# 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-16-079

Catalog of Federal Domestic Assistance (CFDA) No. 93.917

#### FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2016

**Application Due Date: November 20, 2015** 

Ensure SAM.gov and Grants.gov registrations and passwords are current immediately!

Deadline extensions are not granted for lack of registration.

Registration in all systems, including SAM.gov and Grants.gov,

may take up to one month to complete.

Release Date: September 21, 2015 Issuance Date: September 21, 2015

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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 fiscal year (FY) 2016 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. 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
Funding Opportunity Number:	HRSA-16-079
Due Date for Applications:	November 20, 2015
Anticipated Total Annual Available Funding:	\$1,500,000,000
Estimated Number and Type of Award(s):	59 grants
Estimated Award Amount:	Varies- formula calculation
Cost Sharing/Match Required:	Yes for Part B Formula/Base and ADAP
	Supplemental when applicable to specific States
Project Period:	April 1, 2016 – March 31, 2017 (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 Section III-1] of this funding opportunity
	announcement (FOA) for complete eligibility
	information.]

## **Application Guide**

All applicants are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at

http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this FOA to do otherwise. A short video for applicants explaining the new *Application Guide* is available at <a href="http://www.hrsa.gov/grants/apply/applicationguide/">http://www.hrsa.gov/grants/apply/applicationguide/</a>.

## **Technical Assistance**

An FOA webinar will be held on Wednesday, October 7, 2015 at 3:00 PM EST. To join the web portion, please use the following link: <a href="https://hrsa.connectsolutions.com/xo7">https://hrsa.connectsolutions.com/xo7</a> foa review/. To join the audio portion, please Dial: 888-603-9810; and the participant passcode: 1165029.

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## I. Program Funding Opportunity Description

## 1. Purpose

This announcement solicits applications for the fiscal year (FY) 2016 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). The purpose of this grant 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 (NHAS) which is inclusive of the HIV Continuum of Care Initiative. The goals of NHAS 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 appropriate 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 <a href="http://www.aidsinfo.nih.gov">http://www.aidsinfo.nih.gov</a>).

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

#### Important Notes:

- The Early Identification of Individuals with HIV/AIDS (EIIHA) requirements in this funding announcement have been updated and streamlined. Please review carefully when preparing this section of your application.
- The application includes requests for information about the jurisdiction's HIV Care Continuum. Applicants should include a table and narrative for the jurisdiction's HIV Care Continuum and discuss how the HIV Care Continuum is being utilized for planning and service implementation.

The following information will assist 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 portion of the grant remaining after reserving amounts for administration, planning/evaluation and clinical quality management be used to

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provide core medical services that are needed in the State/Territory for PLWH who are identified and eligible under the RWHAP. Support services allowed under RWHAP Part B are limited to services that are needed for individuals with HIV to achieve their medical outcomes as defined by the RWHAP. The most recent service definitions can be found in the latest version of the National Monitoring Standards.

- Applicants seeking a waiver to the core medical services requirement must submit a waiver request either with this grant application, at any time up to the application submission, or up to four (4) months after the start of the grant award for FY 2016. Submission should be in accordance with the Federal Register Notice, Vol. 78, No.101, dated Friday, May 24, 2013, found at <a href="http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12354.pdf">http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12354.pdf</a>. The HAB Policy 13-07, Federal Register Notice and Sample Letters can all be found at <a href="http://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>. If submitting with the application, a core medical services waiver request should be included as <a href="https://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>.
- Agreements and Compliance Assurances are included (<u>Appendix A</u>) with this funding opportunity announcement (FOA), and require the signature of the Chief Elected Official (CEO), or the CEO's designee; this document should be included as <u>Attachment 9</u>.

## 2. Background

This program is authorized by the PHS Act, Sections 2611-23 and 2693, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87). The 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 website: <a href="http://hab.hrsa.gov/">http://hab.hrsa.gov/</a>.

## **Affordable Care Act**

As part of the Affordable Care Act (ACA), the health care law enacted in 2010, several significant changes have been made in the health insurance market that expand options for health care coverage, including those options for PLWH. The ACA creates new State-based health care coverage marketplaces, also known as exchanges, and a federally-facilitated health care coverage marketplace to offer millions of Americans access to affordable health insurance coverage. Under the ACA individuals with incomes between 100 to 400 percent of the Federal Poverty Level (FPL) may be eligible to receive advance payments of premium tax credits and/or cost-sharing reductions to help pay for the cost of enrolling in qualified health insurance plans and for coverage of essential health benefits. In States that choose to expand Medicaid, non-disabled adults with incomes of up to 133 percent of FPL become eligible for the program, providing new coverage options for many individuals who were previously ineligible for Medicaid. In addition, the law requires health plans to cover certain recommended preventative services without cost-sharing making health care more affordable and accessible for Americans. These health care coverage options may be reviewed at http://hab.hrsa.gov/affordablecareact/keyprovisions.pdf.

Outreach efforts continue to be needed to ensure families and communities understand these new health care coverage options and to provide eligible individuals assistance to secure and retain coverage. HRSA/HAB recognizes that outreach to and enrollment of RWHAP clients into the expanded health insurance coverage is critical. As appropriate and allowable by statute, RWHAP recipients are strongly encouraged to support ACA-related outreach and enrollment activities to ensure that clients fully benefit from the new health care coverage opportunities. For

information on allowable outreach and enrollment activities, visit <a href="http://www.hab.hrsa.gov/affordablecareact/outreachenrollment.html">http://www.hab.hrsa.gov/affordablecareact/outreachenrollment.html</a>. Recipients and subrecipients should also assure that individual clients are enrolled in any appropriate health care coverage whenever possible or applicable, and informed about the financial or coverage consequences if they choose not to enroll. For more information on the marketplaces and the health care law, visit <a href="http://www.healthcare.gov">http://www.healthcare.gov</a>.

## **HIV Care Continuum**

Identifying people infected with HIV and linking them to HIV primary care with initiation and long-term maintenance of life-saving antiretroviral treatment (ART), are important public health steps toward the elimination of HIV in the United States. The continuum of interventions that begins with outreach and testing and concludes with HIV viral load suppression is generally referred to as the HIV Care Continuum or the HIV Treatment Cascade. The HIV Care Continuum includes the diagnosis of HIV, linkage to HIV medical care, lifelong retention in HIV medical care, appropriate prescription of ART, and ultimately HIV viral load suppression.

The difficult challenge of executing these lifesaving steps is demonstrated by the data from the Centers for Disease Control and Prevention (CDC), which estimate that only 30 percent of individuals living with HIV in the United States have complete HIV viral suppression. Data from the 2013 Ryan White Services Report (RSR) indicate that there are better outcomes in RWHAP funded agencies with approximately 79 percent of individuals who received RWHAP-funded HIV primary care being virally suppressed. The national (CDC) estimate includes all persons living with HIV infection in the U.S., including those who are unaware of their HIV infection, whereas the RWHAP (RSR) estimate does not. Such findings underscore the importance of supporting effective interventions for linking HIV-positive individuals into care, retaining them in care, and helping them adhere to their combination antiretroviral regimens.

RWHAP recipients are encouraged to assess the outcomes of their programs along the HIV Care Continuum. Recipients should work with their community and public health partners to improve outcomes across the HIV Care Continuum, so that individuals diagnosed with HIV are linked and engaged in care and started on ART as early as possible. HAB encourages recipients to use the <u>performance measures</u> developed for the RWHAP at their local level to assess the efficacy of their programs and to analyze and improve the gaps along the HIV Care Continuum.

The HIV Care Continuum measures also align with the HHS Common HIV Core Indicators approved by the Secretary and announced in August 2012. The HHS Common HIV Core Indicators were developed in coordination with other HHS agencies. RWHAP recipients and providers are required to submit data through the RSR. Through the RSR submission, HAB currently collects the data elements to produce the HHS Common HIV Core Indicators. HAB will calculate the HHS Core Indicators for the entire RWHAP using the RSR data to report six of the seven HHS Common HIV Core Indicators to the HHS, Office of the Assistant Secretary for Health.

## **Integrated Data Sharing and Use**

The HRSA, HAB and CDC, Division of HIV/AIDS Prevention support integrated data sharing, analysis, and use 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 RWHAP Part B recipients to follow 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 use. Integrated HIV data sharing and use approaches by local, State and Territorial Health Departments can help further progress in reaching the goals of the NHAS and improving outcomes on the HIV Care Continuum.

In order to fully benefit from integrated data sharing and use, HRSA HAB strongly encourages complete CD4/VL reporting to the local, State and Territorial Health Departments surveillance systems. CD4 and viral load 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 load 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 viral load test results are reported by all jurisdictions. CDC recommends the reporting of all HIV-related CD4 results (counts and percentages) and all viral load results (undetectable and specific values). Where laws, regulations, or policies are not aligned with these recommendations, jurisdictions might consider 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

This program will provide funding during federal fiscal year 2016. 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 FY 2016 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 one (1) year. Notification of awards will be sent to the CEO or to the delegated administrative agency responsible for dispersing RWHAP Part B Grant Program 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 for the purpose of providing medications or insurance assistance for PLWH.

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 fiscal year, if with respect to such grants for the second preceding fiscal year, 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 will be subject to the Uniform Guidance 2 CFR 200 as codified by HHS at 45 CFR 75, which supersede the previous administrative and audit requirements and cost principles that govern federal monies.

Please see Policy Clarification Notice #15 - 01 for information regarding the statutory 10 percent limitation on administrative costs.

To ensure timely notification of the release of the FY 2016 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.

## III. Eligibility Information

## 1. Eligible Applicants

The following States and Territories are eligible to apply for RWHAP Part B 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.

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.

The data source for establishing eligibility for ADAP Supplemental funding is information provided by the recipient in the ADAP Data Report (ADR) for the previous reporting period. Receipt of ADAP supplemental funding in one year will not guarantee funding in any subsequent year.

## 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 fiscal years (i.e., 2013 and 2014). The State match is listed on the FY 2016 Part B Base and ADAP Base Notice of Award (NoA). A State can meet its match requirement through non-federal cash or in-kind 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 grantee'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). The law also provides for a waiver of the ADAP Supplemental match pursuant to the language in the statute. See page 37 for additional information.

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

#### 3. Other

Any application that fails to satisfy the deadline requirements referenced in *Section IV.3* will be considered non-responsive and will not be considered for funding under this announcement.

*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 (MOE)**

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. The RWHAP legislation requires Ryan White HIV/AIDS Part B Program recipients to maintain State expenditures for HIV-related activities at a level equal to the fiscal year preceding the application deadline for the Ryan White HIV/AIDS Part B grant. Grant funds shall not be used to take the place of current funding for activities described in the application. The recipient must agree to maintain non-federal funding for HIV-related activities at a level which is not less than the level of expenditures for such activities during the one-year period preceding the fiscal year for which the applicant is applying to receive the grant (see Section 2617(b)(7)(E) of the PHS Act). The maintenance of effort (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.

States must submit a signed assurance that MOE has been maintained, a description of a consistent data set of non-RWHAP Part B expenditures for the fiscal year prior to the application deadline that is counted towards the MOE, and methodologies for calculating MOE

expenditures. The description of the non-RWHAP Part B expenditures that count towards the MOE and methodologies for calculating MOE expenditures are submitted in <u>Attachment 7</u>. As part of the MOE, the applicant must 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.

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. Applicants must download the SF-424 application package associated with this FOA following the directions provided at <u>Grants.gov</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 justification, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program specific information below. All applicants are responsible for reading and complying with the instructions included in HRSA's <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.

#### **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 justification, staffing plan and personnel requirements, assurances, certifications, and abstract), please include the following:

## i. Project Abstract

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

In addition, the information below should be provided in brief paragraphs:

- a) A general overview of the HIV epidemiology in the State/Territory including demographics and the geography of the epidemic;
- b) 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:
- c) A general description of the ADAP, including clients served, medication purchasing method, insurance assistance program model, and any cost containment measures in place.

## 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 2016 Part B Base Grant Application
- (B) FY 2016 AIDS Drug Assistance Program (ADAP) Base Grant Application
- (C) Pacific Island Jurisdictions' FY 2016 Part B Grant Application
- (D) FY 2016 ADAP Supplemental Grant Application
- (E) FY 2016 Emerging Communities 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 2016 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 purpose of this section is to describe the HIV/AIDS epidemic in the State/Territory. Section 2617(b)(2) of the PHS Act states that the application for RWHAP Part B Base funds shall contain a determination of the size and

demographics of the population of PLWH in the State.

Please note that both the Epidemiology table and narrative should be included as **Attachment 5**.

Important Note: For programs applying for FY 2016 RWHAP Part B Supplemental (X08) funds and/or FY 2016 RWHAP ADAP Emergency Relief (ERF) (X09) funds, the Epidemiology table and narrative provided in <u>Attachment 5</u> of this application will be provided to the Objective Review Committee (ORC) reviewers for the purpose of scoring the RWHAP Part B Supplemental and/or RWHAP Part B ADAP Emergency Relief application. The RWHAP FY 2016 Part B Supplemental FOA and the RWHAP FY 2016 ADAP ERF FOA will not request Epidemiology data.

#### a) **Table**

Summarize in a table format the HIV (non-AIDS) and AIDS cases by age, sex, race/ ethnicity, and exposure category through December 31, 2014. Place the table in <u>Attachment 5</u> of the application and clearly label the data sources.

#### b) Narrative

Based on the most recent State/Territory HIV/AIDS Epidemiologic Profile, provide a brief narrative description of any trends or changes in the age, sex, race/ethnicity, and exposure categories for prevalent cases and for cases newly diagnosed and reported in the previous two years for which data are available. Place the narrative in <u>Attachment 5</u> of the 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. The public advisory planning process should help the recipient in developing and implementing the Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SCSN) and should include individuals living with HIV, other RWHAP recipients, other federal and local stakeholders, and community leaders. Federally recognized American Indian tribes, as represented in the State, must also be represented in the planning process.

#### a) Needs Assessment

- 1) Describe any current or planned needs assessment, including the geographic and population scope of the needs assessment, who participates in the process, and how participation from PLWH was obtained.
- 2) Describe how planned needs assessments will contribute to the Integrated HIV Prevention and Care Plan, including the SCSN due in September 2016.

## b) Public Advisory Planning Process

 Describe the Public Advisory Planning process model (e.g., integrated care and prevention, statewide or regional, consortia) and indicate the number and affiliations of the participating parties, including PLWH, other RWHAP recipients, other HIV related programs, other general and local stakeholder and community leaders.

- 2) If the 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 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) viral load (VL) testing, 2) CD4 count, or 3) provision of anti-retroviral therapy (ART). Unmet Need is further defined as the need for HIV-related health services by individuals with HIV who are <u>aware</u> of their HIV status, but are not receiving HIV primary health care.

**Note:** Both the Estimated Unmet Need Table and Narrative should be included as **Attachment 8.** The information provided in **Attachment 8** of this application will be used for scoring purposes.

Important Note: For programs that plan on applying for FY 2016 RWHAP Part B Supplemental (X08) funds, the Unmet Need Framework and narrative provided in this application will be provided to the FY 2016 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 2016 Part B Supplemental FOA will not request Unmet Need data.

- a) Provide an updated estimate of Unmet Need in the jurisdiction using the HRSA/HAB Unmet Need Framework. The framework must include the values, all data sources, and calculations. Programs are strongly encouraged to use the Excel worksheets of the Framework to help calculate the estimates of Unmet Need, which can be downloaded from the HAB Web site:

  ftp://ftp.hrsa.gov/hab/unmetneedpracticalguide.pdf
- b) Provide an Unmet Need Narrative description of the following:

*Note:* If no changes will be made in FY 2016 from your FY 2015 application to your 1) unmet need estimation methods, 2) assessment of unmet need, or 3) how your unmet need will be addressed, please note "no changes have been made" to each of these activities in your FY 2016 application.

- 1) <u>Estimation methods</u>: The methods used to develop the Unmet Need estimates, reasons for choosing this method, revisions or updates from the FY 2015 estimates, any limitations, and any cross program collaboration that occurred.
- 2) <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:
  - (a) The demographics and geographic location of people who are aware of their HIV status but are not in care;
  - (b) A description of the Unmet Need trends over the past five years; and
  - (c) An assessment of service needs, gaps, and barriers to care for people not in care.
- 3) <u>Addressing Unmet Need</u>: Describe how the results of the Unmet Need Framework were used in planning and decision making regarding priorities,

resource allocations, and adapting the system of care, including HIV Care Continuum related initiatives.

Describe any activities the State/Territory has carried out or is planning to address Unmet Need including the following activities designed to link those aware of their HIV status into core medical services:

- (a) Outreach activities, Early Intervention Services, Health Education and Risk Reduction:
- (b) HIV Care Continuum Activities; and
- (c) Collaboration with RWHAP and non-RWHAP funded entities, including Prevention.

Describe the challenges the program has encountered in linking the Unmet Need population to care and how these challenges are being addressed.

- 4) <u>Unmet Need Outcomes</u>: Describe the outcomes of the program's FY 2014 Unmet Need activities, including any impact on service utilization.
- **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 as required in Section 2617(b)(8) of the PHS Act. The goals of this initiative are: 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.

#### a) Fiscal Year 2016 EIIHA Plan

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

- 1) Describe the planned activities of the State/Territory EIIHA Plan for FY 2016. Include the following information:
  - (a) An updated estimate of individuals who are HIV positive and do not know their status, including the estimate methodology;
  - (b) All populations for the EIIHA Plan;
  - (c) The primary activities that will be undertaken, including system level interventions (e.g., routine testing in clinical settings, and expanding partner services);
  - (d) Major collaborations with other programs and agencies and community stakeholders, including HIV prevention and surveillance programs; and
  - (e) The planned outcomes of your overall EIIHA strategy, including how the activities will contribute to improving outcomes on the HIV Care Continuum.
- 2) Describe how the Unmet Need estimate and activities related to the Unmet Need population inform and relate to the EIIHA planned activities.
- 3) Describe how the EIIHA Plan for FY 2015 (e.g., process, activities, and outcomes) influenced the development of the EIIHA Plan for FY 2016.
- 4) Describe any planned efforts to remove legal barriers, including State laws and

- regulations, to routine HIV testing.
- 5) Select three (3) distinct target populations for the FY 2016 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 support that decision;
  - (b) Specific challenges with, or opportunities for, working with the targeted population;
  - (c) The specific activities that will be utilized 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 **S**pecific, **M**easurable, **A**chievable, **R**ealistic, and **T**ime 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.
- 6) Describe plans to present, discuss, and/or disseminate the EIIHA Plan and outcomes of your EIIHA Plan activities to stakeholders, (e.g., poster presentations, journal articles, presentations to planning bodies).

#### METHODOLOGY

1. Third Party Reimbursement/Payer of Last Resort: The RWHAP is the payer of last resort, and recipients must ensure that alternate sources of payment are pursued. Recipients are expected to coordinate effectively with third party payers to ensure that costs are recovered for services provided to eligible/covered individuals. Third party sources include Medicaid, Children's Health Insurance Programs (CHIP), Medicare (including the Part D prescription benefit) and private health insurance, including insurance obtained through the Health Insurance Marketplace. Subrecipients providing Medicaid eligible services must be Medicaid certified.

*Note:* The Indian Health Service is exempt from the payer of last resort provision.

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 and other payer sources such as, Medicaid, State Pharmacy Assistance Programs, and CHIP at least every six months. Please see HAB Policy Clarification Notice (PCN) 13-02. <a href="http://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>
- 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 <a href="http://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>
- c) The process used by the State/Territory to ensure that all recipients/subrecipients,

- including consortia contractors/subrecipients, are accessing, receiving, tracking and documenting third party reimbursement. Also describe the contract language or other mechanism(s) to ensure that this takes place.
- d) Please describe any recent changes to the State/Territory's health care environment, including changes in the Medicaid program, Medicaid expansion, and the Marketplace and how those changes have impacted the Ryan White HIV/AIDS Part B Program (e.g., changes in eligibility, enrollment in RWHAP services, usage of ADAP, etc.).
- **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 the designated service area on behalf of the recipient: planning, resource allocation and contracting, program and fiscal monitoring, and/or required reporting. Grant expenditures for or through Consortia are support services not core medical services. Please see 2613(f) of the PHS Act. For States with Consortia, please respond to the following questions:
  - 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/or required reporting and
  - c) Provide a summary of the benefits of utilizing the Consortia model for your State.
- 3. Women, Infants, Children and Youth Proportionate Spending: Recipients are required to use a proportionate amount of their grant dollars to provide services to women, infants, children and youth (WICY) living with HIV, unless a waiver is obtained. Recipients demonstrate compliance with the WICY expenditure requirement in their 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.

## ■ 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.

1. FY 2016 Implementation Plan Table: The Implementation Plan Table illustrates how core medical and support services will be provided in the State/Territory. List each service category and amounts for all RWHAP Part B (X07) funding sources (Part B Base funding, ADAP Base, MAI, ADAP Supplemental (if applicable), and Emerging Communities (if applicable) that will be allocated for each service category in FY 2016. The objectives describe the specific end results that a service is expected to accomplish within a given time period and should represent activities which have the greatest direct impact on the stages of the HIV Care Continuum. A service category may be related to more than one stage on the Continuum. For example, Outpatient Ambulatory Medical

Care impacts Linkage to Care, Retained in Care and Virally Suppressed. HAB has developed a RWHAP Service Categories Crosswalk with the HIV Care Continuum to assist with the identification of funded services along the HIV Care Continuum. Do not include any administrative processes. The Crosswalk and related information can be found on the <a href="https://careacttarget.org/library/sample-template-part-b-implementation-plan">https://careacttarget.org/library/sample-template-part-b-implementation-plan</a>. The Implementation Plan Table should be placed in <a href="https://careacttarget.org/library/sample-template-part-b-implementation-plan">https://careacttarget.org/library/sample-template-part-b-implementation-plan</a>. The

For each service category listed please provide:

- a) Objectives: List at least two objectives for new or continued services. Each objective should describe the specific activities associated with the service being provided.
- b) Service Unit Definition: Provide the name and definition of the unit of service to be provided (e.g., one round-trip bus ride, one prescription).
- c) Quantity: Provide the number of people to be served and service units to be provided during the grant year. Section 3a) List the number of people to be served;
   3b) List the total number of service units to be provided to that number of individuals.
- d) Time Frame: Indicate the estimated duration of the activity relating to the objective listed.
- e) Funds: Provide the approximate amount of RWHAP Part B funds to be used to provide this service. Where multiple objectives exist beneath one service goal, break out the estimated amount of funding by each individual objective listed.
- f) Outcomes: For each SMART objective, 1) name at least one client-level outcome/indicator to be tracked, using the HAB Standard Outcome Measures for Core Medical Services and Support Service Categories <a href="http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html">http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html</a>, 2) provide benchmark (baseline) data, and 3) provide the data source for tracking progress.
- g) Stage of the HIV Care Continuum: Select the Stage (Diagnosed, Linked to Care, Retained in Care, Prescribed Antiretroviral Therapy, and Virally Suppressed) of the HIV Care Continuum related to this service category. More than one Stage may be applicable.
- 2. FY 2016 Implementation Plan Narrative: The FY 2016 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, sex, 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 2016 allocations address significant issues and core service needs identified in the most recent SCSN and Comprehensive Plan;
- h) How the resources of AETC(s) will be used in the development and implementation of Ryan White HIV/AIDS Program Part B programs.
- i) How the services and their goals and objectives relate to the goals of the <u>Healthy</u> <u>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 new health coverage options under the ACA.
- 3. FY 2016 MAI Planning and Implementation: The purpose of this section is to provide a narrative description of the State'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. Please indicate in the narrative whether the program intends to accept or decline MAI funds.
  - a) Provide a description of the FY 2016 MAI planning process in terms of:
    - How program results and data generated from previous MAI-funded outreach/education and/or other RWHAP Part B funded outreach activities are used to increase racial and ethnic minority population participation in the ADAP; and
    - 2) How PLWH, particularly minority individuals, provided input into the MAI planning process.

- b) Describe how the following have been taken into consideration and how they will be coordinated with RWHAP Part B MAI funds:
  - 1) Education and outreach services provided by other RWHAP recipients within the State/Territory that are intended to increase access to ADAP; and
  - 2) 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.
- c) MAI Plan Narrative and ADAP Capacity: Please provide a narrative description of the State's FY 2016 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:
  - 1) Targeted Audiences;
  - 2) Targeted Activities;
  - 3) 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);
  - 4) Geographic locations;
  - 5) Types of agencies and staff to provide services;
  - 6) Coordination with existing services and providers; and
  - 7) Involvement of targeted minority populations in implementation of plan.
- d) Provide an update on the capacity of the ADAP to absorb additional clients (specify the number) reached through MAI-funded services.
- e) To the extent that ADAP resource constraints may exist, describe the plan to ensure that clients not currently enrolled in ADAP are linked to other medication/treatment resources in a timely manner.
- f) Describe the plan for assuring the quality of MAI-funded education and/or outreach services in relation to the FY 2016 Part B/ADAP Clinical Quality Management (CQM) plan.
- g) Describe the impact of these MAI-funded education and/or outreach services as they relate to the HIV Care Continuum (i.e., linkage to care, retention in care and viral load suppression).

#### RESOLUTION OF CHALLENGES

For each of the sections below, please identify any challenges you anticipate encountering and what approaches you will use to resolve those challenges. If applicable, discuss challenges that are likely to be encountered in implementing the activities in a specific section and describe approaches that will be used to resolve those challenges. If there are no additional challenges in a specific section below, please indicate for that section.

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. WICY Proportionate Spending
- 6. Clinical Quality Management
- 7. HIV Care Continuum
- EVALUATION AND TECHNICAL SUPPORT CAPACITY
  - 1. Clinical Quality Management: The purpose of this section is to describe the State/Territory's overall Clinical Quality Management (CQM) Program for the RWHAP Part B, including ADAP. This should include a description of how the results of the RWHAP Part B CQM activities are being or have been used to improve service delivery in the State/Territory. Include any CQM collaborations with other entities, including other RWHAP funded programs, other government entities such as CDC, National Institutes of Health, other State and local government programs and nongovernmental organizations, including faith-based organizations. This section should provide the overview of the CQM Program.

CQM data play a critical role in documenting that services delivered to clients are improving their health status. Information gathered through the CQM Program, as well as client-level health outcomes data, should be used as part of the State/Territory planning process and ongoing assessment of progress toward achieving program goals and objectives, including improving the HIV Care Continuum. The recipient should also use these data to examine and refine processes for administering the grant at the programmatic and fiscal levels.

*Note:* As previously noted, HAB currently has a portfolio of performance measures that include clinical, systems, medical case management, oral health, and ADAP. Recipients can select appropriate performance measures from the portfolio to compose a "local" portfolio of measures. Recipients should select performance measures that are most important to their programs and the populations they serve, as they relate to their overall goals for improving clinical health outcomes. The local portfolio should include measures for all funded service categories. Recipients are strongly encouraged to incorporate HAB's core measures into their portfolio and add other measures as appropriate. HAB's performance measures, as well as frequently asked questions (FAQs), can be found online at:

 $\underline{http://hab.hrsa.gov/deliver hivaids care/habper form measures.html}.$ 

Links to the HHS HIV/AIDS Treatment Guidelines (formerly called the Public Health Service guidelines), the RWHAP legislation, and the resources and technical assistance (TA) available to recipients with respect to improving the quality of care and establishing CQM programs may be found online at: http://hab.hrsa.gov/manageyourgrant/granteebasics.html

HAB Part B Program Monitoring Standards (including the standards for Quality Management) can be found online at:

http://hab.hrsa.gov/manageyourgrant/files/programmonitoringpartb.pdf

- a) Description of CQM Program Infrastructure: Include the ADAP CQM in this description.
  - 1) List the number of staff (Full Time Equivalents-FTE's) assigned to CQM.
  - 2) Describe the CQM Program staff roles and responsibilities.
  - 3) 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.
  - 4) Describe efforts to coordinate CQM activities with other RWHAP recipients in the State/Territory.
- b) Description of the CQM Program Performance Measures.
  - 1) List the service categories for which the applicant has performance measures.
  - 2) List the performance measures for the upcoming year for ADAP, outpatient/ambulatory medical care and medical case management.
  - 3) Describe the frequency of performance measure data collection from subrecipients.
  - 4) Summarize the performance measure data collected for ADAP, outpatient/ ambulatory medical care, and medical case management from the last grant year or calendar year, include any trending data.
- c) Describe how performance measure data are analyzed to evaluate for disparities in care, and actions taken to eliminate disparities.
- d) Describe how stakeholders, including subrecipients, consumers, other RWHAP recipients in the State/Territory, and planning body contribute to the selection of performance measures and receive information about performance measure data.
- e) Description of COM Program Quality Improvement:
  - 1) Describe the process for identifying priorities for quality improvement.
  - 2) Provide examples of specific quality improvement projects undertaken for ADAP, outpatient/ambulatory medical care and medical case management.
  - 3) Describe the process to monitor and support subrecipients' engagement in quality improvement projects.
  - 4) Describe efforts aimed at improving HIV viral load suppression within the State/Territory.
  - 5) Discuss how the CQM data have been used to improve and/or change service delivery in the State/Territory, including long-range service delivery planning.
  - 6) Describe how stakeholders including subrecipients, consumers, other RWHAP recipients in the State/Territory, and planning body contribute to the selection of quality improvement activities undertaken by the applicant.
- f) Data for Program Reporting
  - 1) Name and describe the information/data system(s) used for data collection and reporting operations in the State/Territory.

2) Describe the recipient's 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 calendar year 2014 client-level data. Describe efforts to increase data completeness and validity.

#### ORGANIZATIONAL INFORMATION

1. Grantee 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. The organizational chart is included in <u>Attachment 1.</u>

## 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. Recipients 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

- c) Provide a narrative that describes the following:
  - 1) The roles and responsibilities of program and fiscal staff in ensuring adequate reporting, reconciliation, and tracking of program expenditures and program income. 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 income;
  - 2) The process used to separately track RWHAP Part B Base, ADAP Base, ADAP Supplemental (if applicable), Emerging Communities (if applicable) and MAI (if applicable) grant funds; medication rebates (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;
  - 3) Description of 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;
  - 4) The process used for fiscal and program monitoring, including the type and frequency of required reports;
  - 5) The process and timeline for corrective actions when a fiscal or program—related concern is identified:
  - 6) The process, including a timeline, for receiving vouchers or invoices from

- providers/subrecipients;
- 7) The process, including a timeline, for issuing payments to providers/subrecipients, from receipt of voucher/invoice to reimbursement;
- 8) Describe the ongoing progress by the recipient to implement the National Monitoring Standards;
- 9) The total number of contractors, including consortia, funded in FY 2015; and
- 10) The total number and percentage of contractors that received a fiscal and/or programmatic monitoring site visit in FY 2014 as well as the total number expected to be completed by the end of FY 2015. Also provide answers to the following:
  - (a) Please specify if your State/Territory has an approved annual site visit exemption.
  - (b) Were there improper charges by contractors or other findings in FY 2015? If so, please summarize the corrective actions planned or taken to resolve these findings.
  - (c) The number of contractors that received technical assistance (TA) during FY 2015, including the types of TA, scope, and timeline.
  - (d) The number and percentage of eligible contractors compliant with audit requirements in 45 CFR 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.
  - (e) For those applicants with consortia, describe the State's monitoring requirements for consortia in relation to their contractors and subrecipients, including how those requirements and processes are compliant with the National Monitoring Standards.

## (B) FY 2016 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 AIDS Drug Assistance Program (ADAP), including recipients that had an ADAP waiting list in FY 2015 or anticipate instituting an ADAP waiting list for FY 2016.

ADAP pays for medications to treat HIV disease, health insurance coverage, and services for eligible clients that enhance access, adherence, and monitoring of drug 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. Recipients are required to determine client eligibility on an annual/12 month basis and to recertify eligibility at least every 6 months.

Steady growth in the number of eligible clients combined with rising costs of complex HIV treatments 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.

As covered entities, ADAPs are eligible to participate 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 Rebate Option must be returned to the State/Territory RWHAP Part B Program, with priority given to ADAP. The applicant must ensure that rebates are used consistently with RWHAP requirements. All program income generated as a result of awarded grant funds must be used for approved project-related activities.

## ■ INTRODUCTION

This section should briefly describe how the project will use grant funds to pay for medications to treat HIV disease, health insurance coverage, and services for eligible clients that enhance access, adherence, and monitoring of medication treatment.

#### ■ NEEDS ASSESSMENT

This section should provide a detailed description of the information below:

## 1. Client Utilization of ADAP Services

- a) Provide a narrative describing the demographics of the ADAP clients, including any significant differences in the ADAP clients and the epidemiological data;
- b) Discuss the driving factors for any increases in the ADAP enrollment (e.g., MAI Outreach, EIIHA activities, CDC testing initiatives, economic recession, changes in the Medicaid program) and the subsequent impact on utilization of ADAP resulting from these initiatives;
- c) Discuss how the implementation of the ACA has impacted client utilization of ADAP; and
- d) 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.

#### METHODOLOGY

This section should describe the methods that will be used by the recipient to address the ADAP service utilization and program operation's needs.

## 1. ADAP Funding Resources

Provide a table that lists all sources of funds for the ADAP Program (e.g., State funds, other RWHAP funds, medication rebates) expected for FY 2016. The table should be included as <u>Attachment 4</u>. Indicate if there are anticipated funding shortfalls and by what amount.

## 2. Formulary

The current statute requires that ADAPs include at least one drug from each Food and Drug Administration (FDA)-approved antiretroviral drug class currently available including: Fusion/Entry Inhibitors, Non-nucleoside Reverse Transcriptase Inhibitors, Nucleoside/Nucleotide Reverse Transcriptase Inhibitors, Protease Inhibitors and Integrase Inhibitors. Please refer to Section 2616(c)(1) of the PHS Act.

- a) Provide a narrative that discusses any limitations or barriers that affect the inclusion of these drug classes on the State/Territory ADAP formulary.
- b) If the ADAP Program reduced the number of medications available in the core classes, please describe the process that the ADAP utilized to reduce those medications, and the role of the ADAP Advisory Committee in the reduction process.

## 3. ADAP Coordination

- a) Discuss how the ADAP coordinates with third-party payers (e.g., State Medicaid Program, Medicare Part D plans, and private insurance) to assure that ADAP is the payer of last resort.
- b) Describe any third-party payer limitations that restrict access to HIV pharmaceutical therapies and describe ADAP mechanisms to address gaps or limitations in services.
- c) Describe how the ADAP coordinates with RWHAP Part A, Part C, and Part D recipients to provide comprehensive and equitable pharmacy benefits across the State.
- d) Briefly describe, if applicable, how the ADAP utilizes or coordinates with manufacturer's Patient Assistance Programs (PAPs) and clinical trials.

#### 4. ADAP Cost Saving Strategies

ADAP recipients are required to use every means at their disposal to secure the best price available for all products on their ADAP formularies in order to achieve maximum results with these funds.

#### a) ADAP Purchasing Model

States and Territories should respond to the following section specific to the ADAP

purchasing model used by the State or Territory.

## 1) 340B Direct Purchase

- (a) Provide the name and type of pharmaceutical provider and/or wholesaler currently used.
- (b) Provide the name of the pharmacy benefits manager (PBM), if applicable, and the services provided.
- (c) Describe the State/Territory mechanisms for monitoring ADAP-related contracts or subcontracts.
- (d) Describe the pharmacy network used in FY 2015 for drug distribution (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 used.

## 2) 340B Rebate Option

- (a) In addition to participation in the 340B program, describe the State/Territory's cost-saving practices for FY 2015.
- (b) Provide the name of the PBM used by the program, if applicable, and the services provided.
- (c) Describe the State/Territory mechanisms for monitoring ADAP-related contracts or subcontracts.
- (d) Describe the pharmacy network used, including the number of participating pharmacies in FY 2015 for drug distribution (e.g., national drug chain, mail order, State health department pharmacies, local pharmacies, university or disproportionate share hospital pharmacy).
- (e) The amounts expended for dispensing and service delivery.
- (f) Describe the mechanisms and timelines used by the State/Territory to identify, request, track, and utilize rebates accessed.
- (g) Describe how the State/Territory ensures that manufacturers' rebates are utilized consistent with Section 2616(g) of the PHS Act.

## 3) 340B Dual (Hybrid) States/Territories

This section is for States that distribute their medications through the 340B Direct Purchase model, but collect rebates on ADAP-eligible clients with insurance or Medicare Part D.

- (a) For States that distribute medications utilizing both 340B mechanisms, please describe the contract with the 340B eligible entity and describe the network pharmacy for ADAP-eligible clients that are not receiving their care at the 340B eligible clinic.
- (b) Provide the number of clients who receive medications from the Direct Purchase pharmacy services and the number of ADAP-eligible clients who receive insurance services from the ADAP. Describe how the program ensures that only network pharmacy claims and/or insurance assistance claims are submitted for 340B rebates.

## 4) Department of Defense (DOD) Direct Purchase

*This Section only applies to the District of Columbia* as the District of Columbia is eligible for Department of Defense (DOD) pricing as well as 340B participation.

(a) For the 340B Drug Pricing Program, describe all of the cost-saving strategies used by the ADAP during FY 2015, including any non-340B supplemental rebates and/or discounts received from pharmaceutical manufacturers. Explain how these strategies resulted in additional cost

savings of medications purchased directly through the DOD or the 340B Program.

## b) Prime Vendor Program

Please state if the program participates in HRSA's Prime Vendor Program. Briefly describe the benefit to the ADAP of participation in the program.

## c) ADAP-Funded Health Insurance Assistance

The RWHAP allows States to purchase health insurance and assist with copayments, co-insurance and deductibles. HAB Policy Notice 07-05, HAB Policy Clarification Notices (PCNs) 13-04, 13-05, 13-06, and 14-01 provide guidance and clarification regarding this process. Recipients must assure that the health insurance plan, at a minimum, includes at least one drug in each class of core antiretroviral therapeutics from the HHS Clinical Guidelines for the Treatment of HIV, as well as appropriate primary care services. States must be able to provide HAB with the methodology used to determine that the purchase of health insurance is cost effective compared to the cost of medications in the aggregate. **States may use this application as the Notification of Intent to use RWHAP Part B funds to purchase health insurance and assist with premiums and cost-sharing.** HAB Policy Notices 07-05, 13-04, 13-05, 13-06, and 14-01 can be found at: <a href="http://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>.

- 1) Notification of Intent: Does the ADAP plan to utilize funds for health insurance assistance? Please respond yes or no.
- 2) For States/Territories with existing ADAP-funded health insurance assistance programs, please describe:
  - (a) The use of ADAP funds to purchase insurance in FY 2015 and any anticipated changes for FY 2016;
  - (b) The anticipated amount of ADAP funds to be used for health insurance assistance, what specific health insurance assistance services will be provided (i.e., premium assistance, co-payments, co-insurance, deductibles), the types of health insurance(s) that will be purchased (e.g., COBRA, employer based, Health Insurance Marketplace plans), and the number of projected clients to be served;
  - (c) The current number of clients receiving ADAP-funded health insurance assistance with incomes above 138 percent of FPL; and the percentage of current ADAP-funded health insurance eligible clients that this number represents; and
  - (d) Provide the methodology used to determine that the purchase of health insurance is cost effective compared to the cost of medications in the aggregate.
  - (e) Has the ADAP executed a data-sharing agreement with the Centers for Medicare & Medicaid Services (CMS)?
  - (f) Describe how the ADAP provides insurance assistance (premiums, deductibles, co-insurance, True Out Of Pocket expenditures) to ADAP-eligible clients with prescription coverage under Medicare Part D.
  - (g) How many ADAP-eligible clients does your program anticipate providing Medicare Part D insurance assistance to in FY 2016?
  - (h) What is the projected cost of providing ADAP-eligible clients with

Medicare Part D insurance assistance in FY 2016?

- 3) For those States/Territories establishing new ADAP-funded health insurance assistance programs during FY 2016, please provide a narrative description of:
  - (a) How the State/Territory will ensure 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;
  - (b) How the State/Territory will assess and compare the aggregate cost of paying for the health insurance option versus paying for the full cost for medications;
  - (c) The anticipated amount of ADAP funds to be used for health insurance assistance (i.e., premiums, co-pays and deductibles) and types of insurance(s) that will be purchased using ADAP funds;
  - (d) The anticipated number of clients with incomes above 138 percent of FPL that are projected to be served by the new ADAP-funded insurance program in FY 2016;
  - (e) How the program will account for, and report on, funds used to purchase and maintain insurance policies for eligible clients, including covering any costs associated with these policies (e.g., premiums, co-payments, or deductibles) to ensure that the RWHAP is the payer of last resort;
  - (f) How the program coordinates with any other existing programs utilizing funds for the purchase of health insurance; and
  - (g) How the implementation of this program will impact the ADAP (e.g., the expansion of formulary or the decrease in waiting list).
- 4) If the State expanded Medicaid in FY 2015, specify:
  - (a) The current number of ADAP-eligible clients with incomes below 138 percent of FPL that were eligible for and enrolled in Medicaid during FY 2015; and the percentage of current ADAP eligible clients that this number represents.
- 5) If the State has plans for Medicaid expansion during FY 2016, specify:
  - (a) The current number of ADAP-eligible clients with incomes below 138 percent of FPL that will be eligible to be enrolled in Medicaid; and the percentage of current ADAP eligible clients that this number represents.
- 6) For States not expanding Medicaid during FY 2016, specify:
  - (a) The current number of ADAP-eligible clients with incomes below 100 percent of FPL and the percentage of current ADAP eligible clients that this number represents; and
  - (b) The current number of ADAP-eligible clients with incomes between 100 percent and 138 percent of FPL and the percentage of current ADAP eligible clients that this number represents.

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

This section must be completed by all jurisdictions 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/Territory's ADAP does not adequately address the medication assistance needs of clients in the jurisdiction (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 jurisdiction.

The National Monitoring Standards outline the systemic requirements necessary to comply with the service category definition. 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 National Monitoring Standards for a complete list of LPAP requirements.

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

- 1) 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 jurisdiction's medication needs;
- 2) The component of the medication need that the LPAP will fill;
- 3) How the LPAP will be coordinated with the ADAP:
- 4) The client enrollment and eligibility process including how payer of last resort is ensured;
- 5) 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;
- 6) How the recipient ensures that the LPAP follows the most recent HHS HIV/AIDS Treatment Guidelines; and
- 7) The mechanism to ensure "best price" for medications, (e.g., 340B Drug Pricing Program and/or Prime Vendor Program).
- 5. 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". HAB Policy Notice 07-03, "The Use
  of RWHAP Part B ADAP Funds for Access, Adherence, and Monitoring Services"
  (<a href="http://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>) established guidelines for
  allowable ADAP-related expenditures under the RWHAP for services that improve
  access to medications, increase adherence to medication regimens, and help clients
  monitor their progress in taking HIV-related medications. States may request to
  redirect up to five percent of their ADAP base award for these services under this
  policy, and up to 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. An example of

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an extraordinary circumstance would be identifying a targeted population with low adherence rates (e.g., substance abusers, homeless persons).

**Note:** Those States/Territories applying to use ADAP funds under the Flexibility Policy in FY 2016 for access, adherence, and monitoring services should reply to this section. In order to be eligible the States/Territories cannot have any program restrictions (e.g., waiting list, formulary limitations).

## a) Discussion of Proposed Program

- If you are requesting to redirect a portion of ADAP funding to pay for services under the ADAP Flexibility Policy, provide a narrative description that includes:
  - (a) Proposed services to be funded (access, adherence, and/or monitoring);
  - (b) Amount (and percentage) of the ADAP base award that will be redirected to pay for the proposed services;
  - (c) Methodology used to determine the cost of the proposed services;
  - (d) The total projected expenditures for each service, and the unit cost (e.g., cost for billable hours for adherence and access services, lab services, etc.);
  - (e) The number of clients who will directly benefit from each of the proposed services;
  - (f) How the program will monitor the proposed services to ensure that there are no limitations to accessing the State ADAP;
  - (g) How the ADAP will ensure that comprehensive coverage of antiretroviral and opportunistic infection medications is maintained; and
  - (h) How the ADAP will redirect funds back to the ADAP funding stream should it become necessary to maintain the core purpose of ADAP.

#### ■ WORK PLAN

This section should describe the activities proposed for ADAP in the Methodology section above. The Implementation Plan and CQM Plan information provided in Section (A) of the FY 2016 Part B Base Grant Application applies to this section (i.e., all ADAP-funded services should be included in the Implementation Plan). Therefore, a separate work plan is not needed.

## ■ RESOLUTION OF CHALLENGES

This section should discuss the challenges that may be encountered in the implementation of ADAP activities described above in the Work Plan.

- 1. Questions 1.a) 1.f) are to be completed by States that <u>implemented</u> a waiting list in FY 2015. States with a waiting list newly implemented in FY 2015 should describe the process of deciding for and implementing the waiting list. States with waiting lists implemented prior to FY 2015 or without a waiting list in FY 2015 can skip Questions 1.a) 1.f) and proceed to Question 2.
  - a) What factors (e.g., State general fund cuts, increased enrollment, increased costs of medications or insurance premiums, etc.) contributed to the decision to implement an ADAP waiting list?
  - b) Describe how stakeholders (e.g., ADAP Advisory Body, PLWH, providers) were 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.
- c) What preventative measures and cost containment measures were implemented prior to implementing a waiting list (e.g., formulary reduction, reducing income eligibility, cutting support or core medical services funding, data sharing agreement with CMS, back-billing Medicaid, and purchasing of insurance)?
- d) Describe the process the program employed 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).
- e) What challenges are clients, case managers, physicians, eligibility specialists and providers facing in enrolling clients on PAP? What steps has the program taken to assist in meeting these challenges?
- f) If the waiting list is still in existence as of the time of the application, please answer the following questions:
  - 1) How often are clients on the waiting list re-screened for ADAP eligibility?
  - 2) Please provide a description of the State ADAP waiting list protocol, including whether the waiting list is prioritized by clinical acuity or based on the model of "first come, first served"?
  - 3) Describe the process of how PLWH on the current ADAP waiting list are transitioned into the ADAP when openings arise. How are PLWH and providers informed about the ADAP waiting list protocols and prioritization procedures?
  - 4) Describe how the program coordinates with other RWHAP recipients in the State to ensure that ADAP eligible PLWH have access to medications.
  - 5) What is the average length of time (e.g., one month, three months, etc.) that an ADAP eligible PLWH stays on the current waiting list?
  - 6) How many ADAP eligible PLWH does the ADAP program estimate will be on the waiting list during the 2016 grant year?
- 2. Questions 2.a) 2.f) are to be completed if the program <u>anticipates implementing</u> an ADAP waiting list during the FY 2016 grant year. If program does not anticipate implementing a waiting list, please skip to next section.
  - a) What factors (e.g., State general fund cuts, increased enrollment, increased costs of medications or insurance premiums, etc.) are contributing to the decision to implement an ADAP waiting list?
  - b) Describe how stakeholders (ADAP Advisory Body, PLWH, providers) will be involved in the decision to begin a waiting list. Describe the process the ADAP program will employ to communicate the implementation of a waiting list to stakeholders, providers, PLWH, case managers and eligibility specialists.
  - c) What preventative measures and cost containment measures are being implemented prior to implementing an ADAP waiting list (e.g., formulary reduction, reducing the income eligibility, cutting support or core medical services funding, data sharing agreement with CMS, back-billing Medicaid, and purchasing of insurance)?
  - d) Describe the process that will be used to train and inform consumers, physicians, providers, eligibility specialists and case managers about the availability of medications through the Pharmaceutical Manufacturer PAP.

- e) How many ADAP eligible PLWH does the ADAP program project will be on the waiting list during the FY 2016 grant year?
- f) Describe the plans to coordinate with other RWHAP recipients in the State/Territory to ensure that ADAP eligible PLWH will have access to medications.

## EVALUATION AND TECHNICAL SUPPORT CAPACITY

**FY 2016 Implementation Plan**: For the ADAP specific objectives in the FY 2016 Implementation Plan, describe the data and process that will be used to monitor the Implementation Plan and that will be used to improve access to ADAP medications and services.

#### 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 2015, and any proposed changes for FY 2016. Include an organizational chart if the ADAP is administered by a different agency. Place this chart in **Attachment 1**.

## (C) Pacific Island Jurisdictions' FY 2016 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

<u>Note</u>: For those territories that are eligible to apply for the ADAP Supplemental Grant Application, please refer to and complete the FY 2016 ADAP Supplemental Grant Application Section.

## Project Abstract

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

In addition, the information below should be provided in brief paragraphs:

- a) A general overview of the HIV epidemiology in the Territory including demographics and the geography of the epidemic;
- b) 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 clients served, medication purchasing method, insurance assistance program model, and any cost containment measures in place.

#### 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 needs of PLWH in the Pacific Island Jurisdictions.

**1.** The Territory's HIV/AIDS Epidemiology: The purpose of this section is to describe the HIV/AIDS epidemic in the Territory. Section 2617 (b)(2) of the PHS Act states that the application for RWHAP Part B funds shall contain a determination of the size and demographics of the population of PLWH in the Territory.

*Note:* Both the Epidemiology Table and Narrative should be included as **Attachment 5**.

Important Note: For programs applying for FY 2016 RWHAP Part B Supplemental (X08) funds, the Epidemiology Table and Narrative provided in <u>Attachment 5</u> of this application will be provided to the FY 2016 RWHAP Part B Supplemental Objective Review Committee (ORC) reviewers for the purpose of scoring the RWHAP Part B Supplemental application. The RWHAP FY 2016 Part B Supplemental FOA will not request Epidemiology data.

## a) Table

Summarize in a table format the HIV (non-AIDS) and AIDS cases by age, race/ethnicity, and exposure category through December 31, 2014. Place the table in **Attachment 5** of the application and clearly label the data sources.

#### b) Narrative

Based on the most recent Territory HIV/AIDS Epidemiologic Profile, provide a narrative description of trends in the age, race/ethnicity, and exposure categories for prevalent cases and for cases newly diagnosed and reported in the previous two years for which data are available. Place the narrative in <u>Attachment 5</u> of the 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 how the HIV Care Continuum for PLWH will be developed, 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 2016 (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 NHAS. The Executive Order implementing NHAS for the United States for 2015 2020 was released on July 30, 2015, and is available at <a href="https://www.whitehouse.gov/the-press-office/2015/07/30/executive-order-implementing-national-hivaids-strategy-united-states">https://www.whitehouse.gov/the-press-office/2015/07/30/executive-order-implementing-national-hivaids-strategy-united-states</a>.
  - 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 sub-populations or communities.
  - g) Describe efforts to inform individuals living with HIV about services and to engage individuals in HIV care.
  - h) 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.

1. FY 2016 Implementation Plan Table: The Implementation Plan Table illustrates how core medical and support services will be provided in the Territory. List each service category and amounts for all RWHAP Part B (X07) funding sources (Part B Base funding, ADAP Base, MAI, ADAP Supplemental (if applicable), and Emerging Communities (if applicable) that will be allocated for each service category in FY 2016. The objectives describe the specific end results that a service is expected to accomplish within a given time period and should represent activities which have the greatest direct impact on the stages of the HIV Care Continuum. A service category may be related to more than one stage on the Continuum. For example, Outpatient Ambulatory Medical Care impacts Linkage to Care, Retained in Care and Virally Suppressed. HAB has developed a RWHAP Service Categories Crosswalk with the HIV Care Continuum to assist with the identification of funded services along the Continuum. Do not include any administrative processes. The Crosswalk and related information can be found on the HRSA/HAB website. The suggested format for the Implementation Plan can be found at https://careacttarget.org/library/sample-template-part-b-implementation-plan. The table should be placed in **Attachment 6**.

For each service category listed please provide:

- a) Objectives: List at least two objectives for new or continued services. Each objective should describe the specific activities associated with the service being provided.
- b) Service Unit Definition: Provide the name and definition of the unit of service to be provided (e.g., one round-trip bus ride, one prescription).
- c) Quantity: Provide the number of people to be served and service units to be provided during the grant year. Section 3a) List the number of people to be served;
   3b) List the total number of service units to be provided to that number of individuals.
- d) Time Frame: Indicate the estimated duration of the activity relating to the objective listed.
- e) Funds: Provide the approximate amount of RWHAP Part B funds to be used to provide this service. Where multiple objectives exist beneath one service goal, break out the estimated amount of funding by each individual objective listed.
- f) Outcomes: For each SMART objective, (1) name at least one client-level outcome/indicator to be tracked, using the HAB Standard Outcome Measures for Core Medical Services and Support Service Categories <a href="http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html">http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html</a>, (2) provide benchmark (baseline) data, and (3) provide the data source for tracking progress.
- g) Stage of the HIV Care Continuum: Select the stage (Diagnosed, Linked to Care, Retained in Care, Prescribed Antiretroviral Therapy, and Virally Suppressed) of the HIV Care Continuum related to this service category. More than one stage may be

applicable.

2. FY 2016 Implementation Plan Narrative: The FY 2016 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 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:

- 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, sex, 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 Territory;
- f) How the activities described in the plan will address the needs of emerging populations;
- g) How proposed FY 2016 allocations address significant issues and core service needs identified in the most recent SCSN and Comprehensive Plan;
- h) 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
- i) Outreach and enrollment activities to enroll RWHAP clients into the new health coverage options under the ACA.

## 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, to include the CQM and Implementation Plan, and describe the approaches that will be used to address these challenges.

- EVALUATION AND TECHNICAL SUPPORT CAPACITY
  - **1. FY 2016 Implementation Plan**: Describe the data and process that will be used to monitor the Implementation Plan.
  - 2. The Territory's Clinical Quality Management Program: <u>HAB's Definition of Quality</u>: "Quality is the degree to which a health or social service meets or exceeds established professional standards and user expectations." Evaluations of the quality of care should consider: 1) the quality of the inputs; 2) the quality of the service delivery process; and 3) the quality of outcomes, in order to continuously improve systems of care for individuals and populations.
    - a) HAB has established the following minimum expectations of RWHAP recipients regarding quality management. At a minimum, recipients are expected to:
      - 1) Establish and implement a quality management plan;
      - 2) Establish processes for ensuring that services are provided in accordance with HHS treatment guidelines and standards of care; and
      - 3) Incorporate quality-related expectations into Requests for Proposals and Part B contracts, if applicable.
    - b) Provide a narrative which describes how the Territory ensures the quality of HIV care provided to PLWH. Discuss how Part B funded services, including support services, are improving HIV-related clinical health outcomes of PLWH in the Territory.
    - c) Describe the system and processes that will support the CQM program's requirements through effective tracking of performance outcomes. Include a description of how data are to be collected and managed that allows for accurate and timely reporting of performance measures. Describe the data collecting strategy to collect, analyze, and track data to measure process and impact outcomes of different cultural groups (e.g., race, ethnicity) and explain how data will be used to inform program development and service delivery. CQM data play a critical role in documenting that services delivered to clients are improving their health status. Information gathered through the CQM program, as well as client-level health outcomes data, should be used as part of the Territory planning process and ongoing assessment of progress toward achieving program goals and objectives, including improving the HIV Care Continuum. These data should also be used by the recipient to examine and refine processes for administering the grant at the programmatic and fiscal levels.

*Note:* As previously noted, HAB currently has a portfolio of performance measures that include clinical, systems, medical case management, oral health, and ADAP. Recipients can select appropriate performance measures from the portfolio to

compose a "local" portfolio of measures. Recipients should select performance measures that are most important to their programs and the populations they serve, as they relate to their overall goals for improving clinical health outcomes. The local portfolio should include measures for all funded service categories. Recipients are strongly encouraged to incorporate HAB's core measures into their portfolio and add other measures as appropriate. HAB's performance measures, as well as frequently asked questions (FAQs), can be found online at: <a href="http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html">http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html</a>.

Links to the HHS HIV/AIDS Treatment Guidelines (formerly called the Public Health Service guidelines), the RWHAP legislation, and the resources and technical assistance (TA) available to recipients with respect to improving the quality of care and establishing CQM programs may be found online at:

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

HAB Part B Program Monitoring Standards (including the standards for Quality Management) can be found online at:

http://hab.hrsa.gov/manageyourgrant/files/programmonitoringpartb.pdf.

## 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 grant-related reporting and monitoring responsibilities.

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

## a) Coordination with other Federal Programs:

- 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
  - 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).
- 2) For those Territories eligible for Global AIDS Funds, describe any ongoing or planned activities the Territory is participating in through the Global AIDS

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Fund and how these activities are coordinated with the Part B program.

## (D) ADAP Supplemental Grant Application

This Section should be completed only by eligible applicants as listed below.

States/Territories Eligible to Apply for an ADAP Supplemental Treatment Drug Grant 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. This funding will be available to States and Territories based on one of the following criteria as reported on the 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.

Georgia	Nebraska	
Idaho	Oklahoma	
Illinois	Puerto Rico	
Indiana	Texas	
Iowa	Utah	
Mississippi	Virginia	
Montana		

## 1. Additional Eligibility Criteria

- a) In order to be eligible for FY 2016 ADAP Supplemental funds, States/Territories must have obligated 75 percent of their FY 2015 RWHAP Part B award within 120 days of receipt of grant funds and have reported on the FY 2015 Interim Federal Financial Report (FFR), within 150 days after receipt of grant funds.
- b) It is important to note that ADAP Supplemental funding will be determined on an annual basis based on the ADR. The data source for establishing eligibility for ADAP Supplemental funding is the previous period of the ADR for the eligibility criteria. Receipt of ADAP Supplemental funding in one year will not guarantee funding in any subsequent year.
- c) States/Territories must use ADAP Supplemental funds to provide HIV-related medications or the devices needed to administer them, and shall coordinate the use of such funds with the amounts otherwise provided under Section 2616 of the PHS Act (ADAP) in order to maximize drug coverage.

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. If the State/Territory is requesting a waiver to the match, please attach a waiver request letter as **Attachment 10**. Submit this request along with the other application information.

## ■ INTRODUCTION

The States and Territories with demonstrated severe need must provide a summary using the following factors.

- **1.** Provide a description of how the project will use ADAP supplemental funds to pay for medications to treat HIV disease or for health insurance.
- **2.** ADAP Supplemental Grants require a State match of 25 percent, unless a waiver is requested and approved. If the State/Territory is unable to meet the match requirement, please provide the dollar amount (i.e., funding cap) for which the State/Territory would be able to meet the match requirement.

#### NEEDS ASSESSMENT

States and Territories applying for these funds must describe the severity of need for ADAP supplemental funds using the factors below:

- **1.** Describe any ADAP eligibility restrictions.
- 2. Identify the barriers in meeting the requirement for maintaining a minimum drug list that includes all currently available FDA-approved antiretroviral drug classes. ADAPs are required to include at least one drug from each FDA-approved antiretroviral drug classes currently available including Fusion/Entry Inhibitors, Non-nucleoside Reverse Transcriptase Inhibitors, Nucleoside/nucleotide Reverse Transcriptase Inhibitors, Protease Inhibitors and Integrase Inhibitors.
- **3.** Identify the number of eligible individuals to whom a State or Territory is unable to provide therapeutics to treat HIV.
- **4.** Discuss any unanticipated increase in service utilization and program costs (i.e., due to the addition of a new drug or class of drug, or to an unexpected increase in eligible individuals with HIV).

#### METHODOLOGY

The methodology section responses in sections A (Part B Base) and B (ADAP) apply to this section.

#### ■ WORK PLAN

The FY 2016 Implementation Plan provided in the RWHAP Part B Base and ADAP Base sections apply to this section. Please add the information regarding the services that will be provided with this funding following the format of the FY 2016 Implementation Plan.

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- 1. Objective/s: List objectives for the ADAP Supplemental services. Each objective should describe the specific activities associated with the service being provided.
- **2.** Service Unit Definition: Provide the name and definition of the unit of service to be provided (e.g., one prescription).
- **3.** Quantity: Provide the number of people to be served and service units to be provided during the grant year.
  - a) List the number of people to be served;
  - b) List the total number of service units to be provided to that number of individuals.
- **4.** Time Frame: Indicate the estimated duration of the activity relating to the objective listed.
- **5.** Funds: Provide the approximate amount of ADAP Supplemental funds to be used to provide this service.

## RESOLUTION OF CHALLENGES

The Resolution of Challenges section responses in the ADAP Base sections apply to this section. No further information is required for this section.

## EVALUATION AND TECHNICAL SUPPORT CAPACITY Describe the data and process that will be used to monitor the specific

Describe the data and process that will be used to monitor the specific ADAP Supplemental objectives.

## ORGANIZATIONAL INFORMATION

The Organization Information provided in the RWHAP Part B Base sections and the ADAP Base section above applies to this section. No further information is required for this section.

## (E) Emerging Communities FY 2016 Grant Application

## This Section should be completed only by eligible applicants as listed below.

The following States are responsible for applying for the eligible Metropolitan Statistical Areas (MSAs) below:

States	Emerging Communities
Alabama	Birmingham-Hoover, AL MSA
California	Bakersfield, CA MSA
Delaware	Phil., PA-NJ-DE-MD MSA – Wilmington
Florida	Lakeland, FL MSA
	Port St. Lucie-Fort Pierce, FL MSA
	Sarasota-Bradenton-Venice, FL MSA
Georgia	Augusta-Richmond County, GA-SC MSA
Kentucky	Louisville, 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-Cary, NC MSA
Ohio	Cincinnati-Middletown, OH-KY-IN, MSA
	Columbus, OH MSA
Oklahoma	Oklahoma City, OK MSA
Pennsylvania	Pittsburgh, PA MSA
Rhode Island	Providence-New Bedford-Fall River, RI-MA MSA
South Carolina	Columbia, SC MSA
	Charleston, SC MSA
Virginia	Richmond, VA MSA
Wisconsin	Milwaukee-Waukesha-West Allis, WI MSA
Total: 16 States	Total: 22 Emerging Communities

**Program Authority and Eligibility:** The Emerging Communities (EC) Supplemental Grant award is authorized under Section 2621 of the PHS Act. It is intended to enable eligible States to provide comprehensive services of the type described in Section 2612(a) of the PHS Act to supplement the services otherwise provided by the State under a grant under RWHAP Part B in EC within the State that are not eligible to receive grants under the RWHAP Part A. An eligible State shall agree that the grant will be used to provide funds directly to EC in the State, separately from other funds under this title that are provided by the State to such communities.

Eligibility for EC grants depends in part on the number of confirmed AIDS cases within a statutorily specified "metropolitan area." The Secretary of Health and Human Services 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. The only exception is Ponce, Puerto Rico, a Part A recipient, which uses different boundaries than those that were in effect when that jurisdiction first received funding. The decision to change the boundaries for this particular metropolitan area was the result of litigation, which is currently on appeal. HRSA has consistently maintained that the RWHAP legislation requires that geographic boundaries for metropolitan areas, including eligible metropolitan areas, transitional grant areas, and ECs, must remain fixed in time.

An EC must have between 500-999 cumulative AIDS cases during the most recent five years. Recipients with jurisdictions that were 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 have been met. Areas can retain their eligibility so long as they have not fallen below the required incidence level already specified and required prevalence level for three consecutive years. Areas are notified by letter when they are at risk of losing eligibility. According to the past eligibility numbers, all the above ECs will be eligible in FY 2016. Cumulative AIDS cases are reported and confirmed by the Director of the CDC as of December 31 of the most recent calendar year.

#### ■ 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 Metropolitan Statistical Areas (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.
  - 1) 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;
  - 2) Affected communities and PLWH are included in the planning process; and
  - 3) The proposed services are consistent with the local needs assessments and the most recent SCSN.

## 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 Emerging Community Funds: States with multiple ECs should describe the use of funds for each EC separately.

#### Please describe:

- 1. What services were provided in FY 2015 using EC funds;
- 2. What services will be provided in FY 2016;
- **3.** How the activities will be used to address gaps/barriers and improve the HIV Care Continuum;
- **4.** 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 continuum;
- **5.** Any significant health disparities brought to light related to race, gender, sexual orientation and age among populations within your jurisdiction's HIV Care Continuum

and current or planned activities targeted to address these disparities;

- **6.** How the activities in the plan address Unmet Need and reduce the number of persons out of care;
- 7. How any recent needs assessments or updates are linked or may be related to the HIV Care Continuum, including results of the Unmet Need Framework and any new or different initiatives funded;
- **8.** How the activities described in the plan will ensure geographic parity in access to HIV services throughout the EC;
- 9. How the activities described in the plan will address the needs of emerging populations;
- **10.** How proposed FY 2016 allocations address significant issues and core service needs identified in the most recent SCSN and Comprehensive Plan;
- 11. How the services and their goals and objectives relate to the goals of the <u>Healthy</u>

  <u>People 2020</u> initiative, particularly the objectives related to the HIV listing under the Topics and Objectives tab; and
- **12.** Outreach and enrollment activities to enroll RWHAP clients into the new health coverage options under the ACA.

#### ■ 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 2016 Emerging Communities Implementation Plan as provided above.

## ORGANIZATIONAL INFORMATION

The Organization Information section responses in the RWHAP Part B Base apply to 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 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 2016 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);
- **3.** Consortia/Emerging Communities This column should include all funds allocated to consortia and emerging communities; 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 health insurance continuation.

The Consolidated and Further Continuing Appropriations Act, 2015, Division G, § 203 (P.L. 113-235) 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 will apply in FY 2016, as required by law.

## iv. Budget Justification Narrative

See Section 4.1.v. of HRSA's <u>SF-424 Application Guide</u>. In addition, the FY 2016 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 justification 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 justification 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, Emerging Communities, and Minority AIDS Initiative (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 Policy Clarification Notice (PCN) 15-01 (<a href="http://hab.hrsa.gov/affordablecareact/pcn1501.pdf">http://hab.hrsa.gov/affordablecareact/pcn1501.pdf</a>).

<u>Payer of Last Resort</u>: 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 6 months (please see HAB Policy 13-02, 13-03, 13-04, 13-05, 13-06 and 14-01 at

http://hab.hrsa.gov/manageyourgrant/policiesletters.html). 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 ACA Marketplace. Subrecipients providing Medicaid eligible services must be Medicaid certified.

## 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 SF-424 Application Guide)

Keep each job description to one page in length as much as possible. Include the role, 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, not to exceed two pages in length. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch.

## Attachment 4: ADAP Funding Sources Table

Provide a table that lists all sources of funds for the ADAP program (e.g., State funds, other RWHAP funds, medication rebates) expected for FY 2016. Indicate if there are anticipated funding shortfalls and by what amount.

## Attachment 5: HIV/AIDS Epidemiology Table and Narrative

Summarize in a table format the HIV (non-AIDS) and AIDS cases by age, race/ethnicity, and exposure category through December 31, 2014. Also include a brief narrative description of any trends or changes in the age, race/ethnicity, and exposure categories for prevalent cases and for cases newly diagnosed and reported in the previous two years for which data are available.

## Attachment 6: Implementation Plan (includes MAI, if applicable)

In a table, list each service category and amounts for all Part B funding sources to include: Part B Formula funding, ADAP, MAI, ADAP Supplemental (if applicable), and ECs (if applicable) that will be allocated for each service category in FY 2016. Do not include any administrative processes. The suggested format can be found at <a href="https://careacttarget.org/library/sample-template-part-b-implementation-plan">https://careacttarget.org/library/sample-template-part-b-implementation-plan</a>.

## Attachment 7: Maintenance of Effort Documentation

Applicants must provide a baseline aggregate expenditure for their fiscal year prior to the application deadline. Please provide a description of the non-RWHAP Part B/ADAP expenditures for FY 2014 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 change.

NON-FEDERAL EXPEND	ITURES	
FY Prior to Application Actual prior FY non-fec including in-kind, exper proposed in this applica	deral funds, anded for activities	Current FY of Application (Estimated) Estimated current FY non-federal funds, including in-kind, designated for activities proposed in this application.
Amount: \$		Amount: \$
Fiscal Chief Financial Agen	- t	Ryan White Part B Program Director

Attachment 8: Unmet Need Framework Table and Narrative

The table must include the values, all data sources, and calculations for Unmet Need. Programs are strongly encouraged to use the Excel worksheets of the Framework to help calculate the estimates of Unmet Need, which can be downloaded from the HAB Web site: <a href="ftp://ftp.hrsa.gov/hab/unmetneedpracticalguide.pdf">ftp://ftp.hrsa.gov/hab/unmetneedpracticalguide.pdf</a>.

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 9: 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 (<u>Appendix A</u>) with this FOA, and require the signature of the CEO, or the CEO's designee.

Attachment 10: Core Medical Services, ADAP Supplemental Match and/or Annual Site Visit Exemption Waiver Request(s) and justification, if applicable Please include here 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 grant application, any time up to the application submission, or up to four months after the grant award for FY 2016. Submission should be in accordance with the information and criteria published by HRSA in the Federal Register Notice, Vol. 78, No. 101, dated Friday, May 24, 2013, and may be found at <a href="http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12354.pdf">http://www.gpo.gov/fdsys/pkg/FR-2013-05-24/pdf/2013-12354.pdf</a>.

In addition, recipients are advised that a FY 2016 RWHAP Part B waiver request must include funds awarded under the MAI. A waiver request that does not include MAI will not be considered.

## 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. If the State/Territory is requesting a waiver to the match, please attach a waiver request letter.

## **Annual Site Visit Exemption**

Recipients 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 grant application.

## Attachments 11 - 15: 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)

Applicant organizations must obtain a valid DUNS number and provide that number in their application. Each applicant must also register with SAM and continue to maintain active SAM registration with current information at all times during which it has an active federal award or an application or plan under consideration by an agency (unless the applicant is an individual or federal agency that is exempted from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the agency under 2 CFR 25.110(d)).

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

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

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

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

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 funding opportunity announcement is *November 20*, 2015 at 11:59 P.M. Eastern Time.

## 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 100.

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

## 6. Funding Restrictions

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

HRSA/HAB will be strictly enforcing the Ryan White HIV/AIDS Program 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 Application</u> *Guide*, RWHAP Part B funds **cannot** 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) Pre-Exposure (PrEP) or Post-Exposure Prophylaxis (nPEP),
- d) Syringe Services Programs (SSPs),
- e) Cash payments to intended recipients of 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. 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 in to 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 (grantee'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 grantee 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 Policy Clarification Notice (PCN) 15-01 (<a href="http://hab.hrsa.gov/affordablecareact/pcn1501.pdf">http://hab.hrsa.gov/affordablecareact/pcn1501.pdf</a>).

<u>Program Income</u>: HHS Grant 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. Recipients are responsible for ensuring that subrecipients have systems in place to account for program income, and for monitoring to ensure that subrecipients are tracking and using program income consistent with RWHAP Part B requirements. Please see 45 CFR §75.307 for additional information.

Rebate funds are not program income. See HRSA/HAB "Use of Rebate Funds" Policy Letter, dated November 16, 2012 http://hab.hrsa.gov/manageyourgrant/pinspals/habpl1112.pdf.

## 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 Table and Narrative
- Implementation Plan (includes MAI, if applicable)
- Maintenance of Effort Documentation, if applicable.
- Unmet Need Framework and Narrative
- FY 2016 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
- 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 calendar year (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, 2014. 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

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

## 3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of April 1, 2016.

## VI. Award Administration Information

## 1. Award Notices

The Notice of Award will be sent prior to the start date of April 1, 2016. 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 <u>SF-424 Application Guide</u>.

## 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.** The awardee must submit a program terms report to HRSA ninety (90) days after the award is made; further information will be provided in the notice of award.
- **b) MAI Annual Plan and Report.** The awardee 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 notice of award.
- c) Interim Federal Financial Report. The awardee 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 notice of award.
- **d) Expenditure Report.** The awardee must submit a RWHAP Expenditure Report; further information will be provided in the notice of award.
- e) Ryan White Part B Unobligated Balance Estimate/Estimated Carryover Request. The awardee must submit a request for carryover of any estimated Ryan White HIV/AIDS Program Part B Formula UOB to HRSA. Failure to submit an estimated UOB and estimated carryover request to HRSA will result in a recipient being ineligible to receive FY 2015 RWHAP Part B Formula carryover funds.
- f) Ryan White Services Report(s). Acceptance of this award indicates that the recipient assures that it will comply with data requirements of the Ryan White Services Report (RSR) and that it will mandate compliance by each of its recipients and 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 2015. Please refer to the HIV/AIDS Program Client Level Data website at <a href="http://hab.hrsa.gov/manageyourgrant/clientleveldata.html">http://hab.hrsa.gov/manageyourgrant/clientleveldata.html</a> for additional information.
- g) ADAP Data Report. The ADAP Data Report (ADR) is a reporting requirement for ADAPs to provide client level data on individuals served, services being delivered, and costs associated with these services. The ADR replaces the AQR (ADAP Quarterly

Report), which has been retired. Further information can be found at: http://hab.hrsa.gov/manageyourgrant/adr.html.

h) Integrated HIV Prevention and Care Plan. HRSA and CDC issued a joint guidance for the Integrated HIV Prevention and Care Plan, which includes the RWHAP Part B Statewide Coordinated Statement of Need (SCSN). The Integrated HIV Prevention and Care Plan guidance enables the submission of a single statewide document that is responsive to the legislative and programmatic requirements of both HRSA and CDC. The Integrated HIV Prevention and Care Plan will be due in September 2016 and will cover the CY 2017 – 2021 time period.

## **VII. Agency Contacts**

Applicants 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/HRSA Parklawn Building, Room 18-75 5600 Fishers Lane 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

Heather Hauck, MSW, LICSW Director, Division of State HIV/AIDS Programs HIV/AIDS Bureau, HRSA Parklawn Building, Mail Stop 09SWHO3 5600 Fishers Lane

Rockville, Maryland 20857 Telephone: (301) 443-6745

Fax: (301) 443-8143

E-mail: <u>HHauck@hrsa.gov</u>

Applicants may need assistance when working online to submit their application forms electronically. Applicants should always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 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: <a href="mailto:support@grants.gov">support@grants.gov</a>

iPortal: <a href="https://grants-portal.psc.gov/Welcome.aspx?pt=Grantshttps://grants-portal.psc.gov/Welcome.aspx.gov

Successful applicants/awardees 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 Call Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET:

HRSA Contact Center Telephone: (877) 464-4772 TTY: (877) 897-9910

Web: <a href="http://www.hrsa.gov/about/contact/ehbhelp.aspx">http://www.hrsa.gov/about/contact/ehbhelp.aspx</a>

## VIII. Other Information

## 1. Allowable Uses of Funds

For the most up-to-date listing of allowable uses of funds, refer to HAB Policy Notice 10-02: "Eligible Individuals and Allowable Uses of Funds for Discretely Defined Categories of Services" reissued April 8, 2010. HAB Policy Notice 10-02 is available online at: <a href="http://hab.hrsa.gov/manageyourgrant/policiesletters.html">http://hab.hrsa.gov/manageyourgrant/policiesletters.html</a>.

## 2. National Monitoring Standards

Recipients are required to have implemented the RWHAP Part B National Monitoring Standards at the recipient and provider/subrecipient levels. HRSA has developed and distributed guidelines outlining the responsibilities of HRSA, the recipient, and provider staff. The National Monitoring Standards can be found at: <a href="http://hab.hrsa.gov/manageyourgrant/granteebasics.html">http://hab.hrsa.gov/manageyourgrant/granteebasics.html</a>.

## 3. Technical Assistance

An FOA webinar will be held on Wednesday, October 7, 2015 at 3:00PM EST. To join the web portion, please use the following link: <a href="https://hrsa.connectsolutions.com/x07">https://hrsa.connectsolutions.com/x07</a> foa review/. To join the audio portion, please dial: 888-603-9810; and the participant passcode: 1165029.

## IX. Tips for Writing a Strong Application

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

## Appendix A:

# FY 2016 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:

- Federal, State and local funds are otherwise inadequate for the EIS an entity proposes to provide; and,
- The entity will supplement, not supplant, other funds available to the entity for the provision of providing EIS for the fiscal year 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.

## 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.

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

## 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:

- Administer all assistance received under Part B;
- Conduct the needs assessment and prepare the State plan;
- Prepare all applications for assistance under Part B;
- Receive notices with respect to programs under Title XXVI;
- Every two years, collect and submit to the Secretary all audits, consistent with 45 CFR 75
   Subpart F, from recipients within the State, including audits regarding funds expended in accordance to Part B; and
- 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 Program, 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

- 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 fiscal year 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

- 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).

## l.) 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:

- The estimated number of individuals within the State with HIV who do not know their status;
- 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
- 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.

	 Date	
Signature		
Title		
	-	
Address	_	