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

HIV/AIDS Bureau Ryan White HIV/AIDS Program

AIDS Drug Assistance Program (ADAP) Emergency Relief Funds (ERF)

Announcement Type: (New—Limited Competition) Funding Opportunity Number: HRSA-16-080

Catalog of Federal Domestic Assistance (CFDA) No. 93.917

### FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2016

### **Application Due Date: December 15, 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 22, 2015

**Issuance Date: September 22, 2015** 

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Authority: Section 311(c) of the Public Health Service Act, 42 U.S.C. 243(c) and Title XXVI of the Public Health Service Act, Sections 2611-23, (42 U.S.C. 300ff-231-31(b)), 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) is accepting applications for fiscal year (FY) 2016 AIDS Drug Assistance Program (ADAP) Emergency Relief Funds (ERF). The purpose of this program is to provide funding to States/Territories to prevent, reduce, or eliminate ADAP waiting lists, including through cost containment measures (for example, the provision of health insurance assistance). Section 311 of Title III of the Public Health Service (PHS) Act authorizes the Secretary to utilize resources to control epidemics of any disease. These funds are to be used in conjunction with the Ryan White HIV/AIDS Program's (RWHAP) Part B ADAP administered by the HRSA HAB Division of State HIV/AIDS Programs (DSHAP).

Funding Opportunity Title:	AIDS Drug Assistance Program (ADAP)	
	Emergency Relief Funds (ERF)	
Funding Opportunity Number:	HRSA-16-080	
Due Date for Applications:	December 15, 2015	
Anticipated Total Annual Available Funding:	\$75,000,000	
Estimated Number and Type of Award(s):	Up to 59 grants	
Estimated Award Amount:	Up to \$11,000,000	
Cost Sharing/Match Required:	No	
Project Period:	April 1, 2016 through March 31, 2017	
	(1 year)	
Eligible Applicants:	All 50 States, the District of Columbia, the	
	Commonwealth of Puerto Rico, the Virgin	
	Islands, Guam, American Samoa, the	
	Commonwealth of the Northern Mariana	
	Islands, the Republic of Palau, the Federated	
	States of Micronesia, and the Republic of the	
	Marshall Islands.	
	[See <u>Section III-1</u> of this funding opportunity	
	announcement (FOA) for complete eligibility	
	information.]	

### **Application Guide**

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

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

### Technical Assistance

A Funding Opportunity Announcement (FOA) webinar will be held on Wednesday, November 4, 2015, at 3 PM EST. To join the web portion, please use the following link: <u>https://hrsa.connectsolutions.com/adap\_erf\_x09\_foa/</u>. To join the audio portion, dial: 1-800-779-5318; Passcode: 5516246.

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### I. Program Funding Opportunity Description

### 1. Purpose

This announcement solicits applications for the Ryan White HIV/AIDS Program (RWHAP) Part B AIDS Drug Assistance Program (ADAP) Emergency Relief Funding (ERF). ADAP is administered by the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB), Division of State HIV/AIDS Programs (DSHAP).

**Limited New Competing ADAP ERF** awards are intended for States/Territories that demonstrate the need for additional resources to prevent, reduce, or eliminate ADAP waiting lists, including through cost-containment measures (for example, the provision of health insurance assistance). Limited new competing ADAP ERF awards will be based on the applicant's ability to successfully demonstrate need for additional funding. This demonstrated need will be evaluated by an external Objective Review Committee (ORC) based on criteria published in this funding opportunity announcement (FOA), with priority given to addressing waiting lists.

States/Territories with an existing ADAP waiting list reported to HRSA must use all funding awarded under this announcement to remove clients from the waiting list. States/Territories that did not report an existing waiting list to HRSA must use funding awarded under this announcement to prevent a waiting list through "cost-cutting" and/or "cost-saving" measures (e.g., establishment of a health insurance assistance program).

### 2. Background

This program is authorized by Section 311(c) of the Public Health Service Act, 42 U.S.C. 243(c) and Title XXVI of the Public Health Service Act, Sections 2611-23 (42 U.S.C. 300ff-21-31(b)), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87). ADAPs ensure access to medication to treat HIV disease for eligible clients through the direct purchase of medication and through covering the costs of insurance premiums, copays, and deductibles. Client 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 Federal Poverty Level (FPL). ADAPs are required to recertify client eligibility at least every six months.

Steady growth in the number of eligible clients combined with rising costs of complex HIV/AIDS treatments sometimes result 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 a pre-determined criterion. The ADAP manages the waiting list to bring clients into the program as funding becomes available.

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

Eligible States/Territories may request ADAP ERF to implement measures to help achieve and/or maximize HRSA's prioritized cost-containment strategies discussed below. **Note: There is no expectation that all measures will be taken. The measures listed above represent examples of possible measures. HRSA has prioritized the following cost-containment strategies through its monitoring and technical assistance efforts:** purchase of insurance, collection of rebates, back-billing of Medicaid, CMS data-sharing agreements for True Out of Pocket (TrOOP) expenditures, six month re-certification, and controlling ADAP administrative costs.

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. As covered entities, ADAPs are eligible to participate in the 340B Drug Pricing Program under Section 340B of the Public Health Service (PHS) Act. Funds received as a result of participating in the 340B Drug Pricing Program Rebate Option must be returned to the 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 funds must be used for approved project-related activities.

### Affordable Care Act

As part of the Affordable Care Act, 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 people living with HIV/AIDS. The Affordable Care Act 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 Affordable Care Act individuals with incomes between 100 to 400 percent 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 Ryan White HIV/AIDS Program (RWHAP) clients into the expanded health insurance coverage is critical. As

appropriate and allowable by statute, RWHAP recipients are strongly encouraged to support Affordable Care Act-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 <u>http://www.hab.hrsa.gov/affordablecareact/outreachenrollment.html</u>. Recipients and sub-recipients 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 <u>http://www.healthcare.gov.</u>

### **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 <u>HIV Care Continuum</u> or the Care 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 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 Service Report (RSR) indicate that there are better outcomes in Ryan White HIV/AIDS Program (RWHAP) funded agencies with approximately 79 percent of individuals who received RHWAP-funded HIV primary care being virally suppressed. 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 this continuum of care. 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 to and engaged in care and started on ART as early as possible. HRSA 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 <u>HHS Common HIV Core Indicators</u> approved by the Secretary and announced in August 2012. The HHS Common HIV Core Indicators were developed in coordination with other Department of Health and Human Services agencies. RWHAP recipients and providers are required to submit data through the RSR. Through the RSR submission, HRSA HAB currently collects the data elements to produce the HHS Common HIV Core Indicators. HRSA 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 Department of Health and Human Services, Office of the Assistant Secretary for Health.

### **Integrated Data Sharing and Use**

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 local, state and territorial health department 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. In addition, reporting of HIV-1 nucleotide sequences from genotypic resistance testing might also be considered to monitor prevalence of antiretroviral drug resistance, HIV genetic diversity subtypes and transmission patterns.

### **II. Award Information**

### 1. Type of Application and Award

### Type(s) of applications sought: New, Limited Competition

Funding will be provided in the form of a grant.

### 2. Summary of Funding

This program will provide funding during federal fiscal years 2016 - 2017. Approximately \$75,000,000 is expected to be available annually to fund up to 59 recipients. Applicants may apply for a ceiling amount of up to \$11,000,000. 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.

As noted, FY 2016 Limited New Competition ADAP ERF awards will be capped at a maximum of \$11,000,000 with a minimum of \$100,000, subject to the availability of funds and an application reviewed and recommended for approval. The amount of each award will be based on the applicant's ability to demonstrate the need for funding to prevent, reduce, or eliminate a waiting list, including through "cost-cutting" and/or "cost-saving" measures. This determination

will be made by an external ORC. Funding will be based on the ORC review and scoring of the criteria published in Section V.1 of this announcement. Because HRSA places significant importance on the elimination of waiting lists, the applications will be evaluated as follows:

- The ORC scores will be used to establish the rank order for the awarding of funds.
- All applicants that request new competitive ADAP ERF funds to address existing waiting lists and are recommended for an award by the ORC will receive awards based on their ORC scores.
- Once those funds are distributed, then applicants that request funds for "cost-cutting" and/or "cost-saving" measures will receive awards based on their ORC scores.

Applicants with the highest scores will be funded at the full amount requested as long as the amount requested is for allowable services under this FOA, the average client costs calculations outlined in Appendix A are correct, the application was recommended for funding by the ORC, the amount requested falls within the minimum and maximum amount available, and there are still funds available to distribute.

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  $\frac{2}{CFR \ 200}$  as codified by HHS at  $\frac{45 \ CFR \ 75}{75}$ , which supersede the previous administrative and audit requirements and cost principles that govern federal monies.

### **III.** Eligibility Information

### **1. Eligible Applicants**

Limited New Competitive ADAP ERF Awards

States/Territories that reported to HRSA an ADAP waiting list or who have used the ADAP ERF funds to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and August 2015 are eligible to apply for Limited New Competitive ADAP ERF Awards.

All 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the 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 are eligible to apply for funding if they meet the above requirement.

States/Territories that did not report to HRSA an existing ADAP waiting list or use the ADAP ERF funds to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and August 2015 are not eligible to apply for Limited New Competition ADAP ERF Awards.

### 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

### 3. Other

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

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

NOTE: Multiple applications from an organization are not allowable.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates), an application is submitted more than once prior to the application due date, HRSA will only accept the applicant's **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

### **IV. Application and Submission Information**

### 1. Address to Request Application Package

HRSA *requires* applicants for this FOA to apply electronically through Grants.gov. Applicants must download the SF-424 application package associated with this FOA following the directions provided at <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 40 pages when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. We strongly urge applicants to take appropriate measures to ensure the application does not exceed the specified page limit.

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under the announcement.

### **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 must be followed by brief paragraphs that provide updated information, in this order:

- a) General demographics of the State/Territory;
- b) Demographics of HIV/AIDS populations in the State/Territory;
- c) Brief description of the State ADAP and key environmental factors impacting the program;
- d) Description of the need for additional resources to prevent, reduce, or eliminate waiting lists and to address cost-containment measures (including "cost-cutting" and/or "cost-saving"); and
- e) Description of the planned use of ADAP Emergency Relief Funds, if received.

### ii. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Use the following section headers for the Narrative:

- INTRODUCTION -- Corresponds to Section V's Review Criterion (Need) #1
  This introduction section should briefly describe how the State/Territory will utilize Ryan
  White HIV/AIDS ADAP ERF funds in support of preventing, reducing, or eliminating a
  waiting list, including through cost-cutting or cost-savings measures during the project
  period.
- NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion (Need) #1
  The purpose of this section is to demonstrate the severity of the HIV/AIDS epidemic in the
  State/Territory and the need for additional resources to meet the projected ADAP client
  service needs for FY 2016.

### A. State/Territory's HIV/AIDS Epidemiologic Data and ADAP Profile

### 1. HIV/AIDS Epidemiologic Data from the most recent RWHAP Part B Base (HRSA-16-079) application

<u>Applicants are not required to submit this information in this application.</u> The HIV/AIDS epidemiologic data from the most recent RWHAP Part B Base (HRSA-16-079) application will be provided to the ORC. In that application, State/Territories were asked to summarize in a table format the HIV (non-AIDS) and AIDS cases by age, race/ethnicity, and exposure category through December 31, 2013; and, based on the most recent State/Territory HIV/AIDS Epidemiologic Profile, provide 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.

### 2. ADAP State/Territory Profile

All applicants must provide the following information to help reviewers understand eligibility for this award and the structure, functions, and operational processes of the State/Territory's ADAP and the clients that it serves. The ORC will review the ADAP State/Territory Profile for completeness. It will also be used as a reference point by the ORC in reviewing related information provided by applicants in their narrative responses to Criteria 2-6.

### a. Eligibility for ADAP ERF Funding

- i. Did your State/Territory report to HRSA an ADAP waiting list between January 2011 and August 2015? (Yes/No)
  - 1) If "Yes", does your State have an existing ADAP waiting list? (Yes/No)
  - 2) If "Yes", how many clients are currently on the waiting list?
- ii. Did your State/Territory use ADAP ERF funds to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and August 2015? (Yes/No)

# States/Territories that did not report to HRSA an existing ADAP waiting list or use the ADAP ERF funds to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and August 2015 are <u>not eligible</u> to apply for Limited New Competition ADAP ERF Awards.

### b. ADAP Funding Summary for FY 2014 and FY 2015

In a table format, please list <u>all</u> sources of funding for ADAP and the amounts received and expended for each of the years listed:

- i. ADAP Base
- ii. ADAP Supplemental
- iii. RWHAP Part B Base Contribution to ADAP
- iv. RWHAP Part B Supplemental Contribution to ADAP
- v. ADAP ERF Award
- vi. RWHAP Part A Contribution to ADAP
- vii. State Funds
- viii. Drug Rebates
- ix. Carryover
- x. Program Income
- xi. Other Sources (Describe)
- xii. Total of ADAP Funding (for FY 2014 and FY 2015)

### c. Cost-Cutting Measures for FY 2014 and FY 2015

Please identify which of the following cost-cutting measures were in place or newly implemented in FY 2014 and FY 2015:

- i. Enrollment cap (if so, specify the maximum number of enrollees)
- i. Capped number of prescriptions per month (if so, specify the cap)
- ii. Capped expenditure (if so, the amount and timeframe)
- iii. Drug-specific enrollment caps for ARVs (if so, specify)

- iv. Reduction in Formulary (if so, specify)
- v. Decrease in financial eligibility criteria (if so, specify)
- vi. Other (please specify)

### d. Cost-Saving Measures for FY 2014 and FY 2015

Please identify which of the following cost-saving measures were in place or newly implemented in FY 2014 and FY 2015:

- i. Expansion of health insurance assistance (if so, what services are currently offered)
- ii. Enrolling eligible clients in health insurance through the State or federally funded insurance marketplace (if so, how many were enrolled)
- iii. Improved client recertification processes (if so, what was improved)
- iv. Other (if so, specify)

### e. <u>Client Utilization Summary for FY 2014 and FY 2015</u>

- i. Total number of clients enrolled in ADAP for each fiscal year.
- ii. Average number of clients using ADAP each month for each fiscal year.

### f. Affordable Care Act (ACA) Summary

- i. Number of ADAP clients that have transitioned to a Qualified Health Plan (QHP) since January 1, 2014
  - 1) Of these, how many were transitioned off ADAP completely (i.e., no longer receiving any ADAP services)?
  - 2) How many of these are receiving continued services from ADAP, such as wrap-around coverage (i.e., premium, co-payment, co-insurance, or deductible payment) or payment for medication not covered by the OHP?
- ii. Number of ADAP clients that have transitioned to Medicaid since January 1,
  - 2014, if applicable
    - 1) Of these, how many were transitioned off ADAP entirely (i.e., no longer receiving any ADAP services)?
    - 2) How many of these are receiving continued services from ADAP, such as wrap-around coverage (i.e., premium, co-payment, co-insurance, or deductible payment) or payment for medication not covered by Medicaid?

### **B.** Factors Affecting State ADAP Capacity to Meet Need

Applicants must provide a detailed narrative description of at least three of the factors impacting the State/Territory ADAP's need for additional resources to prevent, reduce, or eliminate a waiting list and why the ADAP is unable to meet the need with existing resources. This discussion should be supported by data sources as appropriate when discussing trends and changes (including environmental changes) that have resulted in this need. Examples of factors may include, but are not limited to:

- Trends or changes in the HIV disease prevalence over the past two years (January 1, 2013 to December 31, 2014) that have affected the ADAP, as documented in the State/Territory's HIV/AIDS epidemiologic data and ADAP profile.
- Changes to your State/Territory's service delivery system as a result of the implementation of the Affordable Care Act (ACA), including:
  - the State Medicaid Program;
  - Insurance Marketplace
- Continuing trend in high unemployment rate as compared with previous two years

- Increase in the percentage of ADAP-eligible clients below 100 percent of the FPL as compared with the previous two years
- Increase in the number of HIV positive, newly-aware individuals seeking treatment in 2015 as compared with the previous two years
- Increase in the number of out-of-care HIV positive clients now seeking treatment in 2015 as compared with the previous two years
- Increased cost of ADAP medications
- Increased cost to ADAP for insurance premiums, deductibles, and/or cost-sharing
- Decreased or level State funding for ADAP
- Decreased or level State funding for other HIV/AIDS services
- Decreased or level Federal funding for ADAP
- *METHODOLOGY* -- *Corresponds to Section V's Review Criterion (Response) #2*

### A. ADAP Average Annual Client Costs and Forecasting

All applicants must provide a calculation of their projected average medication cost per client and projected average insurance assistance cost per client for the FY 2016 Competitive ADAP ERF budget period (April 1, 2016-March 31, 2017). These calculations:

- Must be based on client utilization and ADAP cost data for the period January 1, 2015-June 30, 2015; and,
- Must use the instructions/structure provided in Appendix A.

The applicant <u>must use</u> the average cost calculations from Appendix A in developing the proposed budget for the use of the ADAP ERF funds and/or to project the impact of proposed cost-containment measures.

Important Note: The external ORC reviewers will review and determine:

- Whether the average client cost calculations submitted by applicants follow the instructions provided;
- Whether the calculations are correct and reflected in the applicant's plan and budget request; if incorrect, the error will be identified along with its impact on the applicant's average client cost calculations;
- If applicable, whether or not the applicant based budget request on the number of individuals on the State's waiting list.

### 1. ADAP Average Annual Client Costs

### a. Medication Costs

- Please provide:
  - i. Calculations for, and
  - ii. Resulting annual projected average medication cost per client for the FY 2016 ADAP ERF budget period.

### b. <u>Insurance Assistance Costs</u>

- Please provide:
  - i. Calculations for, and
  - ii. Resulting annual projected average insurance assistance cost per client for the FY 2016 ADAP ERF budget period.

### 2. Forecasting

- a. <u>States/Territories Requesting Funds to Purchase Medications or Insurance</u> Assistance to Prevent, Reduce, or Eliminate Waiting Lists:
  - i. What is the current number of ADAP-eligible individuals on your waiting list?
  - Describe the projected impact of ADAP ERF, together with FY 2016 RWHAP Part B funds, funding provided by the State, rebate income, FY 2016 RWHAP Part A contributions and any other projected resources, in addressing:
    - 1) The applicant's projected/potential ADAP waiting list and/or
    - 2) The existing waiting list
- b. <u>States/Territories Requesting Funds for other Cost-Cutting or Cost-Saving</u> <u>Measures to Prevent, Reduce, or Eliminate Waiting Lists:</u>
  - i. Projected impact of Proposed Cost-Cutting or Cost-Saving Measures: for each proposed measure indicated in the work plan, describe the specific projected impact of ADAP ERF on enhancing cost-saving measures, reversing cost-cutting measures, improving ADAP operations, and/or maximizing available ADAP resources.
- WORK PLAN -- Corresponds to Section V's Review Criteria (Response and Impact) #2 and #4

Describe the activities or steps that will be used to achieve each of the activities proposed during the entire project period. This should be presented in the form of a work plan (a table format is suggested) and a narrative.

### A. Planned Services and Work Plan

List each planned ADAP ERF service (e.g., purchase of ADAP medications, purchase of insurance premiums, payment of medication co-payments, deductibles, or co-insurance, etc.) and/or cost-containment measure (i.e., cost-cutting or cost-saving measures) designed to improve ADAP operations and maximize available ADAP resources. The work plan should complement the implementation plan submitted with the most current RWHAP Part B Base/ADAP (X07) application. Applicants are encouraged to use a table format with the following sections:

- **Planned Expenditure Summary** listing the amount budgeted by Service Category, Cost-Containment Measures/Initiatives, and Recipient Administrative costs;
- Planned Expenditures by Service Category with columns for Planned Service, Service Unit Description, # of Service Units, # of Clients and amount budgeted for each service; and
- **Planned Expenditure by Cost-Containment Measures/Initiatives** listing each planned cost-containment initiative with the date initiated and the amount budgeted for each initiative.

Include the work plan as Attachment 1. A sample work plan format may be found at the following link: <u>https://careacttarget.org/library/workplan-template-adap-emergency-relief-funds</u>.

### **B.** Planned Services and Work Plan Narrative

Provide a narrative that describes the following for each activity in the work plan:

- 1. How the recipient will assure that funds allocated for each service/activity will be spent within the twelve month budget period.
- 2. For applicants with an existing ADAP waiting list, how the services/activities will reduce the number of persons on the waiting list.
- 3. For applicants without an existing waiting list:
  - a. How the services/activities will improve ADAP operations and maximize ADAP resources; and
  - b. How the services/activities will prevent the implementation of an ADAP waiting list in FY 2016.

### C. Anticipated Impact of ADAP ERF

Provide a brief description of the anticipated impact of the proposed ADAP ERF-funded activities on currently implemented or anticipated cost-containment measures as it relates to waiting list prevention, reduction, or elimination.

- 1. Describe how the recipient will monitor progress toward meeting the goals and objectives of the proposed project.
- 2. Describe how these activities will support the continued function of the ADAP.
- 3. Describe how the anticipated outcomes will support full and sustained ADAP service provision beyond the funding period.

### **D.** Monitoring

Provide a brief description of the methods in place to monitor and assess the effectiveness of the waiting list prevention, reduction, or elimination activities, including cost-containment measures, proposed on the ADAP ERF work plan. Provide a description of the anticipated outcomes, resulting from ADAP ERF supported activities. The narrative should include a description of how the ADAP will measure and monitor progress on outcomes and how the ADAP will address problems identified through monitoring.

**Important Note:** It is expected that ADAP will utilize the Quality Management Protocols described in the RWHAP Part B FOA (HRSA-16-079) application when implementing services funded through the ADAP ERF award.

 RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion (Response) #2

### A. Affordable Care Act

This section provides an opportunity for States/Territories to describe the impact of ACA implementation on the ADAP, as well as strategies employed to overcome challenges.

- 1. What challenges has the implementation of ACA presented the ADAP in creating fiscal projections for FY 2016 and how does the program propose to overcome those challenges?
- 2. What challenges has ACA implementation presented in determining ADAP need and how does the program propose to overcome those challenges?
- 3. What challenges in ACA implementation are related to the linkage and retention of ADAP clients and how does the program propose to overcome those challenges?

### **B.** State/Territory Actions to Address ADAP Challenges

This section provides an opportunity for States/Territories to describe specific challenges and actions necessary to prevent, reduce, or eliminate an ADAP waiting list in FY 2016. Please describe for each of the following sections how the program has employed cost-cutting and/or cost-saving strategies to prevent ADAP waiting list(s) in FY 2014 and FY 2015. Each section must be supported by data showing how these strategies benefit the ADAP.

1. Improved Program Efficiencies: Please describe how your program has addressed challenges by improving operations

in order to reduce costs and improve efficiency.

Examples include, but are not limited to, a reduction of administrative costs, a renegotiated reduction in dispensing fees, the establishment of a Pharmacy Benefits Manager (PBM) to manage costs, or improved billing systems to ensure that Medicaid is fully back billed for eligible client costs. Be sure to support your description with data showing how the improved operational efficiencies will benefit the ADAP. For example, the amount of funds the program expects to save over the next year based on a reduction in dispensing fees or expected dollar amount to be collected by back billing Medicaid for eligible clients.

 Improved Ability to Enroll Clients in Other Payer Sources: Please describe how your program has addressed challenges by improving systems to increase enrollment in other forms of insurance including Medicare Part D, Medicaid, private insurance options and other options available through the Marketplace.

Examples include but are not limited to: a newly executed data sharing agreement with the Centers for Medicare and Medicaid Services (CMS) to ensure ADAP contributions count toward TrOOP expenses, increased monitoring to ensure all ADAP clients are assessed for insurance eligibility every six months, and/or outreach plans to ensure enrollment in new insurance options afforded through the ACA. Be sure to support your description with data showing how improved enrollment capacity will benefit the ADAP. For example, the cost savings expected by ensuring ADAP contributions count toward Medicare Part D TrOOP expenses as a result of a negotiated data sharing agreement with CMS, or the number of clients expected to roll off of the ADAP as a result of efforts to enroll clients in health insurance through a State or federally run health insurance marketplace.

3. Reallocation of Resources:

Please describe if/how funds have been reallocated to address ADAP challenges. Be sure to indicate if this reallocation represents a one-time augmentation to the program or an expected long-term, sustainable reallocation of funds.

Examples include but are not limited to: a reallocation of RWHAP Part B funding to ADAP, an increased contribution in State funds, and/or an increased contribution by a RWHAP Part A recipient to include funding for ADAP services. Be sure to support your description with data showing how these funds will be utilized to improve the ADAP's ability to prevent, reduce, or eliminate a waiting list.

4. Increased Rebates and Discounts:

Please describe how your ADAP has modified its processes or the monitoring of those processes to ensure that drugs are purchased at the best possible cost and/or that rebates and/or program income are fully collected and applied back to the RWHAP Part B Program, with priority given to ADAP.

Examples include but are not limited to: a renegotiated increase in the up-front discount from participating pharmacies, collection of rebates for insurance assistance, or enrollment in the 340B Prime Vendor Program to ensure the best possible up-front discount. Be sure to support your description with data showing the cost benefit to the ADAP. For example: the amount of money the ADAP expects to save per client as a result of a renegotiated purchasing rate or the amount of money the ADAP expects to collect as a result of increased rebate collection.

• ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criteria (Resources/Capabilities and Support Requested) #5 and #6

### A. ADAP Oversight/Administration

Provide a brief narrative that describes the organizational structure and resources that contribute to the administration of the ADAP to maintain compliance with legislative requirements and program expectations, including those of ADAP ERF funding. Include an organizational chart for the ADAP as Attachment 5.

If ADAP ERF funds are being used to support ADAP personnel, please include position descriptions (as Attachment 2) and biographical sketches (as Attachment 3) for these staff.

If ADAP ERF funds will not be used for staffing costs, please indicate that here for ORC review purposes. In this case, do not include position descriptions or biographic sketches, but rather upload a document that indicates "Not Applicable" as **Attachment 2** and **Attachment 3**.

### **B.** Compliance with Reporting Requirements

Describe how the State/Territory will be able to meet reporting requirements by tracking and reporting ADAP ERF specific expenditures and client utilization.

### NARRATIVE GUIDANCE

In order to ensure that the Review Criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria.

Narrative Section	Review Criteria	
Introduction	(1) Need	
Needs Assessment	(1) Need	
Methodology	(2) Response	
Work Plan	(2) Response & (3) Impact	
Resolution of Challenges	(2) Response	
Organizational Information	(4) Resources/Capabilities & (5) Support Requested	
Budget and Budget Narrative	(5) Support Requested	

### 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 RWHAP Part B ADAP ERF requires 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, and then provide a line item budget using Section B Object Class Categories of the SF-424A. In Section B, budget categories are limited to two columns. The required columns are:

**Medications/Insurance:** The first column should include all FY 2016 ADAP ERF grant funds allocated to prevent, reduce, and/or eliminate the applicant's waiting list through the purchase of medication and/or insurance assistance. It may NOT include any funds for planning and evaluation or clinical quality management as defined by the RWHAP Part B program. These funds may not be used to supplant funds budgeted for any other Federal grant or State program.

**Other Cost Containment:** The second column should include all funds allocated to grant activities to address any other "cost-cutting" and/or "cost-saving" measures to be charged to the FY 2016 ADAP ERF award. It may NOT include any funds for planning and evaluation or clinical quality management as defined by the RWHAP Part B program. These funds may not be used to supplant funds budgeted for any other Federal grant or State program.

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</u> <u>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 SF-424 Application Guide.

### v. Attachments

Please provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Each attachment must be clearly labeled**.

### Attachment 1: Work Plan (Required)

Attach the work plan for the project that includes all information detailed in Section IV. ii. Project Narrative.

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

If ADAP ERF funds are being used to support ADAP personnel, please include position descriptions here for these staff. Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff.

If the ADAP will not be utilizing ADAP ERF for staffing costs, attach a document that indicates "Not Applicable".

Attachment 3: Biographical Sketches of Key Personnel (Required, if relevant) If ADAP ERF funds are being used to support ADAP personnel, include biographical sketches for persons occupying the 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.

If the ADAP will not be utilizing ADAP ERF for staffing costs, attach a document that indicates "Not Applicable".

Attachment 4: Agreement and Compliance Assurances (Required) Please complete and include Appendix B, Agreements and Compliance Assurances.

Attachment 5: ADAP Organizational Chart (Required) Provide a one-page figure that depicts the organizational structure of the ADAP.

Attachments 6 – 15: Other Relevant Documents (Not required)

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.).

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

For further details, see Section 3.1 of HRSA's SF-424 Application Guide.

Applicants that fail to allow ample time to complete registration with SAM or Grants.gov will not be eligible for a deadline extension or waiver of the electronic submission requirement.

### 4. Submission Dates and Times

### **Application Due Date**

The due date for applications under this FOA is December 15, 2015 at 11:59 P.M. Eastern Time.

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

### 5. Intergovernmental Review

ADAP ERF applicants are not subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100. See Executive Order 12372 in the <u>HHS Grants Policy Statement</u>.

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 no more than \$11,000,000 for a project period of up to one (1) year.

In addition to the general Funding Restrictions included in section 4.1.iv of the <u>SF-424</u> <u>Application Guide</u>, funds under this announcement may not be used for the following purposes:

- Planning and evaluation activities as defined by the Ryan White HIV/AIDS Part B Program;
- Clinical Quality Management;
- International Travel;
- Construction; however, minor alterations and renovations to an existing facility to make to more suitable for the purposes of the award program are allowable with prior HRSA approval;
- HIV test kits;
- Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis—Ryan White HIV/AIDS Program funds cannot pay for PrEP or Post-Exposure Prophylaxis as the person using PrEP or Post-Exposure Prophylaxis is not HIV infected and therefore not eligible for Ryan White HIV/AIDS Program funded medication.

These funds may not be used to supplant funds for any other Federal grant or State funds. This emergency relief funding is intended to supplement, not supplant, State/Territory funding for ADAP activities during the project period.

For further information regarding allowable and non-allowable costs, please refer to <u>http://hab.hrsa.gov/manageyourgrant/policiesletters.html</u> and at <u>45 CFR 75</u> Subpart E Cost Principles.

The General Provisions in Division G of the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) apply to this program. Please see Section 4.1 of HRSA's <u>SF-424 Application Guide</u> for additional information. Note that these or other restrictions will apply in FY 2016, as required by law.

All program income generated as a result of awarded funds must be used for approved projectrelated activities. The statutorily permitted purpose of RWHAP ADAP ERF program income include only the provision of medications and/or cost containment strategies that prevent, reduce or eliminate an ADAP waiting list in the State.

### V. Application Review Information

### 1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant in presenting pertinent information related to that criterion and to

provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

These criteria are the basis upon which the reviewers will evaluate the application. The entire proposal will be considered during objective review.

Review criteria are used to review and rank applications. The *Ryan White HIV/AIDS Program Part B ADAP ERF program* has *five (5)* review criteria:

### Criterion 1: NEED (25 points) – Corresponds to Section IV's Introduction and Needs Assessment

This section corresponds to the Introduction and Needs Assessment Sections of the Project Narrative. Scoring will be based on how well the application narrative describes the problem and associated contributing factors to the problem as well as steps to be taken to prevent, reduce, or eliminate a waiting list including through reversing cost-cutting measures and/or enhancing cost-saving measures.

### Introduction (5 points)

• The extent to which the applicant describes how the State/Territory will utilize Ryan White HIV/AIDS Program ADAP ERF funds in support of preventing, reducing, or eliminating a waiting list including through cost-cutting or cost-saving measures during the project period.

### State/Territory's HIV/AIDS Epidemiological Data and ADAP Profile (10 points)

• The extent to which the applicant provided complete information regarding the State/Territory ADAP Profile for Fiscal Years 2014 and 2015.

### Factors Affecting the State ADAP Capacity to Meet Need (10 points)

- The comprehensiveness of the provided factors impacting the State/Territory ADAP's need for additional resources to prevent, reduce, or eliminate a waiting list and why the ADAP is unable to meet the need with existing resources.
- The strength of examples and data provided to support the narrative description.

### *Criterion 2: RESPONSE (40 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges*

This section corresponds to the Methodology, Work Plan, and Resolution of Challenges sections of the Project Narrative. Scoring will be based on the extent to which the proposed project responds to the "Purpose" included in the program description and the extent to which the activities described in the application are capable of addressing the problem and attaining the project objectives of avoiding, reducing, or eliminating a waiting list.

### ADAP Average Annual Client Costs and Forecasting (10 points)

The accuracy of the calculations and reasonableness of annual client costs and forecasting submitted by applicant; if incorrect, the error will be identified by the ORC along with its impact on the applicant's average client cost calculations and budget request.

### Work Plan and Work Plan Narrative (15 points)

The strength and feasibility of the following:

• The proposed services, cost containment measure/initiative, and projected expenditures

detailed in the work plan to address the problem and align with the project objectives of preventing, reducing, or eliminating a waiting list.

- Evidence that funds allocated for each service/activity will be spent within the twelvemonth budget period.
- For applicants with an ADAP waiting list, proposed services/activities to reduce the number of persons on the waiting list.
- For applicants without a waiting list:
  - Proposed services/activities to improve ADAP operations and maximize ADAP resources; and
  - Proposed services/activities to prevent the implementation of a waiting list in FY 2016.

State/Territory Actions to Address ADAP Challenges (15 points)

• <u>ACA-related Challenges:</u>

The extent to which proposed activities demonstrate a thorough understanding of the impact of ACA implementation on the ADAP program, as well as strategies employed to overcome challenges, including:

- The challenges the implementation of ACA presented the ADAP in creating fiscal projections for FY 2016 and the strength and feasibility of how the proposed activities overcome those challenges.
- The challenges ACA implementation presented in determining ADAP need and whether the ADAP is structured to most effectively meet those challenges.
- The challenges in ACA implementation related to the linkage and retention of ADAP clients, and how the program proposes to overcome those challenges.
- Other Challenges

The extent to which the applicant demonstrates a thorough understanding of specific challenges and actions necessary to prevent, reduce, or eliminate an ADAP waiting list in FY 2016, and used data to support the description. This section will be scored on how well the applicant described challenges using both narrative and data in the following areas:

- Improved Program Efficiencies: How the program has addressed challenges by improving operations in order to reduce costs and improve efficiency.
- Improved Ability to Enroll Clients in Other Payer Sources: How the program has addressed challenges by improving systems to increase enrollment in other forms of insurance, including Medicare Part D, Medicaid, private insurance options and other options available through the Marketplace.
- Reallocation of Resources: How funds have been reallocated to address the ADAP crisis, and an indication of whether this reallocation represents a one-time augmentation to the program or an expected long-term, sustainable reallocation of funds.
- Increased Rebates and Discounts: How the ADAP has modified its processes or the monitoring of those processes to ensure that drugs are purchased at the best possible cost and/or that rebates and/or program income are fully collected and applied back to the RWHAP Part B program, with priority given to ADAP.

### Criterion 3: IMPACT (5 points) – Corresponds to Section IV's Work Plan

This section will be scored on the strength and feasibility of the following:

• The stated capacity of the State/Territory to meet reporting requirements by tracking and reporting ADAP ERF specific expenditures and client utilization; and,

• How proposed improved operations will enable the ADAP to sustain the program beyond the FY 2016 ADAP ERF budget period.

*Criterion 4: RESOURCES/CAPABILITIES (15 points) – Corresponds to Section IV's Organizational Information and the Staffing Plan and Biographical Sketches, if applicable* This section corresponds to the Organizational Information section of the Project Narrative, and the Staffing Plan and Biographical Sketches (if applicable) and will be scored on the extent to which the project narrative describes the applicant's ability to implement the ADAP ERF. This includes:

- A description of the organizational structure and resources that contribute to the administration of the ADAP to maintain compliance with legislative requirements and program expectations, including those of ADAP ERF funding.
- A review of the organizational chart for the ADAP in Attachment 5.
- Position descriptions (in Attachment 2) and biographical sketches (in Attachment 3) for key ADAP staff, if ADAP ERF funds are being used to support staffing.

### *Criterion 5: SUPPORT REQUESTED (15 points) – Corresponds to Section IV's Budget and Budget Narrative, and Organizational Information*

This section corresponds to the budget section/documents, staffing plan, and Organizational Information Section of the Project Narrative and will be scored on the following:

- The reasonableness of the proposed budget for the project period (1 year) in relation to the objectives and the anticipated results.
- The extent to which costs, as outlined in the budget and required resources sections, are reasonable and allocable to the scope of work.
- If applicable, the extent to which the applicant accurately based its budget request on the number of individuals on the State ADAP waiting list.

### 2. Review and Selection Process

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

This program does not have any preferences or special considerations. This program does provide a priority for applications intended to address existing ADAP waiting lists.

### 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 *SF-424 Application Guide* for additional information.

### 2. Administrative and National Policy Requirements

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

### 3. Reporting

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

### A) **Progress Report**(s)

The recipient must submit a mid-year and final progress report to HRSA. The report will collect information on progress toward strategies of meeting the goals of the project, accomplishments, and any barriers encountered and how they were addressed. Further information will be provided in the Notice of Award (NoA).

### B) Other required reports and/or products

- ADAP Data Report (ADR). Acceptance of this award indicates that the recipient assures that it will comply with data requirements of the ADAP Data Report (ADR) and that it will mandate compliance by each of its contractors and subcontractors. The ADR captures information necessary to demonstrate program performance and accountability. Please refer to the ADR webpage at <a href="http://hab.hrsa.gov/manageyourgrant/adr.html">http://hab.hrsa.gov/manageyourgrant/adr.html</a> for additional information. Further information will be provided in the NoA.
- **Consolidated List of Contractors (CLC).** The recipient must submit a Consolidated List of Contractors (CLC) for all providers receiving ADAP ERF funding/contracts. The CLC must be submitted through the HRSA Electronic Handbook (EHB) using the format provided in that system.

### **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 HRSA Division of Grants Management Operations, OFAM Parklawn Building, Room 18-75 5600 Fishers Lane Rockville, MD 20857 Telephone: (301) 443-3555 Fax: (301) 594-4073 E-mail: <u>KMayo@hrsa.gov</u>

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 Health Resources and Services Administration Director, Division of State HIV/AIDS Programs HIV/AIDS Bureau, HRSA Parklawn Building, Mail Stop 09SWH03 5600 Fishers Lane Rockville, MD 20857 Telephone: (301) 443-6745 Fax: (301) 443-3143 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, seven days a week, excluding federal holidays at:

Grants.gov Contact Center Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035) E-mail: <u>support@grants.gov</u> iPortal: <u>https://grants-portal.psc.gov/Welcome.aspx?pt=Grants</u>

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET:

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

### VIII. Other Information

### **Technical Assistance:**

A Funding Opportunity Announcement (FOA) webinar will be held on Wednesday, November 4, 2015, at 3 PM EST. To join the web portion, please use the following link: <u>https://hrsa.connectsolutions.com/adap\_erf\_x09\_foa/</u>. To join the audio portion, dial: 1-800-779-5318; Passcode: 5516246.

### HIV/AIDS PERFORMANCE MEASURES

The HRSA HAB has developed HIV/AIDS Performance Measures for Adults and Adolescents and a companion guide to assist grantees in the use and implementation of the core clinical performance measures. Information on Performance Measures may be found at: <a href="http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html">http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html</a>.

### NATIONAL MONITORING STANDARDS

As a Condition of Award, recipients are required to utilize the National Monitoring Standards at both the recipient and contractor levels. To help our recipients meet this requirement, HRSA has developed guidelines outlining the responsibilities of HRSA, the recipient, and provider staff. The National Monitoring Standards can be found at:

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

### IX. Tips for Writing a Strong Application

See Section 4.7 of HRSA's <u>SF-424 Application Guide</u>.

### **X. APPENDICES**

### **Appendix A: Instructions for Calculating Average Client Costs**

### **Average Client Cost Calculations**

The purpose of this appendix is to provide instructions for calculating, assessing, and projecting costs to address a new or existing waiting list or to keep clients off of an ADAP waiting list through cost containment measures in FY 2016. These calculations are required for the development of the work plan and narrative for the budget and budget narrative.

All applicants must provide a calculation of their projected average medication cost per client and projected average insurance assistance cost per client for the FY 2016 ADAP ERF budget period (April 1, 2016 – March 31, 2017). Due to the timing of this FOA, these calculations must be based on client utilization and ADAP cost data for the January 1, 2015 to June 30, 2015 period, following the instructions provided. The calculations must incorporate all clients who received at least one medication through ADAP during the January 1, 2015 to June 30, 2015 period, including clients who were enrolled in ADAP temporarily or part of the year (e.g., because they experienced changes in their insurance coverage, moved out of state, or died). **States/Territories must provide the step by step calculations and clearly identify all data elements required to complete the calculations, not just the resulting average client cost.** In addition, applicants must use the results of their respective average client cost calculations in developing their budget request and narrative for the use of the ADAP ERF funds. All cost calculations provided by applicants are subject to verification by the ORC.

### I. Average Cost per Client to Provide Medications

Step 1: Baseline Average Annual Client Medication Cost:

Determine the total amount spent to purchase prescription medications (<u>not</u> health insurance) in the January 1, 2015 to June 30, 2015 period. Divide this amount by the total number of ADAP clients who received at least one (1) prescription medication in the same periods. Multiply that amount by two to determine the ADAP's baseline average annual medication cost per client.

### Step 2: Average Annual Client Rebate Reduction:

Determine the total amount of rebate income received by the State/Territory.

- For applicants operating a 340B Rebate State, ADAP, this includes all 340B rebates and other negotiated rebates (e.g., ADAP Crisis Task Force rebates) received by the State in the January 1, 2015 to June 30, 2015 period.
- For applicants operating a 340B State Direct Purchase ADAP, this includes all negotiated rebates (e.g., ADAP Crisis Task Force rebates) received by the State in the January 1, 2015 to June 30, 2015 period.

Divide the total amount of rebate income by the total number of ADAP clients that received at least one prescription medication in the January 1, 2015 to June 30, 2015 period. Multiply that amount by two to determine the average rebate reduction per client.

**Note:** the impact of rebates for insurance deductibles and co-payments is addressed in the insurance section below.

### Step 3: <u>Adjusted Average Client Medication Cost:</u>

Subtract the Average Annual Client Rebate Reduction amount determined in Step 2 from the Baseline Average Annual Client Medication Cost determined in Step 1.

### Step 4: <u>Average Annual Client Dispensing Fee:</u>

Determine the total number of prescriptions filled in the January 1, 2015 to June 30, 2015. Multiply that number by the dispensing fee for a single pharmacy prescription in the January 1, 2015 to June 30, 2015 period. Divide the resulting product by the total number of ADAP clients that received at least one prescription in the same period. Multiply that amount by two for the average annual dispensing fee cost per client.

### Step 5: <u>Average Annual Medication Cost per Client:</u>

Add the Average Annual Client Dispensing Fee cost determined in Step 4 to the Adjusted Average Annual Medication Cost calculated in Step 3. The sum of these two amounts will be your State's Average Annual Medication Cost per Client.

### Example:

~			
Step 1	In the January 1, 2015 to June	\$7,410,000/1,000 = <b>\$7,410</b>	Baseline Average Six Month
	30, 2015 period, the ADAP		Client Medication Cost
	spent a total of \$7,410,000 for		
	prescription drugs; a total of		Baseline Average Annual
	1,000 clients received at least	\$7,410 x 2 = <b>\$14,820</b>	Client Medication Cost
	one prescription medication.		
Step 2	In that same period, the ADAP	\$555,000 + \$100,000 =	Total Rebates Received by the
•	received \$555,000 in total 340B	\$655,000	State
	rebates and \$100,000 in		
	negotiated rebates.		Average Six Month Client
	8	\$655,000/1,000 clients = <b>\$655</b>	Rebate Reduction
			Average Annual Client
		\$655 x 2 = <b>\$1,310</b>	Rebate Reduction
Step 3	Adjusted Average Annual Cost	\$14,820 - \$1,310 = <b>\$13,510</b>	
Step 5	per Client: Baseline Average	$\varphi_1, \varphi_2, \varphi_1, \varphi_1, \varphi_1, \varphi_1, \varphi_1, \varphi_1, \varphi_1, \varphi_1$	
	Annual Client Medication cost		
	minus Average Annual Client		
	Rebate Reduction		
Step 4	The ADAP filled 10,000	\$10 x 10,000 = <b>\$100,000</b>	Total Dispensing Fee
Step 4	prescriptions in the January 1,	\$10 x 10,000 - <b>\$100,000</b>	Expenditures
	2015 to June 30, 2015 period of		Expenditules
	-	\$100,000/1,000 alignets \$100	Awara as Six Month Client
	CY 2015 and the dispensing fee	\$100,000/1,000 clients = <b>\$100</b>	Average Six Month Client
	per prescription was \$10; 1,000		Dispensing Fee
	ADAP clients received at least		
	1 ADAP prescription.	100 x 2 = 200	Average Annual Client
			Dispensing Fee
Step 5	Add amount calculated in Step	\$13,510 + \$200 = <b>\$13,710</b>	Average Annual Medication
	3 to amount calculated in Step		Cost per Client
	4.		

### Note: For States/Territories with Hybrid/Dual ADAPs:

- Step 1: Determine the number and percentage of clients who received medications through the 340B Rebate model and the number and percentage who received medications through the 340B Direct Purchase model.
- *Step 2:* For each cohort of clients, determine the total amount spent to provide medications for that cohort.
- Step 3: Determine the average client costs for the rebate cohort, follow the instructions above in Steps 2 through 5. For the direct purchase cohort, follow the instructions above in Steps 2 through 5.

### II. Average Cost per Client to Provide Insurance Assistance

All ADAPs providing access to prescription medications through insurance assistance must provide step by step calculations of average costs per client, making sure all required data elements for each calculation are clearly identified.

#### **Step 1: Total Insurance Expenditures:**

Add the total amount spent on insurance premiums, deductibles, co-payments/coinsurance in the January 1, 2015 to June 30, 2015 period. This includes amounts spent for ADAP eligible clients who are also eligible for Medicare Part D, including payments for Part D premiums, deductibles, co-payments, and TrOOP.

#### **Step 2: Rebate Reduction:**

Determine the total amount of manufacturer's rebates received in the January 1, 2015 to June 30, 2015 period on insurance deductibles, co-payments/co-insurance, and Medicare Part D TrOOP expenditures.

#### **Step 3: Adjusted Six Month Total Insurance Cost:**

Subtract the total amount of manufacturers' rebates received from the Total Insurance Expenditures calculated in Step 1. This is the applicant's Adjusted Six Month Total Insurance Cost.

## Step 4: Average Annual Cost per Client for Insurance Assistance (including COBRA, High Risk Health Insurance Pools, private insurance, State-sponsored insurance, PCIP, and Medicare Part D):

Divide results from Step 3 by the total number of clients on whose behalf the ADAP paid at least one premium, co-payment/co-insurance, deductible, or TrOOP payment in the January 1, 2015 to June 30, 2015 period. Multiply by two for average annual cost per client for insurance assistance.

### Example:

The AD	The ADAP spent \$1,500,000 in the January 1, 2015 to June 30, 2015 period to pay for insurance premiums						
plus \$300,000 on co-payments/co-insurance, deductibles, and TrOOP, providing assistance to 300 ADAP							
eligible	eligible clients.						
Step 1	Add insurance premiums expenditures to	\$1,500,000 + \$300,000 = <b>\$1,800,000</b>	Total Six Month Insurance Expenditures				
	expenditures for co-		-				
	payments/co-insurance,						
	deductibles, and TrOOP.						
Step 2	Determine the total amount	\$50,000	Total Six Month Rebates				
	of rebates received by		Received				
	adding the manufacturers						
	rebates received each						
	quarter on insurance co-						
	payments/co-						
	insurance/deductibles.						
Step 3	Total Six Month Insurance	\$1,800,000 - \$50,000 = <b>\$1,750,000</b>	Adjusted Total Insurance				
	Expenditures minus Total		Cost				
	Six Month Rebates						
	Received						
Step 4	Divide Adjusted Total	\$1,750,000/300 = <b>\$5,833</b>	Average Six Month Cost				
	Insurance Cost by total		per Client for Insurance				
	clients served. Multiply the		Assistance				
	Average Six Month Cost						
	per Client by two to	\$5,833 x 2 = <b>\$11,666</b>	Average Annual Cost Per				
	calculate the Average		Client for Insurance				
	Annual Cost per Client.		Assistance				

### **Appendix B: Agreements and Compliance Assurances**

### FY 2016 Ryan White HIV/AIDS Program ADAP Emergency Relief Awards **Agreements and Compliance Assurances**

I, the Governor of the State or Territory or her/his official designee for the Ryan White \_\_\_\_\_, pursuant to Title XXVI of HIV/AIDS Part B Program Grant, the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, hereby certify that:

- A. Pursuant to Sections 2016 and 311 of the PHS Act, these funds will be used specifically for the provision of medications and/or cost containment strategies that prevent, reduce, or eliminate an ADAP waiting list in the State.
- B. These funds and services will be allocated and administered in accordance with the FY 2016 Part B Ryan White HIV/AIDS Program Agreements and Compliance Assurances submitted to the Health Resources and Services Administration.

SIGNED:

Governor or Official Designee Title:

Date: