sigma, etc.) you have implemented. Describe the processes for identifying priorities for quality improvement. Provide

examples of specific quality improvement projects undertaken in the last project period. Describe the process to monitor and support subrecipient engagement in quality improvement projects.

- ii) Describe quality improvement activities you implemented in the last project period aimed at improving HIV viral suppression within the jurisdiction. Describe how subrecipients were involved in improving HIV viral suppression.
- iii) Discuss how the CQM data have been used to improve and/or change service delivery in the jurisdiction, including strategic long-range service delivery planning.
- iv) Describe how stakeholders including subrecipients, consumers, other RWHAP recipients in the Territory, and planning body contribute to the selection of quality improvement activities you undertake.
- d) Data for Program Reporting
  - i) Name and describe the information/data system(s) used for data collection and reporting operations in the Territory.
  - ii) Describe your current capabilities of collecting client level data included in the RSR and ADR. Include the percentage of subrecipients that were able to report calendar year 2015 client-level data. Describe efforts to increase data completeness and validity.

## ORGANIZATIONAL INFORMATION

This section should describe the organizational structure and resources that contribute to the administration of the Territory's RWHAP in compliance with legislative requirements and program expectations.

- 1) The Territory's Organizational Structure: Within the Territory's structure, identify the proposed entity or entities responsible for managing and administering Part B Programs, including health ministry or department, unit, staff, fiscal agents, and planning/advisory evaluation bodies. Highlight any changes that occurred over the past year or that are planned for the next year.
  - a) Identify the entity responsible for financial management of the Part B Program, including health ministry or department.
  - b) Describe how the fiscal and program entities work together to fulfill grantrelated reporting and monitoring responsibilities.

# 2) The Territory's Ryan White HIV/AIDS Program Coordination of Planning and Services

## a) Coordination with other Federal Programs:

 i) Describe how the Part B program coordinates HIV funding and service delivery with non-RWHAP programs. *Examples Include*: Other HRSA funded programs (including Maternal and Child Health, Migrant Health Programs, and Community Health Clinics); CDC (Prevention, Surveillance, STD programs); Medicaid (including Medicaid managed care); Medicare; Veterans Affairs programs; Territory funds; and other programs/initiatives (such as substance abuse prevention and treatment services or Territory social and welfare services).

 For those Territories eligible for Global AIDS Funds, describe any ongoing or planned activities the Territory is participating in through the Global AIDS Fund and how these activities are coordinated with the Part B program.

## (D) ADAP Supplemental Award Application

Section 2618(a)(2)(F)(ii) of the PHS Act states that five percent of the ADAP appropriation will be reserved as supplemental funding to purchase medications for States and Territories with demonstrated severe need. A State/Territory must meet certain established criteria in order to be eligible to apply for an ADAP Supplemental Grant.

See <u>Section III. 1</u> of this FOA for complete eligibility information for ADAP Supplemental Grant awards.

Based on the eligibility criteria, the following States/Territories are eligible to apply for a FY 2017 ADAP Supplemental Grant. Only eligible applicants (as listed below) who are interested in receiving an ADAP Supplemental Grant should complete this section.

Georgia	Mississippi
Idaho	Montana
Illinois	Puerto Rico
Indiana	Texas
Iowa	Utah

## **Use of ADAP Supplemental Grant Funds**

States/Territories must use ADAP Supplemental funds to provide HIV-related medications or the devices needed to administer them.

## State Match Requirement for ADAP Supplemental Grant Funds

The ADAP Supplemental Grants require a State match of 25 percent (i.e., \$1 for each \$4 of federal funds provided), unless a waiver is requested and approved (Section 2618(a)(2)(F)(ii)(III) of the PHS Act). A State/Territory is eligible for a waiver from the match requirement for ADAP Supplemental funding if it also has a State match requirement for the RWHAP Part B Formula/ADAP Base funding, and it meets that match requirement. If the State/Territory is requesting a waiver to the match, please attach a waiver request letter as <u>Attachment 8</u>. Submit this request along with the other application information.

# INTRODUCTION

Provide the following information:

- A description of how the State/Territory will use ADAP Supplemental funds for medication assistance in order to address one or more of the ADAP Supplemental eligibility criteria.
- 2) ADAP Supplemental Grants require a State match of 25 percent, unless a waiver is requested and approved.
  - a) Is the State/Territory submitting a State match waiver (as Attachment 8) with this application? Respond yes or no.
    - If yes, skip to the next section.
    - If no, is the State/Territory able to meet the anticipated match requirement? Respond yes or no.
      - o If yes, skip to the next section.
      - If no, please provide the maximum match dollar amount (and corresponding maximum grant dollar amount) the State/Territory would be able to meet (e.g., the State can meet up to \$25,000 in State match, for a maximum grant award of \$100,000).

## NEEDS ASSESSMENT

This section should provide a description of the need for ADAP Supplemental funding in the State/Territory, providing the information as requested below:

- 1) Describe the severity of need for ADAP Supplemental funds as framed by the following eligibility criteria. Specify if a criterion is not relevant to the need for ADAP supplemental funds.
  - a) Financial requirement of FPL = or <200 percent;
  - b) Limited formulary compositions for all core classes of antiretroviral medications;
  - c) Waiting list, capped enrollment, or capped expenditures; and
  - d) An unanticipated increase of eligible individuals with HIV.
- **2)** Describe any other factors impacting the severity of need for ADAP Supplemental funds.
- METHODOLOGY

This section should describe the methods that you will use to address the need for ADAP Supplemental funding.

WORK PLAN

The intent of this section is to describe the activities proposed for ADAP Supplemental funds in the Methodology section above. The Implementation Plan and CQM Plan information provided in Section (A) of this FY 2017 Part B Base Grant Application applies to this ADAP Supplemental section (i.e., all ADAPfunded services, including ADAP Supplemental, should be included in the Implementation Plan). Therefore, the submission of a separate ADAP Supplemental work plan is not required. RESOLUTION OF CHALLENGES

The responses provided to 'Resolution of Challenges' in the ADAP Base section of this FY 2017 Part B Base Grant Application apply to this section. No further information is required for this section.

EVALUATION AND TECHNICAL SUPPORT CAPACITY

The responses provided to 'Evaluation and Technical Support Capacity' in the ADAP Base section of this FY 2017 Part B Base Grant Application apply to this section. No further information is required for this section.

ORGANIZATIONAL INFORMATION

The responses provided to 'Organizational Information' in the ADAP Base section of this FY 2017 Part B Base Grant Application apply to this section. No further information is required for this section.

# (E) Emerging Communities FY 2017 Grant Application

This Section should be completed only by eligible applicants as listed below.
The following States are responsible for applying for the eligible MSAs below:

States	Emerging Communities
Alabama	Birmingham-Hoover, AL MSA
California	Bakersfield, CA MSA
Delaware	Philadelphia-Camden-Wilmington, PA-NJ-DE-MD MSA
Florida	Lakeland-Winter Haven, FL MSA
	Port St. Lucie, FL MSA
	North Port-Sarasota-Bradenton, FL MSA
Georgia	Augusta-Richmond County, GA-SC MSA
Kentucky	Louisville/Jefferson County, KY-IN MSA
Mississippi	Jackson, MS MSA
New York Albany-Schenectady-Troy, NY MSA	
	Buffalo-Niagara Falls, NY MSA
	Rochester, NY MSA
North Carolina	Raleigh, NC MSA
Ohio	Cincinnati, OH-KY-IN MSA
Oklahoma	Oklahoma City, OK MSA
Pennsylvania	Pittsburgh, PA MSA
Rhode Island	Providence-Warwick, RI-MA MSA
South Carolina	Columbia, SC MSA
	Charleston-North Charleston, SC MSA
Virginia	Richmond, VA MSA
Wisconsin	Milwaukee-Waukesha-West Allis, WI MSA
Total: 16 States	Total: 21 Emerging Communities

\*The list of RWHAP Part B ECs uses the most recent MSA names pursuant to OMB Bulletin 15-01. Only the EC MSA names have been updated; the MSA codes and boundaries remain the same. Source:

<u>https://www.whitehouse.gov/sites/default/files/omb/bulletins/2015/15-01.pdf</u>. The AIDS cases for determining eligibility have been reported to and confirmed by the Director of the CDC, based on the boundaries that were in effect when the EC first received funding.

EC formula awards are based on the number of reported living cases of AIDS within a specific MSA in the most recent calendar year as confirmed by CDC and submitted to HRSA.

**Program Authority and Eligibility**: The EC Supplemental Grant award is authorized under Section 2621 of the PHS Act. It is intended to enable States to supplement RWHAP Part B services in communities with emerging HIV epidemics within the State. A State receiving EC funding must ensure that the grant will be used only within the EC in the State.

See <u>Section III. 1</u> of this FOA for complete eligibility information for EC Supplemental Grant awards.

INTRODUCTION

The purpose of the EC Supplemental Funds under RWHAP Part B is to enhance a comprehensive array of RWHAP core and supportive services for communities in need within the MSAs that are not eligible to receive additional grants under RWHAP Part A. Please briefly describe what the EC funding will be used for in the MSA.

NEEDS ASSESSMENT

# 1) Planned Services for Emerging Community Funds

- a) Please describe how the planning process for the EC funds meets the following requirements. A State with multiple ECs should describe each EC planning process separately, if the process differs.
  - i) The allocation of the funds is based in accordance with the local demographic incidence of HIV including appropriate allocations for services for infants, children, women and families with HIV;
  - ii) Affected communities and PLWH are included in the planning process; and
  - iii) The proposed services are consistent with the local needs assessments and the Integrated HIV Prevention and Care Plan.

# METHODOLOGY

Please describe the following:

- 1) How the State disseminates/will disseminate EC funds within the MSA;
- 2) How the State will ensure that the current level of support for the activities in the EC is not supplanted by this funding; and
- 3) How the State utilizes the funds in a manner that is responsive to the needs of the MSA, and is cost effective.

WORK PLAN

Implementation Plan for EC funds: States with multiple ECs should describe the use of funds for each EC separately.

Please describe:

- 1) What services will be provided in FY 2017;
- Any significant health disparities related to race, gender, sexual orientation and age among populations within the MSA's HIV care continuum and current or planned activities targeted to address these disparities;
- 3) How the activities described in the plan will ensure geographic parity in access to HIV services throughout the EC;
- 4) How the activities described in the plan will address the needs of emerging populations;
- 5) How proposed FY 2017 allocations address significant issues and core service needs identified in the Integrated HIV Prevention and Care Plan; and
- 6) How the services and their goals and objectives relate to the goals of the <u>Healthy People 2020</u> Initiative, particularly the objectives related to the HIV listing under the Topics and Objectives tab.

# RESOLUTION OF CHALLENGES

The purpose of this section is to describe any challenges that may occur in implementing the proposed activities that are described in the Work Plan and approaches that will be used to address these challenges.

- EVALUATION AND TECHNICAL SUPPORT CAPACITY Describe the data and process that will be used to monitor the objectives in the FY 2017 EC Implementation Plan as provided above.
- ORGANIZATIONAL INFORMATION
   The responses provided to the "Organizational Information" section in the FY 2017 RWHAP Part B Base Grant Application apply to this section. No further information is required for this section.

## iii. 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 may 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 FY 2017 Ryan White HIV/AIDS Program - Part B Base, Minority AIDS Initiative, AIDS Drug Assistance Program, Pacific Island Jurisdiction, ADAP Supplemental Awards, and Emerging Communities programs require the following:

Please complete Sections A, B, E, and F of the SF-424A Budget Information – Non-Construction Programs form included with the application kit for the year of the project period, and then provide a line item budget using Section B Object Class Categories of the SF-424A.

In Section B, the four required columns are:

- (1) Administration This column should include all funds allocated to the following grant activities: recipient administration, planning and evaluation, and quality management;
- (2) ADAP This column should include all funds allocated to ADAP (including medication and health insurance assistance and ADAP Flex);
- (3) Consortia/Emerging Communities This column should include all funds allocated to consortia and ECs; and
- (4) Direct Services This column should include all funds allocated to the following grant activities: State direct services, home and community-based care, MAI, and the Health Insurance Premium and Cost-Sharing Assistance service category.

The General Provisions in Division H, § 202, of the Consolidated Appropriations Act, 2016 (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.

## iv. Budget Narrative

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

In addition, the FY 2017 Ryan White HIV/AIDS Program - Part B Base, Minority AIDS Initiative, AIDS Drug Assistance Program, and Pacific Island Jurisdictions, ADAP Supplemental Awards, and Emerging Communities program requires the following:

Provide a narrative that explains the amounts requested for each line in the budget. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. The budget period is for ONE year. Line item information must be provided to explain the costs entered in the SF-424A. Be very careful about showing how each item in the "other" category is justified. The budget narrative MUST be concise. Do NOT use the justification to expand the project narrative.

The budget narrative format should explain the amounts requested for the following: RWHAP Part B Base, ADAP, ADAP Supplemental, Consortia, EC, and MAI, and the relevant RWHAP budget categories. The narrative should explain how the line items listed support the overall service delivery system and include justification for any applicable object class categories: Personnel, Fringe Benefits, Travel, Equipment, Supplies, Contractual, Construction, Other and Indirect Charges. For employees who are less than one (1) FTE on the grant, please identify all funding sources outside of RWHAP Part B funding for Personnel and Fringe Benefits costs.

<u>Caps on Expenses</u>: RWHAP Part B recipient administrative costs may not exceed 10 percent of the total grant award. Planning and Evaluation costs may not exceed 10 percent of the total grant award. Collectively, recipient Administration and Planning and Evaluation may not exceed 15 percent of the total award. Recipients may allocate up to five percent of the total grant award or \$3,000,000 (whichever is less) for CQM.

Subrecipient administrative costs are capped at **10 percent in the aggregate**. Subrecipient administrative activities include:

- usual and recognized overhead activities, including established indirect rates for agencies;
- management oversight of specific programs funded under the RWHAP; and
- other types of program support such as quality assurance, quality control, and related activities (exclusive of RWHAP CQM).

If a RWHAP Part B grant recipient has contracted with an entity to provide statewide or regional RWHAP management and fiscal oversight (i.e., the entity has entered into a vendor or procurement relationship with the recipient, and is acting on behalf of the recipient), the cost of that contract, exclusive of subawards to providers, would count toward the recipient's 10 percent administrative cap. Providers that have contracted to provide health care services for the lead agency are considered to be first-tier entities (subrecipients) of the recipient and are subject to the aggregate 10 percent administrative cap for subrecipients.

For further guidance on the treatment of costs under the 10 percent administrative limit, refer to <u>PCN 15-01</u>.

<u>Payer of Last Resort</u>: Charges that are billable to third party payers (e.g., private health insurance, prepaid health plans, Medicaid, Medicare, HUD, other RWHAP funding including ADAP) are unallowable. The RWHAP is the payer of last resort, and recipients must vigorously pursue alternate sources of payments. HRSA expects recipients to certify eligibility every 12 months/annually and recertify eligibility at least every six months (please see HAB PCNs 13- 02, 13-03, 13-04, 13-05, 13-06 and 14-01 at <a href="http://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>). Recipients are required to use effective strategies to coordinate with third party payers that are ultimately responsible for covering the cost of services provided to eligible or covered persons. Third party sources include, Medicaid, Children's Health Insurance Programs (CHIP), Medicare, including Medicare Part D, basic health plans, and private insurance, including those purchased through the Health Insurance Marketplace. Subrecipients providing Medicaid eligible services must be Medicaid certified.

RWHAP Part B funds are subject to Section 2612(b) of the PHS Act which requires that not less than 75 percent of the funds remaining after reserving funds for administration and clinical quality management be used to provide core medical services.

### 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: Project Organizational Chart

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

# Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of the HRSA's <u>SF-424 Application Guide</u>)

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

#### Attachment 3: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in Attachment 2 that reflect changes since the last application, not to exceed two (2) pages.

#### Attachment 4: ADAP Funding Sources Table

Provide a table that lists all sources of funds for the ADAP Program (e.g., ADAP Base, State funds, other RWHAP funds, rebates) for FY 2016 and those anticipated for FY 2017.

#### Attachment 5: Maintenance of Effort (MOE) Documentation

Applicants must provide a baseline aggregate expenditure for their FY prior to the application deadline. Please provide a description of the non-RWHAP Part B/ADAP expenditures that count towards the MOE and methodologies for calculating MOE expenditures. Also include a brief narrative explaining any changes in the data set where HIV-related expenditures have been reduced or where the purpose of an HIV-related expenditure has changed. HRSA will enforce statutory MOE requirements through all available mechanisms.

NON-FEDERAL EXPENDITURES					
	FY Prior to Application (Actual)	Current FY of Application (Estimated)			
	Actual prior FY non-federal funds, including in-kind, expended for activities proposed in this application.	Estimated current FY non-federal funds, including in-kind, designated for activities proposed in this application.			
	Amount: \$	Amount: \$			
Recipient Budget (Fiscal) Officer		Recipient Project Director			

## Attachment 6: Unmet Need Framework Table and Narrative

The table must include the values, all data sources, and calculations for Unmet Need. A description of the information to include in the Unmet Need narrative is located in the Unmet Need Section of this FOA under the Project Narrative.

# Attachment 7: Ryan White HIV/AIDS Program Part B Agreements and Compliance Assurances

The Ryan White HIV/AIDS Program Part B Agreements and Compliance Assurances are included (**Appendix A**) with this FOA, and require the signature of the CEO, or the CEO's designee.

# Attachment 8: Core Medical Services, ADAP Supplemental Match and/or Annual Site Visit Exemption Waiver Request(s) and justification

Please see below for information about waiver requirements and submission deadlines. If applicable, please include waiver requests for all of the following:

## **Core Medical Services**

Applicants seeking a waiver of the core medical services requirement (Section 2612(b)(2) of the PHS Act) must submit a waiver request either with this application, any time up to the application submission, or up to four months after the grant award for FY 2017. Submission should be in accordance with HAB PCN 13-07, and may be found at

http://hab.hrsa.gov/manageyourgrant/policiesletters.html.

If you are seeking a waiver of the core medical services requirement and you receive MAI funds, you must include the MAI funds in your waiver request. If you do not include the MAI funds in your waiver request, HRSA HAB will not consider the request.

## ADAP Supplemental Match

The ADAP Supplemental Grants require a State match of 25 percent (i.e., \$1 for each \$4 of federal funds provided), unless a waiver is requested and approved (Section 2618(a)(2)(F)(ii)(III) of the PHS Act). A State/Territory is eligible for a

waiver from the match requirement for ADAP Supplemental funding if it also has a State match requirement for the RWHAP Part B Formula/ADAP Base funding, and it meets that match. If the State/Territory is requesting a waiver to the match, please attach a waiver request letter.

#### Annual Site Visit Exemption

You must submit a request for an exemption to the annual site visit requirement through the prior approval portal in EHB within thirty (30) days after the submission of the application.

## Attachment 9-12: Other Relevant Documents

Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). List all other support letters on one page.

# 3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)

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

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

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

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

- <u>Dun and Bradstreet (http://fedgov.dnb.com/webform/pages/CCRSearch.jsp)</u>
- System for Award Management (SAM) (https://www.sam.gov)
- <u>Grants.gov</u> (<u>http://www.grants.gov/</u>)

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 November 21, 2016 at 11:59 *P.M. Eastern Time*.

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

#### 5. Intergovernmental Review

The HIV Care Grant Program Part B applicants are not subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's <u>SF-424 Application Guide</u> for additional information.

## 6. Funding Restrictions

Applicants responding to this announcement may request funding for a project period of up to one (1) year.

HRSA HAB will strictly enforce the RWHAP authorizing statute, which states:

Section 2618(c)(1)--Expedited Distribution,-

- IN GENERAL, Section 2618(c)(1)(B)--Not less than 75 percent of the amounts received under a grant awarded to a State under Section 2611 shall be obligated to specific programs and projects and made available for expenditure not later than
  - a) in the case of the first FY for which amounts are received, 150 days after the receipt of such amounts by the State; and
  - b) in the case of succeeding FYs, 120 days after receipt of such amounts by the State.

## Section 2618(d)(2)--Reallocation-

Any portion of a grant made to a State under Section 2611 for a FY that has not been obligated as described in subsection (c) ceases to be available to the State or Territory and shall be made available by the Secretary for grants under Section 2620, in addition to amounts made available for such grants under Section 2623(b)(2).

In addition to the general Funding Restrictions included in Section 4.1 of the <u>SF-424</u> <u>Application Guide</u>, RWHAP Part B funds <u>cannot</u> be used for:

- a) International travel,
- b) Construction (however, minor alterations and renovations to an existing facility to make it more suitable for the purpose of the grant program is allowable with prior HRSA approval),
- c) PrEP or Post-Exposure Prophylaxis (nPEP),
- d) <u>Syringe Services Programs</u> (SSPs). Some aspects of SSPs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy. See <u>https://www.aids.gov/federal-resources/policies/syringe-services-</u>

programs/,

- e) Cash payments to intended recipients of RWHAP services, or
- f) To develop materials designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual.

<u>Caps on Expenses</u>: RWHAP Part B recipient administrative costs may not exceed 10 percent of the total grant award. Planning and evaluation costs may not exceed 10 percent of the total grant award. Collectively, recipient administration, and planning and evaluation costs may not exceed 15 percent of the total award. You may allocate up to five percent of the total grant award or \$3,000,000 (whichever is less) for CQM.

Subrecipient administrative costs are capped at **10 percent in the aggregate**. Subrecipient administrative activities include:

- usual and recognized overhead activities, **including established indirect rates** for agencies;
- management oversight of specific programs funded under the RWHAP; and
- other types of program support such as quality assurance, quality control, and related activities (exclusive of RWHAP CQM).

If a RWHAP Part B grant recipient has contracted with an entity to provide statewide or regional RWHAP management and fiscal oversight (i.e., the entity has entered into a vendor or procurement relationship with the recipient, and is acting on behalf of the recipient), the cost of that contract, exclusive of subawards to providers, would count toward the recipient's 10 percent administrative cap. Providers that have contracted to provide health care services for the lead agency are considered to be first-tier entities (subrecipients) of the recipient and are subject to the aggregate 10 percent administrative cap for subrecipients.

For further guidance on the treatment of costs under the 10 percent administrative limit, refer to <u>PCN 15-01</u>.

<u>Program Income</u>: HHS Regulations require recipients and/or subrecipients to collect and report program income. Program income shall be monitored by the recipient, retained by the recipient (or subrecipient if earned at the subrecipient level), and used to provide RWHAP Part B services/ADAP services to eligible clients. Program income is gross income—earned by a recipient, subrecipient, or a contractor under a grant directly generated by the grant-supported activity or earned as a result of the RWHAP Part B award. Program income includes, but is not limited to, income from fees for services performed (e.g., direct payment, or reimbursements received from Medicaid, Medicare and third-party insurance). Direct payments include charges imposed by recipients and subrecipients for RWHAP Part B ADAP services as required under Section 2617(c) of the PHS Act. You are responsible for ensuring that subrecipients have systems in place to account for program income, and for monitoring to ensure that subrecipients are tracking and using program income consistent with RWHAP Part B requirements.

All program income generated as a result of awarded funds must be used for approved project-related activities.

All pharmaceutical rebates collected as a result of awarded funds must be used for approved project-related activities.

For more information, see the following:

- <u>PCN 15-03: Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income and 45 CFR §75.307</u>
- PCN 15-04: Utilization and Reporting of Pharmaceutical Rebates
- Frequently Asked Questions for Policy Clarification Notices 15-03 and 15-04

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 <u>SF-424 Application</u> <u>Guide</u> for additional information. Note that these or other restrictions will apply in FY 2017, as required by law.

You are required to have the necessary policies, procedures and financial controls in place to ensure that your organization complies with all the federal funding requirements and prohibitions such as lobbying, gun control, abortion, etc. The effectiveness of these policies, procedures and controls is subject to audit.

# V. Application Review Information

## 1. Review Criteria

The Ryan White HIV/AIDS Part B Program is a formula-based grant program that does not undergo a formal objective review process. Procedures for assessing the technical merit of applications have been instituted to provide for an internal review of applications and to assist the applicant in understanding the standards against which each application will be reviewed. Applications will be reviewed for completeness of submission of required information as follows:

- Project Organizational Chart
- Staffing Plan and Job Descriptions for Key Personnel
- Biographical Sketches of Key Personnel
- ADAP Funding Sources Table
- HIV/AIDS Epidemiology Narrative
- Implementation Plan (includes MAI, if applicable)
- Maintenance of Effort Documentation, (if applicable)
- Unmet Need Framework and Narrative
- FY 2017 Core Medical Services Waiver Request (if applicable)
- State Match Information
- Ryan White HIV/AIDS Program Part B Agreements and Compliance Assurances
- ADAP Supplemental Match Waiver Request (if applicable)
- Grantee Administration and Accountability
- Early Identification of Individuals with HIV/AIDS
- Clinical Quality Management
- Women, Infants, Children, and Youth (WICY)

The RWHAP Part B does not have funding priorities based on scoring because the funds are distributed according to a formula.

The RWHAP Part B Base, ADAP, and EC awards are based on the number of reported living cases of HIV in the State or Territory in the most recent CY as confirmed by CDC data submitted to HRSA. Similarly, for recipients applying for MAI formula funds, awards are based on the number of reported and confirmed living minority cases of HIV for the most recent CY submitted to HRSA. The most recently completed CY ended December 31, 2015. Supplemental ADAP grants are awarded by formula to States meeting any of the criteria indicated in that section of the FOA.

# 2. Review and Selection Process

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

The funds appropriated for the Ryan White HIV/AIDS Part B Program are distributed among eligible recipients as a formula-based award.

This program does not have any funding priorities, preferences or special considerations.

# 3. Assessment of Risk and Other Pre-Award Activities

HRSA may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements (<u>45 CFR § 75.205</u>).

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

Effective January 1, 2016, HRSA is required to review and consider any information about the applicant that is in the <u>Federal Awardee Performance and Integrity</u> <u>Information System (FAPIIS)</u>. 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 <u>FAPIIS</u> 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 <u>45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.</u>

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

# 4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of April 1, 2017.

To ensure timely notification of the release of the FY 2017 RWHAP Part B awards and other important documents relating to the RWHAP Part B grant, States/Territories must update personnel, address, and e-mail or telephone changes in the Electronic Handbook (EHB) using the instructions at https://help.hrsa.gov/display/public/EHBSKBFG/User+Profile+Management+FAQs.

# VI. Award Administration Information

# 1. Award Notices

HRSA will issue the NoA prior to the start date of April 1, 2017. See Section 5.4 of HRSA's <u>SF-424 Application Guide</u> for additional information.

# 2. Administrative and National Policy Requirements

See Section 2 of HRSA's SF-424 Application Guide.

# 3. Reporting

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

- a) **Program Terms Report**. You must submit a program terms report to HRSA ninety (90) days after the award is made; further information will be provided in the NoA.
- **b) MAI Annual Plan and Report**. You must submit an annual plan on the proposed services provided with MAI funds, as well as an annual report on the outcomes of the services provided; further information will be provided in the NoA.
- c) Interim Federal Financial Report. You must submit an interim Federal Financial Report SF-425 (FFR) reflecting the amount of RWHAP Part B funds obligated during the first 120 days of the project period. Further information will be provided in the NoA.
- d) Expenditure Report. You must submit a RWHAP Expenditure Report; further information will be provided in the NoA.
- e) Ryan White Part B Unobligated Balance Estimate/Estimated Carryover Request. You must submit a request for carryover of any estimated RWHAP Part B Formula Unobligated Balance (UOB) to HRSA. If you fail to submit an estimated UOB and estimated carryover request to HRSA you will be ineligible to receive FY 2016 RWHAP Part B Formula carryover funds. You may also request that HRSA deem that certain UOB funds be reduced by the amount of rebate funds actually expended.
- f) Ryan White HIV/AIDS Program Services Report(s). Acceptance of this

award indicates that you assure that you will comply with data requirements of the RSR and that you will mandate compliance by each of your subrecipients. The RSR captures information necessary to demonstrate program performance and accountability. All RWHAP core service and support service providers are required to submit client level data for CY 2016. Please refer to the HIV/AIDS Program Client Level Data website at <u>http://hab.hrsa.gov/manageyourgrant/clientleveldata.html</u> for additional information.

- **g) ADAP Data Report.** Acceptance of this award indicates that you assure that you will comply with data requirements of the ADR. The ADR is a reporting requirement for ADAPs to provide client level data on individuals served, services being delivered, and costs associated with these services. Further information can be found at: <u>http://hab.hrsa.gov/manageyourgrant/adr.html</u>.
- h) Quality Management Plan. You must submit an updated Quality Management Plan describing all aspects of the CQM program including infrastructure, priorities, performance measures, quality improvement activities, action plan with a timeline and responsible parties, and evaluation of the CQM program. See PCN 15-02 for more information.

# VII. Agency Contacts

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

Karen Mayo Grants Management Specialist Division of Grants Management Operations, OFAM Health Resources and Services Administration 5600 Fishers Lane Room 10NWH04 Rockville, Maryland 20857 Telephone: (301) 443-3555 Fax: (301) 594-4073 E-mail: KMayo@hrsa.gov

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

Michael Goldrosen Director, Division of State HIV/AIDS Programs Attn: HIV/AIDS Bureau Health Resources and Services Administration 5600 Fishers Lane, Room 09W52 Rockville, Maryland 20857 Telephone: (301) 945-9779 Fax: (301) 443-8143 E-mail: mgoldrosen@hrsa.gov You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 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: <u>support@grants.gov</u> Self-Service Knowledge Base: <u>https://grants-</u> <u>portal.psc.gov/Welcome.aspx?pt=Grants</u>

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, excluding federal holidays at:

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

# **VIII. Other Information**

# 1. Allowable Uses of Funds

For the most up-to-date listing of allowable uses of funds, refer to <u>HAB PCN 16-02:</u> <u>"Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of</u> <u>Funds</u>" These service definitions are effective for awards issued for Fiscal Year 2017.

## 2. National Monitoring Standards

You are required to have implemented the RWHAP Part B NMS at the recipient and provider/subrecipient levels. HRSA has developed and distributed guidelines outlining the responsibilities of HRSA, the recipient, and provider staff. The NMSs can be found at: <u>http://hab.hrsa.gov/manageyourgrant/granteebasics.html</u>

## 3. Technical Assistance

An FOA webinar will be held on Wednesday, October 26, 2016 at 3:00 PM to 4:00 PM EST. To join the web portion, please use the following link: <u>https://hrsa.connectsolutions.com/pre-app\_ta\_fy17/</u>. To join the audio portion, please dial: 800-779-9011; and the participant passcode: 6765852.

# IX. Tips for Writing a Strong Application

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

# Appendix A:

# FY 2017 AGREEMENTS AND ASSURANCES Ryan White HIV/AIDS Treatment Extension Act of 2009 Part B Grant Program

I, the Governor, or Authorized Designated Official, of the State or Territory of

\_\_\_\_\_, hereinafter referred to as

"State," assure that:

# 1. Pursuant to Section 2612<sup>1</sup>

- a) Section 2612(a) Amounts provided will be expended on core medical services, support services, and administrative expenses only.
- b) Section 2612(b)(1)

Unless a waiver is obtained, not less than 75 percent of the portion of the grant remaining after reserving amounts for administration, planning/evaluation and clinical quality management will be used to provide core medical services that are needed in the State for individuals with HIV who are identified and eligible under this title (including services regarding the co-occurring conditions of the individuals).

c) Section 2612(d)(2)

Entities providing Early Intervention Services (EIS) will ensure that the following conditions have been met:

- 1. Federal, State and local funds are otherwise inadequate for the EIS an entity proposes to provide; and,
- 2. The entity will supplement, not supplant, other funds available to the entity for the provision of providing EIS for the FY involved.
- d) Section 2612(e)

For each of such populations in the eligible area, the State will use not less than the percentage constituted by the ratio of the population involved (infants, children, youth, or women in such area) with HIV to the general population in such area of individuals with HIV, unless a waiver is obtained from the Secretary.

e) Section 2612(f)

No amounts received under the grant will be used to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

<sup>&</sup>lt;sup>1</sup> All statutory references are to the Public Health Service Act, unless otherwise specified.

# 2. Pursuant to Section 2613

#### Section 2613(b)

All required assurances will be obtained from applicants who apply to the State for assistance to provide consortia services.

## 3. Pursuant to Section 2615

#### Section 2615(b)

Assistance will not be used to pay any costs associated with the creation, capitalization, or administration of a liability risk pool (other than those costs paid on behalf of individuals as part of premium contributions to existing liability risk pools); or to pay any amount expended by a State under Title XIX of the Social Security Act.

## 4. Pursuant to Section 2616

a) Section 2616(c)(1)

The therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary are at a minimum the treatments provided by the State.

b) Section 2616(g)

Any drug rebates received on drugs purchased from funds provided under the grant are applied to activities supported under Part B, with priority given to AIDS Drug Assistance Program activities.

## 5. Pursuant to Section 2617

a) Section 2617(b)(4)

The State shall designate a lead State agency that will:

- 1) Administer all assistance received under Part B;
- 2) Conduct the needs assessment and prepare the State plan;
- 3) Prepare all applications for assistance under Part B;
- 4) Receive notices with respect to programs under Title XXVI;
- 5) Every two years, collect and submit to the Secretary all audits, consistent with 45 CFR Part 75 Subpart F, from recipients within the State, including audits regarding funds expended in accordance to Part B; and
- 6) Carry out any other duties determined appropriate by the Secretary to facilitate the coordination of programs under Title XXVI.
- b) Section 2617(b)(6)

The public health agency that is administering the grant for the State periodically convenes a meeting that includes individuals with HIV, members of a federally recognized Indian tribe as represented in the State, representatives of recipients under each of the Ryan White HIV/AIDS Programs, providers, public agency representatives, and if applicable, entities on Part A Planning Councils, in developing the Statewide Coordinated Statement of Need (SCSN).

c) Section 2617(b)(7)(A)

The public health agency that is administering the grant for the State engages in a public advisory planning process, including public hearings, that includes individuals with HIV, members of a federally recognized Indian tribe as represented in the State, representatives of recipients under each Part of Title XXVI of the Public Health Service Act, providers, public agency representatives, Part A Planning Councils (or other planning body), in developing the comprehensive plan and commenting on the implementation of such plan.

d) Section 2617(b)(7)(B)(i)

HIV-related health care and support services delivered pursuant to a program established with assistance provided under Part B will be provided without regard to the ability of the individual to pay for such services and without regard to the current or past health condition of the individual living with HIV, to the maximum extent practicable.

e) Section 2617(b)(7)(B)(ii)

Such services will be provided in a setting that is accessible to low-income individuals living with HIV.

f) Section 2617(b)(7)(B)(iii)

Outreach to low-income individuals living with HIV will be provided to inform them of the services available under Part B.

g) Section 2617(b)(7)(B)(iv)

If using amounts provided under the grant for health insurance coverage, the State will submit a plan that assures that

- 1) such amounts will be targeted to individuals who would not otherwise be able to afford health insurance coverage; and
- income, asset, and medical expense criteria will be established and applied by the State to identify those individuals who qualify for assistance under such a program; and that information concerning such criteria will be made available to the public.
- h) Section 2617(b)(7)(C)

The State will provide for periodic independent peer review to assess the quality and appropriateness of health and support services provided by entities that receive funds from the State under Part B.

i) Section 2617(b)(7)(D)

The State will permit and cooperate with any Federal investigations undertaken regarding programs conducted under Part B.

j) Section 2617(b)(7)(E)

The State will maintain HIV-related activities at a level that is equal to not less than the level of such expenditures by the State for the one-year period preceding the FY for which the State is applying to receive a grant under Part B.

k) Section 2617(b)(7)(F)

Grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or reasonably can be expected to be

made, with respect to that item or service

- 1) under any State compensation program, insurance policy, Federal or State health benefits program; or
- by an entity that provides health services on a prepaid basis (except for a program administered by or providing the services of the Indian Health Services).
- I) Section 2617(b)(7)(G)

Entities within areas in which activities under the grant are carried out will maintain appropriate relationships with entities in the area serviced that constitute key points of access to the health care system for individuals with HIV (including emergency rooms, substance abuse treatment programs, detoxification centers, adult and juvenile detention facilities, STD clinics, HIV counseling and testing sites, mental health programs, and homeless shelters) and other entities under Section 2612(c) and 2652(a) (eligible to apply for Part B Early Intervention Service Grants) for the purpose of facilitating early intervention for individuals newly diagnosed with HIV and individuals knowledgeable of their HIV status but not in care.

m) Section 2617(b)(8)

The State will develop a comprehensive plan describing:

- 1) The estimated number of individuals within the State with HIV who do not know their status;
- 2) Activities undertaken by the State to find such individuals and to make them aware of their status;
- The manner in which the State will provide undiagnosed individuals who are made aware of their status with access to medical treatment for their HIV; and
- 4) Efforts to remove legal barriers, including State laws and regulations, to routine testing.
- n) Section 2617(c)

The State will comply with the statutory requirements regarding imposition of charges for services, for those providers who charge for services.

o) Section 2617(d)(1)

If subject to the matching requirement detailed in Section 2617(d), non-Federal contributions will be made available (either directly or through donations from public or private entities).

# 6. Pursuant to Section 2618

a) 2618(a)(2)(F)(ii)

States and Territories applying for ADAP Supplemental Treatment Drug Grants will make available non-Federal contributions (directly or through donations from public or private entities) in an amount equal to \$1 for each \$4 of Federal funds awarded, unless a waiver is obtained.

b) 2618(b)(3)(A-D)

The State will comply with the limitations of grant funds for administration;

planning and evaluation; and clinical quality management activities. In the case of subrecipients, the State will ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10 percent (without regard to whether particular entities expend more than 10 percent for such expenses).

c) 2618(b)(3)(E)(i)

The State will provide for the establishment of a clinical quality management program to assess the extent to which HIV health services provided to patients under this grant are consistent with the most recent Public Health Service guidelines for treatment of HIV and related opportunistic infections, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to, and quality of HIV health services.

d) 2618(c)(1)

The State will ensure that 75 percent of Part B funds will be obligated within 120 days of the start date of the grant award, and that if such funds are not obligated, they will be made available promptly to the Secretary for reallocation.

## 7. Pursuant to Section 2622

The State will comply with statutory requirements regarding the timeframe for obligation and expenditure of funds, and will comply with any cancellation of unobligated funds.

## 8. Pursuant to Section 2681(d)

Services funded will be integrated with other such services, programs will be coordinated with other available programs (including Medicaid), and that the continuity of care and prevention services of individuals with HIV is enhanced.

# 9. Pursuant to Section 2684

No funds shall be used to develop materials designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual.

	Da	Date	
Signature			

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Title

Address