#### U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



#### HIV/AIDS Bureau Division of State HIV/AIDS Programs

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

Funding Opportunity Number: HRSA-19-028
Funding Opportunity Type: New—Limited Competition
Catalog of Federal Domestic Assistance (CFDA) Number: 93.917

#### NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2019

Application Due Date: October 25, 2018

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

HRSA will not approve deadline extensions for lack of registration.

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

may take up to 1 month to complete.

Issuance Date: June 25, 2018

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Authority: Public Health Service Act, Sections 311(c) and 2616 (42 U.S.C. 243(c) and 300ff-26), 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) is accepting applications for fiscal year (FY) 2019 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. 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-19-028
Due Date for Applications:	October 25, 2018
Anticipated Total Available	\$65,000,000
FY 2019 Funding:	
Estimated Number and Type of Award(s):	Up to 15 grants
Estimated Award Amount:	Up to \$11,000,000 dependent on the
	availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	April 1, 2019 through
	March 31, 2020
	(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 Section III-1 of this notice of funding
	opportunity (NOFO) for complete
	eligibility information.

#### **Application Guide**

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

#### **Technical Assistance**

HRSA has scheduled the following technical assistance webinar:

Webinar

Day and Date: Wednesday, July 11, 2018 Time: 3:00 – 4:00 p.m. ET

Call-In Number: 1-888-603-9632

Participant Code: 1763826

Weblink: <a href="https://hrsa.connectsolutions.com/adap\_erf\_hrsa-19-028">https://hrsa.connectsolutions.com/adap\_erf\_hrsa-19-028</a>

HAB will record the TA webinar and make it available on the TARGET Center website.

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#### I. Program Funding Opportunity Description

#### 1. Purpose

This notice solicits applications for the Ryan White HIV/AIDS Program (RWHAP) Part B AIDS Drug Assistance Program (ADAP) Emergency Relief Funds (ERF). The Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB), Division of State HIV/AIDS Programs (DSHAP) administers this program.

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). HRSA will base ADAP awards upon applicants' ability to successfully demonstrate need for additional funding. An external objective review committee (ORC) will evaluate this need based on criteria published in this notice of funding opportunity (NOFO), with priority given to addressing existing waiting lists.

HRSA first funded the ERF initiative in August 2010, when numerous states/territories were experiencing ADAP waiting lists. At the time of publication of this NOFO, there are no ADAP waiting lists. HRSA continues to provide funding under this initiative to maintain infrastructure in those states/territories that had previously imposed waiting lists, and to ensure that no new waiting lists are established. States/territories that have not reported an existing waiting list to HRSA must do so immediately and use funding awarded under this NOFO to remove clients from the waiting list.

Applicants are encouraged to consider how their proposed activities with the ADAP ERF funding support HRSA's emphasis on innovation, collaboration, impact, and effectiveness.

#### 2. Background

This program is authorized by Public Health Service Act, Sections 311(c) and 2616 (42 U.S.C. 243(c) and 300ff-26), 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. The state or territory determines client eligibility, which 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 treatments sometimes result in states/territories experiencing greater demand for ADAP services than available resources can cover. A state/territory implements an ADAP waiting list when adequate funding is not available to provide medications to eligible persons requesting enrollment in their ADAP and the jurisdiction 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. At the time of publication of this NOFO, there are no ADAP waiting lists.

Eligible states/territories may request ADAP ERF to implement measures to help achieve and/or maximize cost-containment strategies. "Cost-containment" strategies employed by ADAPs can include "cost-cutting" measures 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 funded health insurance assistance eligibility criteria.

Examples of "cost-saving" measures include: RWHAP Part B program structural or operational changes such as expanding health insurance assistance; strategies to increase enrollment in health care coverage; improved systems and procedures for the collection of rebates; and data-sharing agreements, including agreements with the Centers for Medicare and Medicaid Services for Medicare Part D.

ADAPs 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 PHS Act. Funds received as a result of participating in the 340B Drug Pricing Program must be returned to the RWHAP Part B program, with priority given to ADAP (see <a href="Policy Clarification Notices 15-03">Policy Clarification Notices 15-03</a> and 15-04 for more information). You must ensure that you use rebates and program income consistent with RWHAP requirements.

#### **National Goals to End the HIV Epidemic**

The RWHAP promotes robust advances and innovations in HIV health care using national goals to end the epidemic as its framework. Therefore, activities funded by RWHAP focus on addressing these four goals:

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

To achieve these shared goals, recipients should align their organization's efforts, within the parameters of the RWHAP statute and program guidance, to ensure that PLWH are linked to and retained in care, and have timely access to HIV treatment and the supports needed (e.g., mental health and substance abuse services) to achieve HIV viral suppression.

#### **HIV Care Continuum**

Diagnosing PLWH, linking PLWH to HIV primary care, and PLWH achieving viral suppression are important public health steps toward ending the HIV epidemic in the United States. The HIV care continuum has five main "steps" or stages that include: HIV diagnosis, linkage to care, retention in care, antiretroviral use, and viral

suppression. The HIV care continuum provides a framework that depicts the series of stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication. It shows the proportion of individuals living with HIV or individuals diagnosed with HIV who are engaged at each stage. The HIV care continuum allows recipients and planning groups to measure progress and to direct HIV resources most effectively.

According to recent data from the 2016 Ryan White Services Report (RSR), the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2010 to 2016, HIV viral suppression among RWHAP patients who have had one or more medical visits during the calendar year and at least one viral load with a result of <200 copies/mL reported, has increased from 69.5 percent to 84.9 percent. and racial/ethnic, age-based, and regional disparities have decreased. These improved outcomes mean more PLWH in the United States will live near normal lifespans and have a reduced risk of transmitting HIV to others.<sup>2</sup> In a September 27, 2017, Dear Colleague letter, the Centers for Disease Control and Prevention (CDC) notes that scientific advances have shown that antiretroviral therapy (ART) preserves the health of PLWH. There is also strong evidence of the prevention effectiveness of ART. When ART results in viral suppression, it prevents sexual HIV transmission. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner. Such findings underscore the importance of supporting effective interventions for linking PLWH into care, retaining them in care, and helping them adhere to their ART.

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. HRSA encourages recipients to use the <a href="mailto:performance measures">performance measures</a> 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.

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

HRSA and the CDC's Division of HIV/AIDS Prevention support integrated data sharing, analysis, and utilization for the purposes of program planning, needs assessments, unmet need estimates, reporting, quality improvement, the development of your HIV care continuum, and public health action. HRSA strongly encourages RWHAP Part B recipients to follow the principles and standards in the <a href="Data Security and Confidentiality Guidelines for HIV">Data Security and Confidentiality Guidelines for HIV</a>, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. HRSA strongly encourages establishing data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization. Integrated HIV data sharing, analysis, and

<sup>&</sup>lt;sup>1</sup> Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2016. http://hab.hrsa.gov/data/data-reports. Published December 2017. Accessed December 1, 2017.

<sup>&</sup>lt;sup>2</sup> National Institute of Allergy and Infectious Disease (NIAID). Preventing Sexual Transmission of HIV with Anti-HIV Drugs. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 Mar 29]. Available from: <a href="https://clinicaltrials.gov/">https://clinicaltrials.gov/</a> NCT00074581 NLM Identifier: NCT00074581.

utilization approaches by state and territorial health departments can help further progress in reaching the national goals to end the HIV epidemic and improve outcomes on the HIV care continuum.

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

#### **Special Projects of National Significance (SPNS)**

Through its SPNS Program, HRSA funded demonstration project initiatives focused on the development of effective interventions to quickly respond to emerging needs of PLWH receiving assistance under the RWHAP. Through these demonstration projects, SPNS evaluated the design, implementation, utilization, cost, and health related outcomes of innovative treatment models, while promoting dissemination, replication, and uptake of successful interventions. SPNS findings have demonstrated promising new approaches to linking and retaining into care underserved and marginalized populations living with HIV. All RWHAP recipients are encouraged to review and integrate a variety of SPNS evidence-informed tools within their HIV system of care as resources permit, in accordance with the allowable service categories defined in PCN 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds. You can find SPNS tools at the following locations:

- Integrating HIV Innovative Practices (IHIP) Intervention or Strategy. Resources on
  the IHIP website include easy-to-use training manuals, curricula, case studies,
  pocket guides, monographs, and handbooks as well as informational handouts and
  infographics about SPNS generally. IHIP also hosts technical assistance (TA)
  training webinars designed to provide a more interactive experience with experts,
  and a TA help desk exists for you to submit additional questions and share your own
  lessons learned.
- Replication Resources from the SPNS Systems Linkages and Access to Care.
   There are intervention manuals for patient navigation, care coordination, state bridge counselors, data to care and other interventions developed for use at the State and regional levels to address specific HIV care continuum outcomes among hard-to-reach populations living with HIV.

• <u>Dissemination of Evidence-Informed Interventions</u>. The Dissemination of Evidence-Informed Interventions initiative will run from 2015-2020 and disseminate four adapted linkage and retention interventions from prior SPNS and the Secretary's Minority AIDS Initiative Fund (SMAIF) initiatives to improve health outcomes along the HIV care continuum. The end goal of the initiative is to produce four evidence-informed Care And Treatment Interventions that are replicable; cost-effective; capable of producing optimal HIV care continuum outcomes; and easily adaptable to the changing healthcare environment. Manuals are currently available at the link provided and will be updated on an ongoing basis.

#### **II.** Award Information

#### 1. Type of Application and Award

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

HRSA will provide funding in the form of a grant.

#### 2. Summary of Funding

HRSA expects approximately \$65,000,000 to be available to fund up to 15 recipients. You may apply for a ceiling amount of up to \$11,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The actual amount available will not be determined until enactment of the final FY 2019 federal appropriation. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds in a timely manner. The period of performance is April 1, 2019 through March 31, 2020 (1 year).

As noted, HRSA will cap FY 2019 ADAP ERF awards at a maximum of \$11,000,000 with a minimum of \$100,000, subject to the availability of funds. HRSA will base the amount of each award 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. HRSA will base funding decisions on an external ORC review and scoring of the criteria published in Section V.1 of this notice.

HRSA places significant importance on the elimination of waiting lists and therefore:

- HRSA will use the ORC scores to establish the rank order for awarding funds.
- HRSA will award funds to all applicants that request funds to address a newly imposed waiting list that are recommended for an award by the ORC based on their ORC scores.
- Once those funds are distributed, HRSA will award funds to applicants that request funds for "cost-cutting" and/or "cost-saving" measures based on their ORC scores.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles and Audit Requirements at 45 CFR part 75.

#### **III. Eligibility Information**

#### 1. Eligible Applicants

Eligible applicants are limited to RWHAP Part B states/territories that reported to HRSA a new ADAP waiting list or who have used the ADAP ERF to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and July 2018.

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 a new ADAP waiting list or use the ADAP ERF to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and July 2018 are not eligible to apply.

#### 2. Cost Sharing/Matching

Cost sharing/matching not required for this program.

#### 3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in *Section IV.4* non-responsive and will not consider it for funding under this notice.

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 your **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* you to apply electronically. HRSA encourages you to apply through <u>Grants.gov</u> using the SF-424 workspace application package associated with this NOFO following the directions provided at <a href="http://www.grants.gov/applicants/apply-for-grants.html">http://www.grants.gov/applicants/apply-for-grants.html</a>.

HRSA recommends that you supply an email address to Grants.gov on the grant opportunity synopsis page when accessing this notice of funding opportunity (NOFO) (also known as "Instructions" on Grants.gov) or workspace application package. This allows Grants.gov to email organizations in the event HRSA changes and/or republishes the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. Please note you are ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities.

#### 2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 Application Guide</u> provides instructions for the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 Application Guide</u> except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

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 NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly urge you to take appropriate measures to ensure your 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 this notice.

#### Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

 The prospective recipient certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.

- 2) Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. 3321).
- 3) Where the prospective recipient is unable to attest to the statements in this certification, an explanation shall be included in Attachment 6: Other Relevant Documents.

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

#### **Program-Specific Instructions**

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u> (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), include the following:

#### i. Project Abstract

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

In addition, provide brief updated information, in this order:

- General demographics of the state/territory
- Demographics of the populations living with HIV in the state/territory
- Brief description of the State ADAP and key environmental factors impacting the program
- 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")
- Description of the planned use of ADAP ERF, 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.

Successful applications will contain the information below. Please use the following section headers for the narrative:

- INTRODUCTION -- Corresponds to Section V's Review Criterion 1 (Need) This introduction section should briefly describe how you will utilize RWHAP ADAP ERF 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 1 (Need) The purpose of this section is to demonstrate the severity of the HIV epidemic in the state/territory and the need for additional resources to meet the projected ADAP client service needs for FY 2019.

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

### 1) HIV Epidemiologic Data from the 2017-2021 Integrated HIV Prevention and Care Plan

You are not required to submit this information in this application. HRSA will use the HIV epidemiologic data from the 2017-2021 Integrated HIV Prevention and Care Plan to meet this requirement, and will provide it to the ORC.

#### 2) ADAP State/Territory Profile

You must provide the following information regarding eligibility for this award and the structure, functions, and operational processes of the ADAP and the clients that it serves.

#### a) Eligibility for ADAP ERF Funding

- i. Did you report to HRSA an ADAP waiting list between January 2011 and July 2018? (Yes/No)
- ii. Did you use ADAP ERF funds to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and July 2018? (Yes/No)

Reminder: 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 July 2018 are not eligible to apply for ADAP ERF Awards.

#### b) ADAP Funding Summary for FY 2017 and FY 2018

In a table format, please list all sources of funding for ADAP and the amounts received and expended during the FY 2017 project period (April 1, 2017 through March 31, 2018) and year-to-date for the FY 2018 project period (April 1, 2018 through March 31, 2019):

- 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

#### c) ADAP Funding Summary Narrative for FY 2017 and FY 2018

In a narrative format, briefly describe the following:

- Steps you have taken over the last two fiscal years to maximize the funding for the ADAP
- ii. How efforts to maximize funding have impacted the overall funding portfolio as described in the ADAP Funding Summary for FY 2017 and FY 2018 table above.

#### d) Cost-Cutting Measures for FY 2017 and FY 2018

Please identify which, if any, of the following cost-cutting measures were in place or newly implemented in FY 2017 and FY 2018 for your ADAP:

- i. Enrollment cap (if so, specify the maximum number of enrollees)
- ii. Capped number of prescriptions per month (if so, specify the cap)
- iii. Capped expenditure (if so, the amount and timeframe)
- iv. Drug-specific enrollment caps for antiretroviral (if so, specify)
- v. Reduction in formulary (if so, specify)
- vi. Decrease in financial eligibility criteria (if so, specify)
- vii. Other (please specify)

#### e) Cost-Saving Measures for FY 2017 and FY 2018

Please identify which, if any, of the following cost-saving measures were in place or newly implemented in FY 2017 and FY 2018 for your ADAP:

- i. Expansion of health insurance assistance (if so, what services are currently offered)
- ii. Enrolling eligible clients in health insurance (if so, how many were enrolled and through what mechanism)
- iii. Enrolling eligible clients through Medicaid
- iv. Improved client recertification processes (if so, what was improved)
- v. Decrease in administrative expenditures
- vi. Other (please specify)

#### f) Client Utilization Summary for FY 2017 and FY 2018

- 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

#### B. Factors affecting State ADAP Capacity to Meet Need

You must provide a detailed narrative description of at least three factors impacting the 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. You should support this discussion by data sources as appropriate when discussing trends and changes (including environmental changes) that have resulted in this need. Examples of factors include, but are not limited to:

- Trends or changes in the HIV disease prevalence over the past two calendar years (January 1, 2016 through December 31, 2017) that have affected the ADAP.
- Changes to the state/territory's service delivery system that may include client need and/or administrative burden as a result of the changing health care landscape.
- Changes in client population or demographics over the last two years including but not limited to increased eligible applicants, increased percentage of eligible clients below 100 percent of the FPL, high unemployment rates, increased co-morbidities (e.g., opioid addiction), and/or increased number of out-of-care clients seeking treatment.

- Increased program costs including but not limited to the cost of ADAP medications and/or cost to ADAP for insurance premiums, deductibles, and/or cost-sharing.
- Decreased or level funding from state or federal resources for ADAP and/or HIV services.

# METHODOLOGY -- Corresponds to Section V's Review Criterion 2 (Response) A. ADAP Average Annual Client Costs and Forecasting You must provide a calculation of the projected average cost per client for medication assistance and/or health insurance assistance for the FY 2019 ADAP ERF project period (April 1, 2019 through March 31, 2020). Important Note: You do not need to provide an average cost per client for a type of assistance for which you are not requesting funding.

You must determine the average cost per client through your own calculations, or through the cost calculation template in **Appendix A**. Whichever calculation methodology is used, you must provide the step-by-step calculations utilized in developing the average cost per client. You must use the calculated **average cost per client in developing the proposed budget for the use of the ADAP ERF funds and/or to project the impact of proposed cost-containment measures**. Provide the calculation(s) that show how you multiplied the average cost per client by the projected number of clients to be served to determine the budget request for medication assistance and/or health insurance assistance.

#### 1) ADAP Average Annual Client Costs

#### a) Medication Costs

If requesting funding for medication assistance, please provide:

- i. Calculations for, and
- ii. Resulting projected annual average medication cost per client for the FY 2019 ADAP ERF budget period.

#### b) Health Insurance Assistance Costs

If requesting assistance for health insurance assistance, please provide:

- i. Calculations for, and
- ii. Resulting projected annual average insurance assistance cost per client for the FY 2019 ADAP ERF project period.

#### 2) Forecasting

# a) <u>States/Territories Requesting Funds to Purchase Medications or Health Insurance Assistance to Prevent, Reduce, or Eliminate Waiting Lists:</u>

- i. For applicants with an existing ADAP waiting list, provide the current number of individuals on the waiting list.
- ii. Describe the projected impact of ADAP ERF, together with FY 2019 RWHAP Part B funds, any RWHAP Part B carryover funds, funding provided by the state/territory, resources generated by rebates and program income, FY 2019 RWHAP Part A contributions, and any projected resources, in addressing:
  - 1) Your projected/potential ADAP waiting list, and/or

#### 2) Your current waiting list

## b) <u>States/Territories Requesting Funds for other Cost-Cutting or Cost-Saving Measures to Prevent, Reduce, or Eliminate Waiting Lists:</u>

For each proposed cost-cutting or cost-saving 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 2 (Response) and 3 (Impact)

Describe the steps that you will take to carry out each of the activities proposed during the entire work period. Please present this in the form of a work plan (HRSA suggests a table format), which is uploaded as **Attachment 1**, and a narrative.

#### A. Planned Services and Work Plan

List each planned ADAP ERF service (e.g., purchase of ADAP medications, purchase of health insurance premiums, payment of medication co-payments, deductibles, or co-insurance) and/or cost-containment measures (i.e., cost-cutting or cost-saving measures) designed to improve ADAP operations and maximize available ADAP resources. HRSA encourages you 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;
- 2) Planned Expenditures by Service Category with columns for Planned Service, Service Unit Description, # of Service Units, # of Clients and amount budgeted for each service;
- Planned Expenditure by Cost-Containment Measures/Initiatives listing each planned cost-containment initiative with the date initiated and the amount budgeted for each initiative;
- 4) **SMART Objectives:** Provide the SMART objective associated with the planned service category, cost-containment measures/initiatives, and recipient administrative costs that will be funded with FY 2019 ADAP ERF funds. SMART objectives are **S**pecific—identifying target population and activity, **M**easurable—indicating how much or how many, **A**ttainable—must be realistically accomplished using resources provided, **R**ealistic—addressing and establishing reasonable programmatic steps, and **T**imesensitive—indicating a timeline during which you will accomplish the objective; and
- 5) **Service Unit Definition:** Describe the definition of the unit of service for the planned service category, cost-containment, measure/initiative, and recipient administrative cost that you will fund with FY 2019 ADAP ERF.

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

Provide a narrative that describes the following for each planned service, cost-containment measure/initiative, and recipient administrative cost identified in the work plan:

- 1) How you will assure that you will spend funds allocated for each service/activity within the twelve month project period;
- 2) If you have a new ADAP waiting list, how the services/activities will reduce the number of persons on the waiting list;
- 3) If you do not have 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 2019 (4/1/19-3/31/20).

#### C. Anticipated Impact of ADAP ERF

Provide a brief description of the anticipated impact of the proposed ADAP ERFfunded planned service, cost-containment measure/initiative, and recipient administrative cost activities on currently implemented or anticipated costcontainment measures as it relates to waiting list prevention, reduction, or elimination.

- 1) Describe how you will monitor progress toward meeting the goals and objectives of the proposed period.
- Describe how these activities will support the continued function of the ADAP.
- 3) Provide a description of the anticipated outcomes resulting from ADAP ERF supported activities.
- 4) Describe how the anticipated outcomes will support full and sustained ADAP service provision beyond the funding period. If you cannot support full and sustained ADAP service provision beyond the funding period, identify any sustainability barriers and describe the plans on how to address them in the future.

#### D. Monitoring

Provide a brief description of the methods in place to monitor and assess the effectiveness of the activities to prevent, reduce, or eliminate the waiting list, including cost-containment measures, proposed on the ADAP ERF work plan. 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:** HRSA expects that the ADAP will utilize its current RWHAP Part B Quality Management Program when implementing services funded through the ADAP ERF award.

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

#### A. State/Territory Actions to Address ADAP Challenges

This section provides an opportunity for you to describe specific challenges and barriers and actions necessary to prevent, reduce, or eliminate an ADAP waiting list in FY 2019 (4/1/19-3/31/20). 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 2017 and FY 2018. Support each section by data showing how these strategies benefit the ADAP.

#### 1) Improved Program Efficiencies:

Please describe any challenges regarding program efficiencies and how your program has addressed challenges, including through the use of ADAP ERF (X09) funding, by improving operations in order to reduce costs and improve efficiency. Support your description with data showing how the improved operational efficiencies will benefit the ADAP.

#### 2) Improved Ability to Enroll Clients in Other Payor Sources:

Please describe any challenges to enrolling clients in other payor sources, and how your program has addressed challenges by improving systems to increase enrollment in other forms of insurance including Medicare Part D, Medicaid, and other health insurance options. Be sure to support your decision with data showing how improved enrollment in other payor sources will benefit the ADAP.

#### 3) Reallocation of Resources:

Please describe any challenges/limits with ADAP resources, and if/how you have reallocated funds 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.

#### 4) Increased Rebates and Discounts:

Please describe any challenges with the generation or collection of rebates and discounts. Include how your ADAP has modified its processes or the monitoring of those processes to ensure that you purchase drugs 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.

 ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criteria 4 (Resources/Capabilities) and 5 (Support Requested)

#### A. ADAP Oversight/Administration

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

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

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

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

Describe how you will be able to meet reporting requirements by tracking and reporting ADAP ERF specific expenditures and client utilization.

#### **NARRATIVE GUIDANCE**

To ensure that you fully address the review criteria, 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 and (3) Impact
Resolution of Challenges	(2) Response
Organizational Information	(4) Resources/Capabilities & (5) Support Requested
Budget and Budget Narrative (below)	(5) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

#### iii. Budget

See Section 4.1.iv of HRSA's <u>SF-424 Application Guide</u>. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the Application Guide and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for funding, you will have a well-organized plan and by carefully following the approved plan can avoid audit issues during the implementation phase.

**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 program 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 package, 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:

- 1) Medications/Insurance: The first column should include all FY 2019 ADAP ERF funds allocated to prevent, reduce, and/or eliminate your waiting list through the purchase of medication and/or health 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 award or state program.
- 2) Other Cost-Containment: The second column should include all funds allocated to award activities to address any other "cost-cutting" and/or "cost-saving" measures to be charged to the FY 2018 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 award or state program.

The Consolidated Appropriations Act, 2018 (P.L. 115-141), Division H, § 202 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." See Section 4.1.iv Budget – Salary Limitation of HRSA's <u>SF-424 Application Guide</u> for additional information. Note that these or other salary limitations may apply in FY 2020, as required by law.

#### iv. Budget Narrative

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

#### v. Attachments

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. You must clearly label **each attachment**.

#### 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, either Staffing Plan and Job Descriptions for Key Personnel or 'Not Applicable' document)

If you are using ADAP ERF 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. Also, please include a description of your organization's time keeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

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

## Attachment 3: Biographical Sketches of Key Personnel (Required—either Biographical Sketches or 'Not Applicable' document)

If you are using ADAP ERF funds 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 whom you have not yet hired, please include a letter of commitment from that person with the biographical sketch.

If the ADAP will <u>not</u> 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 Data Universal Numbering System (DUNS) Number and System for Award Management

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

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

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

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

- Dun and Bradstreet (http://www.dnb.com/duns-number.html)
- System for Award Management (SAM) (<a href="https://www.sam.gov">https://www.sam.gov</a>)
- 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.

ALERT from SAM.gov: You must now provide an original, signed notarized letter stating that you are the authorized Entity Administrator before your registration will be activated by SAM.gov. Please read these FAQs to learn more about this process change. Plan for additional time associated with submission and review of the notarized letter. This requirement is effective March 22, 2018 for new entities registering in SAM. This requirement is effective April 27, 2018 for existing registrations being updated or renewed. Entities already registered in SAM.gov are advised to log into SAM.gov and review their registration information, particularly their financial information.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you 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 NOFO is *October 25, 2018 at 11:59 p.m.*Eastern Time. HRSA suggests submitting applications to Grants.gov at least **3 days**before the deadline to allow for any unforeseen circumstances.

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

#### 5. Intergovernmental Review

The ADAP ERF is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

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

#### 6. Funding Restrictions

You may request funding for a period of performance of up to 1 year, at no more than \$11,000,000 (inclusive of direct **and** indirect costs).

The General Provisions in Division H of the Consolidated Appropriations Act, 2018 (P.L. 115-141) apply to this program. Please see Section 4.1 of HRSA's <u>SF-424 Application</u> <u>Guide</u> for additional information. Note that these or other restrictions will apply in FY 2020, as required by law.

In addition to the funding restrictions included in section V.1iv of the <u>SF-424 Application</u> <u>Guide</u>, you cannot use funds under this notice for the following purposes:

- Payment 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 benefits program, or any entity that provides health services on a prepaid basis (except for a program administered by or providing the services of the Indian Health Service).
- Planning and evaluation activities as defined by RWHAP Part B.
- Cash payment to intended recipients of RWHAP services.
- Clinical quality management.
- International travel.
- Construction (minor alterations and renovations to an existing facility to make it more suitable for the purposes of the award program are allowable with prior HRSA approval).
- HIV test kits.
- Syringe Services Programs (SSPs). Some aspects of SSPs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy.
- Development of materials designed to directly promote or encourage intravenous drug use or sexual activity, whether homosexual or heterosexual.
- Pre Exposure Prophylaxis (PrEP) medications and related medical services or Post-Exposure Prophylaxis (PEP), as the person using PrEP or PEP is not living with HIV and therefore not eligible for RWHAP funded medication.

You may not use these funds to supplant funds for any other federal award 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 <a href="https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters">https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters</a> and at 45 CFR 75 Subpart E Cost Principles.

You are required to have the necessary policies, procedures and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for

all other applicable grants requirements, the effectiveness of these policies, procedures and controls is subject to audit.

All program income generated as a result of awarded funds is considered additive and must be used for otherwise allowable costs to further the objectives of the RWHAP Part B ADAP ERF program. You may only use program income generated by the RWHAP ADAP ERF for the provision of medications and/or cost containment strategies that prevent, reduce, or eliminate an ADAP waiting list in your state/territory. Post-award requirements for program income can be found at 45 CFR § 75.307. Per 45 CFR Section 75.305 (b)(5), to the extent available, you must disburse funds available from program income before requesting grant funds.

#### V. Application Review Information

#### 1. Review Criteria

HRSA has instituted procedures for assessing the technical merit of applications to provide for an objective review of applications and to assist you in understanding the standards against which your application will be judged. HRSA has developed critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. See the review criteria outlined below with specific detail and scoring points.

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

Review criteria are used to review and rank applications. The RWHAP Part B ADAP ERF has five review criteria:

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

The extent to which the application demonstrates the problem and associated contributing factors to the problem as well as the feasibility and applicability of the 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 description of how the state/territory will utilize RWHAP ADAP ERF in support of preventing, reducing, or eliminating a waiting list during the project period is feasible in addressing the problem.

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

The strength, completeness, and clarity of the information in the State/Territory ADAP Profile for Fiscal Years 2017 and 2018.

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

The strength and clarity of the demonstrated need for additional resources to prevent, reduce, or eliminate a waiting list and clarity as to why the ADAP is unable to meet the

need with existing resources; and the strength of the data provided to support the narrative description.

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

The extent to which the proposed project responds to the "Purpose" included in the ADAP ERF program included in Section 1 of the NOFO and the extent to which the activities described in the application (including Attachment 1) are capable of addressing the problem and attaining the project objectives of avoiding, reducing, or eliminating a waiting list through cost-cutting and/or cost-saving measures.

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

The strength, completeness, and clarity of the following:

- A step-by-step methodology for calculating average cost per client for medication assistance and/or health insurance assistance (depending on the type of assistance requested);
- Accurate calculations of annual client costs, reflected in plan and budget, and
  - Note: If the calculations are incorrect, the ORC will identify the error along with its impact on the applicant's average client cost calculations and budget request.
- Information provided in the Forecasting section on the impact of the requested funding on preventing, reducing, or eliminating a waiting list.

#### 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 12month project 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 2018.

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

The strength and clarity of the following:

- The description of the specific challenges facing the ADAP in the following areas:
  - o program efficiencies;
  - o the ability to enroll clients in other payor sources;
  - ADAP resources;
  - o generation or collection of rebates and discounts;
- The cost-cutting or cost-saving strategies taken in response to these challenges and the extent to which they could prevent, reduce, or eliminate an ADAP waiting list in FY 2019.

• The data provided for each challenge area demonstrates how these strategies benefit the ADAP.

Criterion 3: IMPACT (10 points) – Corresponds to Section IV's Work Plan 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;
- The applicant's description of their ability to sustain the program beyond the FY 2019 ADAP ERF project period.

Criterion 4: RESOURCES/CAPABILITIES (10 points) – Corresponds to Section IV's Organizational Information and the Staffing Plan and Biographical Sketches, if applicable

The strength and completeness of the description of the applicant's ability to implement the ADAP ERF, as evidenced by:

- The strength 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.
- The clarity of the organizational chart for the ADAP in Attachment 5.
- The strength and appropriateness of the position descriptions (in Attachment 2) and biographical sketches (in Attachment 3) for key ADAP staff to impact the stated problem, if ADAP ERF funds are being used to support staffing.

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

The strength and completeness of the description of the applicant's ability to implement the ADAP ERF, as evidenced by.

- The reasonableness of the proposed budget for the project period (one year) in relation to the objectives and the anticipated results.
- The ability to allocate the costs outlined in the budget and budget narrative sections to the scope of work.
- If applicable, the accuracy with which the applicant based its budget request on the average cost per client calculated, and/or the accuracy with which the applicant based its budget request on the number of individuals on the ADAP waiting list.

#### 2. Review and Selection Process

The independent review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. In addition to the ranking based on merit criteria, HRSA approving officials will apply other factors below in award selection (e.g., geographical distribution).

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

#### **Funding Preferences**

This program provides a funding preference for some applicants. Applicants receiving the preference will be placed in a more competitive position among applications that can be funded. Applications that do not receive a funding preference will receive full and equitable consideration during the review process. HRSA staff will determine the funding factor and will grant it to any qualified applicant that demonstrates that they meet the criteria for the preference:

Name of the funding preference: Current ADAP Waiting List

Qualification to meet the funding preference:

You can request funding preference if you demonstrate within the application that you have a current ADAP waiting list.

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

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

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

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

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

HRSA will report to FAPIIS a determination that an applicant is not qualified (45 CFR § 75.212).

#### 4. Anticipated Announcement and Award Dates

HRSA anticipates issuing/announcing awards prior to the start date of April 1, 2019.

#### VI. Award Administration Information

#### 1. Award Notices

HRSA will issue the Notice of Award prior to the start date of April 1, 2019. See Section 5.4 of HRSA's *SF-424 Application Guide* for additional information.

#### 2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's <u>SF-424 Application Guide</u>.

#### Requirements under Subawards and Contracts under Grants

The terms and conditions in the Notice of Award (NOA) apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients and contractors under grants, unless the NOA specifies an exception. See 45 CFR § 75.101 Applicability for more details.

#### 3. Reporting

Award recipients must comply with Section 6 of HRSA's <u>SF-424 Application Guide</u> and the following reporting and review activities:

- 1) **Progress Report**(s). The recipient must submit a progress report to HRSA on a **semi-annual** basis. Further information will be available in the award notice.
- 2) Other required reports and/or products.

**ADAP Data Report (ADR).** Acceptance of this award indicates that you will comply with data requirements of the ADR and will mandate compliance by each of your contractors and subcontractors. The ADR captures information necessary to demonstrate program performance and accountability. Please refer to the ADR webpage at <u>ADR webpage</u> for more information. HRSA will provide further information in the notice of award.

**Program Terms Report.** You must submit a Program Terms Report through the HRSA Electronic Handbook (EHB) using the format provided

in that system. HRSA will provide further information in the notice of award.

#### **VII. Agency Contacts**

You may request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Nancy Gaines
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857

Telephone: (301) 443-5382 Email: NGaines@hrsa.gov

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Rene Sterling, Ph.D., M.H.A.
Acting Director, Division of State HIV/AIDS Programs
HIV/AIDS Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 09W50
Rockville, MD 20857

Telephone: (301) 443-9017 Email: RSterling@hrsa.gov

You may need assistance when working online to submit your application forms electronically. Always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, 7 days a week, excluding federal holidays at:

Grants.gov Contact Center

Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)

Email: support@grants.gov

Self-Service Knowledge Base: <a href="https://grants-portal.psc.gov/Welcome.aspx?pt=Grants">https://grants-portal.psc.gov/Welcome.aspx?pt=Grants</a>

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 a.m. to 8 p.m. ET, excluding federal holidays at:

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

#### **HIV PERFORMANCE MEASURES**

HRSA has developed HIV Performance Measures for Adults and Adolescents and a companion guide to assist recipients in the use and implementation of the core clinical performance measures. Information on Performance Measures may be found at <a href="https://hab.hrsa.gov/clinical-quality-management/performance-measure-portfolio">https://hab.hrsa.gov/clinical-quality-management/performance-measure-portfolio</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 you meet this requirement, HRSA has developed guidelines outlining the responsibilities of HRSA, you, and provider staff. The National Monitoring Standards can be found at: <a href="https://hab.hrsa.gov/program-grants-management/ryan-white-hivaids-program-recipient-resources">https://hab.hrsa.gov/program-grants-management/ryan-white-hivaids-program-recipient-resources</a>.

#### **Technical Assistance**

HRSA has scheduled following technical assistance webinar:

Webinar

Day and Date: Wednesday, July 11, 2018

Time: 3:00 – 4:00 p.m. ET

Call-In Number: 1-888-603-9632 Participant Code: 1763826

Weblink: <a href="https://hrsa.connectsolutions.com/adap\_erf\_hrsa-19-028">https://hrsa.connectsolutions.com/adap\_erf\_hrsa-19-028</a>

HAB will record the TA webinar and make it available on the TARGET Center website.

#### Tips for Writing a Strong Application

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

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

#### **Average Client Cost Calculations**

You must provide a calculation of your projected average cost per client for medication assistance and/or health insurance assistance for the FY 2019 ADAP ERF project period (April 1, 2019 - March 31, 2020). **Important Note:** You do not need to provide an average cost per client for a type of assistance for which you are not requesting funding. You must determine the average cost per client through your own calculations, or through the cost calculation template in this Appendix. You must use the average cost per client calculated in developing the proposed budget for the use of the ADAP ERF funds and/or to project the impact of proposed cost-containment measures. **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.** 

Due to the timing of this NOFO, the calculations in this model are based on client utilization and ADAP cost data for the January 1, 2018 to June 30, 2018 period. The calculations should incorporate all clients who received at least one medication through ADAP during the January 1, 2018 to June 30, 2018 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).

#### 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, 2018 to June 30, 2018 period. Divide this amount by the total number of ADAP clients who received at least one (1) prescription medication in the same period. Multiply that amount by two (2) 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.

- If you operate a 340B Rebate State ADAP, this includes all 340B rebates and other negotiated rebates (e.g., ADAP Crisis Task Force rebates) you received in the January 1, 2018 to June 30, 2018 period.
- If you operate a 340B State Direct Purchase ADAP, this includes all negotiated rebates (e.g., ADAP Crisis Task Force rebates) you received in the January 1, 2018 to June 30, 2018 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, 2018 to June 30, 2018 period. Multiply that amount by two to determine the average rebate reduction per client.

<u>Note</u>: The insurance section below addresses the impact of rebates for insurance deductibles and co-payments.

#### **Step 3:** Adjusted Average Client Medication Cost:

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:** Average Annual Client Dispensing Fee:

Determine the total number of prescriptions filled in the January 1, 2018 to June 30, 2018 period. Multiply that number by the dispensing fee for a single pharmacy prescription in the January 1, 2018 to June 30, 2018 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:** Average Annual Medication Cost per Client:

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, 2018 to June 30, 2018 period, the ADAP spent a total of \$7,410,000 for prescription	\$7,410,000/1,000 = <b>\$7,410</b>	Baseline Average Six Month Client Medication Cost	
	drugs; a total of 1,000 clients received at least one prescription medication.	\$7,410 x 2 = <b>\$14,820</b>	Baseline Average Annual Client Medication Cost	
Step 2	In that same period, the ADAP received \$555,000 in total 340B rebates and	\$555,000 + \$100,000 = \$655,000	Total Rebates Received by the ADAP	
	\$100,000 in negotiated rebates.	\$655,000/1,000 clients = <b>\$655</b>	Average Six Month Client Rebate Reduction	
		\$655 x 2 = <b>\$1,310</b>	Average Annual Client Rebate Reduction	
Step 3	Adjusted Average Annual Cost per Client: Baseline Average Annual Client Medication cost minus Average Annual Client Rebate Reduction	\$14,820 - \$1,310 = <b>\$13,510</b>		
Step 4	The ADAP filled 10,000 prescriptions in the January 1, 2018 to June 30, 2018	\$10 x 10,000 = <b>\$100,000</b>	Total Dispensing Fee Expenditures	
	period of CY 2017 and the dispensing fee per prescription was \$10; 1,000	\$100,000/1,000 clients = <b>\$100</b>	Average Six Month Client Dispensing Fee	
	ADAP clients received at least 1 ADAP prescription.	\$100 x 2 = <b>\$200</b>	Average Annual Client Dispensing Fee	

Step 5	Add amount calculated in	\$13,510 + \$200 =	Average Annual
	Step 3 to amount calculated	\$13,710	Medication Cost per Client
	in Step 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/co-insurance in the January 1, 2018 to June 30, 2018 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 True out of Pocket (TrOOP).

#### Step 2: Rebate Reduction:

Determine the total amount of manufacturer's rebates received in the January 1, 2018 to June 30, 2018 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 your Adjusted Six Month Total Insurance Cost.

# Step 4: Average Annual Cost per Client for Health Insurance Assistance (including COBRA, High Risk Health Insurance Pools, private insurance, Statesponsored insurance, 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, 2018 to June 30, 2018 period. Multiply by two for average annual cost per client for insurance assistance.

#### Example:

The ADAP spent \$1,500,000 in the January 1, 2018 to June 30, 2018 period to pay for insurance premium \$300,000 on co-payments/co-insurance, deductibles, and TrOOP, providing assistance to 300 ADAP eligical clients.

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Step 1	Add insurance premiums expenditures to expenditures for co-payments/co-insurance, deductibles, and TrOOP.	\$1,500,000 + \$300,000 = <b>\$1,800,000</b>	Total Six Month Insurance Expen
Step 2	Determine the total amount of rebates received by adding the manufacturers rebates received from January 1, 2018 to June 30, 2018 on insurance copayments/coinsurance/deductibles.	\$50,000	Total Six Month Rebates Receive
Step 3	Total Six Month Insurance Expenditures minus Total Six Month Rebates Received	\$1,800,000 - \$50,000 = <b>\$1,750,000</b>	Adjusted Total Insurance Cost
Step 4	Divide Adjusted Total Insurance Cost by total clients served. Multiply the Average Six Month Cost per Client by two to calculate the Average Annual Cost per	\$1,750,000/300 = <b>\$5,833</b>	Average Six Mon Cost per Client for Insurance Assista
	Client.	\$5,833 x 2 = <b>\$11,666</b>	Per Client for Ins Assistance
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#### **Appendix B: Agreements and Compliance Assurances**

# FY 2019 Ryan White HIV/AIDS Program ADAP Emergency Relief Funds Awards Agreements and Compliance Assurances

I, the Governor of the State or Territory or her/his official designee for the Ryan White HIV/AIDS Part B Program Grant,, pursuant to Title XXVI of 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 2616 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 2019 Part B Ryan White HIV/AIDS Program Agreements and Compliance Assurances submitted to the Health Resources and Services Administration.
SIGNED: Title:  Governor or Official Designee
Date: