U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



Health Resources & Services Administration

HIV/AIDS Bureau Division of State HIV/AIDS Programs

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

Funding Opportunity Number: HRSA-21-057 Funding Opportunity Type: New—Limited Competition Assistance Listings (CFDA) Number: 93.917

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: October 26, 2020

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: July 27, 2020

Susan Robilotto, D.O. Director, Division of State HIV/AIDS Programs Telephone: (301) 443-6554 Email: <u>SRobilotto@hrsa.gov</u>

Authority: 42 U.S.C. §§ 243(c) and 300ff-26 (§§ 311(c) and 2616 of the Public Health Service Act).

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2021 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 (RWHAP) Part B ADAP administered by the HRSA, HIV/AIDS Bureau (HAB), Division of State HIV/AIDS Programs (DSHAP).

Funding Opportunity Title:	AIDS Drug Assistance Program (ADAP) Emergency Relief Funds (ERF)
Funding Opportunity Number:	HRSA-21-057
Due Date for Applications:	October 26, 2020
Anticipated Total Annual Available FY 2021 Funding:	\$75,000,000
Estimated Number and Type of Award(s):	Up to 30 grants
Estimated Award Amount:	Up to \$7,000,000 per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	April 1, 2021 through March 31, 2022 (1 year)
Eligible Applicants:	All 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. See <u>Section III.1</u> 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 <u>http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf</u>, except where instructed in this NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance webinar:

Day and Date: Wednesday, August 19, 2020 Time: 1:30–3 p.m. ET Call-In Number: 1-888-989-4986 Participant Code: 3768014 Weblink: https://hrsa.connectsolutions.com/hab-hrsa-21-057-adap-erf-ta/

HAB will record the TA webinar and make it available on the <u>TargetHIV</u> website.

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under 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 ERF 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 this NOFO publication, there are no ADAP waiting lists. States/territories that established a waiting list since the publication of this NOFO must report the waiting list to HRSA immediately and use funding awarded under this NOFO to remove clients from the waiting list. Previously, eligibility for this funding was limited to states/territories that had historically imposed waiting lists. This year, HRSA expects additional state/territory impact on ADAPs due to the economic downturn, resulting in more potential clients in need of ADAP services due to client loss of income and/or client loss of health care coverage. States/territories may use ERF funds to address current or projected increases in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program.

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 42 U.S.C. §§ 243(c) and 300ff-26 (§§ 311(c) and 2616 of the Public Health Service Act). ADAPs ensure access to medication to treat HIV for eligible clients through the direct purchase of medication and through covering the costs of insurance premiums, copays, and deductibles. The state/territory determines client eligibility, which includes verification of positive HIV status, financial eligibility, and residence eligibility criteria. Financial eligibility is usually determined as a percentage of the Federal Poverty Level (FPL). ADAPs are expected to recertify client eligibility at least every 6 months.

Steady growth in the number of eligible clients combined with rising costs of complex HIV treatments sometimes results in states/territories experiencing greater demand for ADAP services than available resources can cover. 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 program eligibility 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 the publication of this NOFO, there are no ADAP waiting lists.

"Cost-containment" strategies employed by ADAPs can include "cost-cutting" measures and "cost-saving" measures. Eligible states/territories may request ADAP ERF funding to implement measures to help reverse cost-cutting measures and/or enhance costsaving 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 datasharing 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 Policy Clarification Notices <u>15-03</u> and <u>15-04</u> for more information). You must ensure that you use rebates and program income consistent with RWHAP requirements.

The Ryan White HIV/AIDS Program (RWHAP) funds direct health care and support services for over half a million people diagnosed with HIV in the United States. RWHAP funds are awarded to cities, states, and local community-based organizations to deliver efficient and effective HIV care, treatment, and support services for low-income people with HIV. Since the program's inception in 1990, RWHAP has developed a comprehensive system of safety net providers who deliver high-quality, innovative HIV health care.

The RWHAP has five statutorily defined Parts (Parts A through D and Part F) that provide funding for core medical and support services, technical assistance, clinical training, and the development of innovative models of care to meet the needs of different communities and populations affected by HIV.

The Strategic Framework

The RWHAP supports the implementation of the National HIV/AIDS Strategy for the United States: Updated 2020 (NHAS 2020). This strategy is a 5-year plan that details principles, priorities, and actions to guide the national response to the HIV epidemic.

The plan also provides a blueprint for collective action across the federal government and other sectors to help achieve the strategy's vision.

To ensure that RWHAP aligns with the National HIV/AIDS Strategy, to the extent possible, activities funded by the program focus on addressing the plan's four goals:

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

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 people with HIV are linked to and retained in care, and have timely access to HIV treatment and the support services needed (e.g., mental health and substance use disorders services) to achieve HIV viral suppression. The RWHAP also provides technical assistance and training initiatives and promotes the effective use of data to enhance recipients' capacity to implement programs that support the strategy's objectives.

HIV Care Continuum

Diagnosing and linking people with HIV to primary care, and ensuring people with HIV achieve viral suppression are important public health steps toward ending the HIV epidemic in the United States. The HIV care continuum has five main 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 also demonstrates the proportion of individuals 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. 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 performance measures 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.

According to recent data from the <u>2018 Ryan White Services Report (RSR)</u>, the RWHAP has made tremendous progress toward ending the HIV epidemic in the United States. From 2014 to 2018, 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 81.4 percent to 87.1 percent. Additionally, racial/ethnic, age-based, and regional disparities reflected in viral suppression rates have decreased.¹ These improved outcomes mean more people with HIV in the United States will live near normal lifespans and have a reduced risk of

¹ Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2018. <u>http://hab.hrsa.gov/data/data-reports</u>. Published December 2019. Accessed December 2, 2019.

transmitting HIV to others.² Scientific advances have shown antiretroviral therapy (ART) preserves the health of people with HIV and 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 people with HIV into care, retaining them in care, and helping them adhere to their ART.

Using Data Effectively: Integrated Data Sharing and Use

HRSA and the Centers for Disease Control and Prevention's (CDC) Division of HIV/AIDS Prevention support integrated data sharing, analysis, and utilization for the purposes of program planning, conducting needs assessments, determining unmet need estimates, reporting, quality improvement, enhancing the HIV care continuum, and public health action. HRSA strongly encourages RWHAP Part B recipients to:

- Follow the principles and standards in the <u>Data Security and Confidentiality</u> <u>Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and</u> <u>Tuberculosis Programs: Standards to Facilitate Sharing and Use of</u> <u>Surveillance Data for Public Health Action.</u>
- Establish data sharing agreements between surveillance and HIV programs to ensure clarity about the process and purpose of the data sharing and utilization.

Integrated data sharing, analysis, and utilization of HIV data by state and territorial health departments can help further progress toward reaching the NHAS 2020 goals and improve outcomes on the HIV care continuum.

HRSA strongly encourages complete CD4, viral load (VL), and HIV nucleotide sequence reporting to the state and territorial health departments' HIV surveillance systems to benefit fully from integrated data sharing, analysis, and utilization. State health departments may use CD4, VL, and nucleotide sequence data to identify cases, identify stage of HIV disease at diagnosis, and monitor disease progression. These data can also be used to evaluate HIV testing and prevention efforts, determine entry into and retention in HIV care, measure viral suppression, monitor prevalence of antiretroviral drug resistance, detect transmission clusters and understand transmission patterns, and assess unmet health care needs. Analyses at the national level to monitor progress toward ending the HIV epidemic can only occur if all HIV-related CD4, VL, and HIV nucleotide sequence test results are reported by all jurisdictions. CDC requires the reporting to the National HIV Surveillance System (NHSS) all HIV-related CD4 results (counts and percentages), all VL results (undetectable and specific values), and HIV nucleotide sequences.

² National Institute of Allergy and Infectious Diseases (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: <u>https://clinicaltrials.gov/</u> NCT00074581 NLM Identifier: NCT00074581.

Expanding the Effort: Ending the HIV Epidemic: A Plan for America

In February 2019 the Administration launched the <u>Ending the HIV Epidemic: A Plan for</u> <u>America</u> (EHE) initiative to further expand federal efforts to reduce HIV infections. This 10-year initiative which began in FY 2020 seeks to achieve the important goal of reducing new HIV infections in the United States to fewer than 3,000 per year by 2030. The first phase of the initiative is focused on 48 counties, Washington, D.C., San Juan, PR, and 7 states that have a substantial rural HIV burden. By focusing on these jurisdictions in the first phase of the initiative, the U.S. Department of Health and Human Services (HHS) plans to reduce new HIV infections by 75 percent within 5 years. The initiative promotes and implements four Pillars to substantially reduce HIV transmissions – Diagnose, Treat, Prevent, and Respond. The initiative is a collaborative effort among key HHS agencies, primarily HRSA, CDC, the National Institutes of Health (NIH), the Indian Health Service (IHS), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Program Resources and Innovative Models

Through the Minority HIV/AIDS Fund from the HHS Secretary's Office (MHAF) and HAB technical assistance (TA) cooperative agreements, HRSA has a number of projects that may be useful for RWHAP recipients to assist with program implementation. Some select examples are:

- Building Futures: Youth Living with HIV at <u>https://targethiv.org/library/hrsa-hab-building-futures-supporting-youth-living-hiv</u>
- The Center for Engaging Black MSM Across the Care Continuum (CEBACC) at <u>https://targethiv.org/cebacc</u>
- E2i: Using Evidence-Informed Interventions to Improve Health Outcomes among People Living with HIV at https://targethiv.org/e2i
- Using Community Health Workers to Improve Linkage and Retention in Care at <u>https://targethiv.org/chw</u>

Through HAB's Special Projects of National Significance (SPNS) Program, HRSA funds demonstration projects focused on the development of effective interventions to respond quickly to emerging needs of people with HIV that receive assistance under the RWHAP. Through these demonstration projects, SPNS evaluates the design, implementation, utilization, cost, and health-related outcomes of innovative treatment models. Evaluating these models enables HRSA to identify successful interventions that can be replicated and disseminated nationally. SPNS findings have demonstrated promising new approaches for linking and retaining into care underserved and marginalized people with HIV. As resources permit RWHAP recipients are encouraged to review and integrate SPNS evidence-informed tools within their HIV system of care in accordance with the allowable service categories defined in <u>PCN 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds</u>. SPNS related tools may be found at the following locations:

• Integrating HIV Innovative Practices (IHIP) (<u>https://targethiv.org/ihip</u>) 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 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 (<u>https://targethiv.org/library/replication-resources-spns-systems-linkages-and-access-care</u>)

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 people with HIV.

• Dissemination of Evidence Informed Interventions

(https://targethiv.org/library/dissemination-evidence-informed-interventions) The Dissemination of Evidence-Informed Interventions initiative runs from 2015-2020 and disseminates four adapted linkage and retention interventions from prior SPNS and MHAF 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 (CATIs) that are replicable, cost-effective, capable of producing optimal HIV care continuum outcomes, and easily adaptable to the changing health care 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 estimates approximately \$75,000,000 to be available annually to fund up to 30 recipients. You may apply for a ceiling amount of up to \$7,000,000 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 2021 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 appropriately. The period of performance is April 1, 2021 through March 31, 2022 (1 year).

As noted, HRSA will cap FY 2021 ADAP ERF awards at a maximum of \$7,000,000 and a minimum of \$100,000, subject to the availability of funds. HAB 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, or the need for additional funding for a current or projected increase in

treatment needs aligned with ending the HIV epidemic, or other unanticipated increases in the number of clients in the program due to new diagnoses, re-engagement in care, client loss of income, and/or client loss of health care coverage. 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 make awards to all applicants that request funds to address a newly imposed waiting list and that are recommended for an award by the ORC based on their ORC scores.
- Once those funds are distributed, HRSA will award funds to remaining applicants based on their ORC scores.

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

III. Eligibility Information

1. Eligible Applicants

Eligible applicants are limited to RWHAP Part B states/territories that:

- reported to HRSA a current ADAP waiting list,
- have used the ADAP ERF to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and July 2020,
- need additional funding for a projected increase in treatment needs aligned with ending the HIV epidemic,
 - or
- need additional funding for other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.

All 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, 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 requirements.

States/territories that did not: 1. report a new ADAP waiting list to HRSA, or 2. use the ADAP ERF to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and July 2020, or 3. that do not have a projected increase in treatment needs aligned with ending the HIV epidemic, or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage, are not eligible to apply.

2. Cost Sharing/Matching

Cost sharing/matching is 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 <u>Section IV.4</u> non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.

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 notice of funding opportunity (NOFO) following the directions provided at <u>http://www.grants.gov/applicants/apply-for-grants.html</u>.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for each NOFO you are reviewing or preparing in the workspace application package in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.

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 included in the page limit 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. Please note: If you use an OMB-approved form that is not included in the workspace application package for the strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. It is therefore important 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.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1) You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are 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 you are 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.

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 319(e) of the Public Health Service (PHS) Act provides the Secretary of HHS with discretion upon request by a state or tribal organization to authorize the temporary reassignment of state, tribal, and local personnel during a declared federal public health emergency. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with § 319(e). Please reference detailed information available on the HHS Office of the Assistant Secretary for Preparedness (ASPR) website via

http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

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 <u>SF-424 Application Guide</u>. In addition, provide brief updated information, in this order:

- General demographics of the state/territory
- Demographics of the populations 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 "costcutting" and/or "cost-saving") or to address a current or projected increase in treatment needs aligned with ending the HIV epidemic, or other unanticipated increases in the number of clients in the program due to new diagnosis, reengagement in care, client loss of income, and/or client loss of health care coverage.
- 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, consistent with forms and attachments, 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 <u>Review Criterion 1 (Need)</u> 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-saving measures, or to address a current or projected increase in treatment needs aligned with ending the HIV epidemic during the period of performance or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.
- NEEDS ASSESSMENT -- Corresponds to Section V's <u>Review Criterion 1 (Need)</u> The purpose of this section is to demonstrate the need for additional resources to meet the projected ADAP client service needs for FY 2021.

A. State/Territory's ADAP 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 2020? (Yes/No)
- ii. Do you have an existing ADAP waiting list as of the date of this application? (Yes/No)
- iii. Did you use ADAP ERF funds to prevent, reduce, or eliminate an ADAP waiting list between January 2011 and July 2020? (Yes/No)
- iv. Do you currently have or project an increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage? (Yes/No)

Reminder: States/territories who answer "No" to all four questions above are not eligible to apply for ADAP ERF funds.

b) ADAP Funding Summary for FY 2019 and FY 2020

In a table format, please list all sources of funding for ADAP and the amounts received and expended during the FY 2019 period of performance (April 1, 2019 through March 31, 2020) and year-to-date for the FY 2020 period of performance (April 1, 2020 through March 31, 2021):

- 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) Cost-Cutting Measures for FY 2019 and FY 2020

Please identify which, if any, of the following cost-cutting measures were in place or newly implemented in FY 2019 and FY 2020 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, specify the amount and timeframe)
- iv. Drug-specific enrollment caps for antiretroviral medication (if so, specify)
- v. Reduction in formulary (if so, specify)
- vi. Decrease in financial eligibility criteria (if so, specify)
- vii. Other (please specify)

d) Cost-Saving Measures for FY 2019 and FY 2020

Please identify which, if any, of the following cost-saving measures were in place or newly implemented in FY 2019 and FY 2020 for your ADAP:

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

e) Client Utilization Summary for FY 2019 and FY 2020

- 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 any key factors impacting the ADAP's need for additional resources to prevent, reduce, or eliminate a waiting list or to address a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage. Include a description of why the ADAP is unable to meet the need with existing resources. You should support this discussion by including 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 2 calendar years (January 1, 2018 through December 31, 2019) that have affected the ADAP.
- Increases in clients engaged in care due to ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.
- 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 2 calendar 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 <u>Review Criterion 2 (Response)</u>

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 2021 ADAP ERF period of performance (April 1, 2021 through March 31, 2022). 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. Current projected annual average medication cost per client, and
- ii. All calculations used to determine such cost.

b) Health Insurance Assistance Costs

If requesting assistance for health insurance assistance, please provide:

- i. Current projected annual average insurance assistance cost per client, and
- ii. All calculations used to determine such cost.

2) Forecasting

a) States/Territories Requesting Funds to Purchase Medications or Health Insurance Assistance:

- 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 2021 RWHAP Part B funds, any RWHAP Part B carryover funds, funding provided by the state/territory, resources generated by rebates and program income, FY 2021 RWHAP Part A contributions, and any projected resources in addressing:
 - 1) Your projected/potential ADAP waiting list,
 - 2) Your current waiting list, and/or
 - 3) Your other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.

b) States/Territories Requesting Funds for other Cost-Cutting or Cost-Saving Measures:

For each proposed cost-cutting or cost-saving measure indicated in the work plan, describe the specific projected impact of ADAP ERF on enhancing costsaving measures, reversing cost-cutting measures, improving ADAP operations, and/or maximizing available ADAP resources.

 WORK PLAN -- Corresponds to Section V's <u>Review Criteria 2 (Response)</u> and <u>3 (Impact)</u>

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:

- 1) **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;
- 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 2021 ADAP ERF funds. SMART objectives are Specific—identifying target population and activity, Measurable—indicating how much or how many, Attainable—must be realistically accomplished using resources provided, Realistic—addressing and establishing reasonable programmatic steps, and Time-sensitive—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 2021 ADAP ERF.

B. Planned Services and Work Plan Narrative

Provide a narrative that describes the following for each planned service, costcontainment 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 12-month period of performance;

- 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 2021 (4/1/21-3/31/22) or address a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.

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.

- 1) Describe how you will monitor progress toward meeting the goals and objectives of the proposed period.
- 2) 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 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 clinical quality management program when implementing services funded through the ADAP ERF award.

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

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 or address a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage in FY 2021 (4/1/21-3/31/22). Please

describe for each of the following sections how the program has employed costcutting and/or cost-saving strategies in FY 2019 and FY 2020. 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 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 <u>Review Criteria</u> <u>4 (Resources/Capabilities)</u> and <u>5 (Support Requested)</u>

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.

iii. Budget

The directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's <u>SF-424 Application</u> <u>Guide</u> 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, may 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) you incur to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by you 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 2021 ADAP ERF funds allocated to prevent, reduce, and/or eliminate your waiting list or to address a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of the clients in the program who are newly diagnosed or re-engaged in care 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 "costsaving" measures to be charged to the FY 2021 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 Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 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</u>

<u>Application Guide</u> for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

iv. Budget Narrative

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

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. Any attachments referenced in a narrative section may be considered during the objective review.

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 and (5) Support Requested
Budget and Budget Narrative	(5) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

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. **Clearly label each attachment**.

Attachment 1: Work Plan (Required)

Attach the work plan for the project that includes all information detailed in <u>Section IV.2.ii. Project Narrative</u>.

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 each 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 timekeeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

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—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 key positions described in *Attachment 2*, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual not yet hired, 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 Data Universal Numbering System (DUNS) Number Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. Beginning in December 2020, the *DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following: <u>Planned UEI Updates in Grant Application Forms</u> and <u>General Service</u> <u>Administration's UEI Update</u> page.

You must also register with 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)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed 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.

*Currently, the Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (<u>http://www.dnb.com/duns-number.html</u>)
- System for Award Management (SAM) (https://www.sam.gov)
- Grants.gov (<u>http://www.grants.gov/</u>)

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

SAM.GOV ALERT: For your SAM.gov registration, you must submit a <u>notarized letter</u> appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages and the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications annually through SAM located at <u>SAM.gov</u>.

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 26, 2020 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar 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 Guide</u> for additional information.

5. Intergovernmental Review

AIDS Drug Assistance Program (ADAP) Emergency Relief Funds (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 <u>SF-424 Application Guide</u> for additional information.

HRSA-21-057

6. Funding Restrictions

You may request funding for a period of performance of up to 1 year, at no more than \$7,000,000 per year (inclusive of direct **and** indirect costs).

The General Provisions in Division A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) apply to this program. Please see Section 4.1 of HRSA's <u>SF-424</u> <u>Application Guide</u> for additional information. Note that these or other restrictions will apply in the following fiscal years, as required by law.

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).
- 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.

For further information regarding allowable and non-allowable costs, please refer to <u>https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters</u> and at <u>45 CFR 75 Subpart E Cost Principles</u>.

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 must be used for purposes for which the award was made. Rebates generated as a result of awarded funds must be used for the statutorily permitted purposes under the RWHAP Part B Program with a priority for ADAP. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at <u>45 CFR § 75.307</u>. Per <u>45 CFR Section 75.305(b)(5)</u>, to the extent available, you must disburse funds available from program income and rebates before requesting grant funds. Please see PCNs <u>15-03</u>: <u>Clarifications Regarding the Ryan</u> <u>White HIV/AIDS Program and Program Income</u> and <u>15-04</u>: <u>Utilization and Reporting of Pharmaceutical Rebates</u> for more information.

V. Application Review Information

1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has 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. 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. See the review criteria outlined below with specific detail and scoring points.

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

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, or to address a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.

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 or addressing a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage is feasible in addressing the problem.

State/Territory's ADAP Profile (10 points)

The strength, completeness, and clarity of the information in the State/Territory ADAP Profile for Fiscal Years 2019 and 2020.

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 or address a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage 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 <u>Methodology</u>, <u>Work</u> <u><i>Plan, and Resolution of Challenges</u>

The extent to which the proposed project responds to the "<u>Purpose</u>" 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 or addressing a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.

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 or addressing a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.

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 or addressing a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage.
- Evidence that funds allocated for each service/activity will be spent within the 12month period of performance.
- For applicants with an ADAP waiting list, proposed services/activities to reduce the number of persons on the 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 2021.

<u>State/Territory Actions to Address ADAP Challenges (15 points)</u> The strength and clarity of the following:

- The description of the specific challenges facing the ADAP in the following areas:
 - program efficiencies;
 - the ability to enroll clients in other payor sources;
 - ADAP resources; and/or
 - 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 or address a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnosis, re-engagement in care, client loss of income, and/or client loss of health care coverage in FY 2020.
- The data provided for each challenge area demonstrates how these strategies benefit the ADAP.

Criterion 3: IMPACT (10 points) – Corresponds to Section IV's <u>*Work Plan*</u> The strength and feasibility of the following:

- I he strength and feasibility of the following:
 - The applicant's description of how it will monitor progress toward meeting the proposed goals and objectives;
 - The applicant's description of how the proposed activities support the continued function of the ADAP;
 - The applicant's description of the anticipated outcomes resulting from ADAP ERF supported activities; and
 - The applicant's description of their ability to sustain the program beyond the FY 2021 ADAP ERF period of performance.

Criterion 4: RESOURCES/CAPABILITIES (10 points) – Corresponds to Section IV's <u>Organizational Information</u> and the <u>Staffing Plan</u> and <u>Biographical Sketches</u>, 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 <u>Organizational Information</u> and <u>Budget</u> and <u>Budget Narrative</u>

- The reasonableness of the proposed budget for the period of performance (1 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 objective 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 (e.g., geographical distribution) described below in selecting applications for award. See Section 5.3 of HRSA's <u>SF-424 Application Guide</u> 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 they meet the criteria for the preference(s) as follows:

Name of the funding preference: Current ADAP Waiting List

Qualification(s) to meet the funding preference(s): You will receive a funding preference if you demonstrate within the application that you have a current ADAP waiting list.

3. Assessment of Risk

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

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.

HRSA is required to review and consider any information about your organization that is in the <u>Federal Awardee Performance and Integrity Information System (FAPIIS</u>). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider your comments, in addition to other information in <u>FAPIIS</u> 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 (<u>45 CFR §</u> <u>75.212</u>).

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of April 1, 2021. See Section 5.4 of HRSA's <u>SF-424 Application Guide</u> for additional information.

2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's SF-424 Application Guide.

Requirements of Subawards

The terms and conditions in the 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 under awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See <u>45 CFR § 75.101 Applicability</u> 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 NOA.

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 <u>ADR webpage</u> for more information. Further information will be available in the NOA.

Program Terms Report. You must submit a Program Terms Report through the HRSA Electronic Handbook (EHB) using the format provided in that system. Further information will be available in the NOA.

VII. Agency Contacts

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

Patryce Peden Grants Management Specialist Division of Grants Management Operations, OFAM Health Resources and Services Administration 5600 Fishers Lane, Mailstop 10SWH03 Rockville, MD 20857 Telephone: (301) 443-2277 Email: <u>PPeden@hrsa.gov</u>

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

Susan Robilotto, D.O. Director, Division of State HIV/AIDS Programs HIV/AIDS Bureau Health Resources and Services Administration 5600 Fishers Lane, Room 09W52 Rockville, MD 20857 Telephone: (301) 443-6554 Email: <u>SRobilotto@hrsa.gov</u>

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: <u>support@grants.gov</u> Self-Service Knowledge Base: <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 <u>HRSA's Electronic Handbooks (EHBs</u>). For assistance with submitting information in the 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: <u>http://www.hrsa.gov/about/contact/ehbhelp.aspx</u>

VIII. Other Information

Technical Assistance

HRSA has scheduled following technical webinar:

Day and Date: Wednesday, August 19, 2020 Time: 1:30–3 p.m. ET Call-In Number: 1-888-989-4986 Participant Code: 3768014 Weblink: https://hrsa.connectsolutions.com/hab-hrsa-21-057-adap-erf-ta/

HAB will record the TA webinar and make it available on the <u>TargetHIV</u> 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 2021 ADAP ERF period of performance (April 1, 2021 – March 31, 2022). **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, 2020 to June 30, 2020 period. The calculations should incorporate all clients who received at least one medication through ADAP during the January 1, 2020 to June 30, 2020 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 (not health insurance) in the January 1, 2020 to June 30, 2020 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, 2020 to June 30, 2020 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, 2020 to June 30, 2020 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, 2020 to June 30, 2020 period. Multiply that amount by two to determine the average rebate reduction per client.

Note: 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, 2020 to June 30, 2020 period. Multiply that number by the dispensing fee for a single pharmacy prescription in the January 1, 2020 to June 30, 2020 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 Medication Cost per Client.

Step 1	In the January 1, 2020 to June 30, 2020 period, the ADAP spent a total of \$7,410,000 for prescription drugs; a total	\$7,410,000/1,000 = \$7,410 \$7,410 x 2 =	Baseline Average 6-Month Client Medication Cost Baseline Average Annual
	of 1,000 clients received at least one prescription medication.	\$14,820	Client Medication Cost
Step 2	In that same period, the ADAP received \$555,000 in total 340B rebates and \$100,000 in negotiated	\$555,000 + \$100,000 = \$655,000	Total Rebates Received by the ADAP
	rebates.	\$655,000/1,000 clients = \$655	Average 6-Month Client Rebate Reduction
		\$655 x 2 = \$1,310	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 = \$13,510	
Step 4	The ADAP filled 10,000 prescriptions in the January 1, 2020 to June	\$10 x 10,000 = \$100,000	Total Dispensing Fee Expenditures
	30, 2020 period of CY 2020 and the dispensing fee per prescription was \$10; 1,000 ADAP clients	\$100,000/1,000 clients = \$100	Average 6-Month Client Dispensing Fee

Example:

	received at least 1 ADAP prescription.	\$100 x 2 = \$200	Average Annual Client Dispensing Fee
Step 5	Add amount calculated in Step 3 to amount calculated in Step 4.	\$13,510 + \$200 = \$13,710	Average Annual Medication Cost per Client

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, and co-payments/coinsurance in the January 1, 2020 to June 30, 2020 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, 2020 to June 30, 2020 period on insurance deductibles, co-payments/co-insurance, and Medicare Part D TrOOP expenditures.

Step 3: Adjusted 6-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 6-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, 2020 to June 30, 2020 period. Multiply by two for average annual cost per client for insurance assistance.

Example:

The ADAP spent \$1,500,000 in the January 1, 2020 to June 30, 2020 period to pay
for insurance premiums and \$300,000 on co-payments/co-insurance, deductibles,
and TrOOP, providing assistance to 300 ADAP eligible clients.

Add insurance premiums	\$1,500,000 +	Total 6-Month
expenditures to expenditures	\$300,000 =	Insurance
for co-payments/co-insurance,	\$1,800,000	Expenditures
deductibles, and TrOOP.		
Determine the total amount of	\$50,000	Total 6-Month
rebates received by adding the		Rebates Received
manufacturers rebates received		
from January 1, 2020 to June		
30, 2020 on insurance co-		
payments/co-		
insurance/deductibles.		
Total 6-Month Insurance	\$1,800,000 -	Adjusted Total
Expenditures minus Total 6-	\$50,000 =	Insurance Cost
Month Rebates Received	\$1,750,000	
Divide Adjusted Total Insurance	\$1,750,000/300 =	Average 6-Month
Cost by total clients served.	\$5,833	Cost Per Client
Multiply the Average 6-Month		Insurance
Cost per Client by two to		Assistance
calculate the Average Annual	\$5,833 x 2 =	Average Annual
Cost per Client.	\$11,666	Cost Per Client for
·		Insurance
		Assistance
	expenditures to expenditures for co-payments/co-insurance, deductibles, and TrOOP. Determine the total amount of rebates received by adding the manufacturers rebates received from January 1, 2020 to June 30, 2020 on insurance co- payments/co- insurance/deductibles. Total 6-Month Insurance Expenditures minus Total 6- Month Rebates Received Divide Adjusted Total Insurance Cost by total clients served. Multiply the Average 6-Month Cost per Client by two to calculate the Average Annual	expenditures to expenditures for co-payments/co-insurance, deductibles, and TrOOP.\$300,000 = \$1,800,000Determine the total amount of rebates received by adding the manufacturers rebates received from January 1, 2020 to June 30, 2020 on insurance co- payments/co- insurance/deductibles.\$50,000Total 6-Month Insurance Expenditures minus Total 6- Month Rebates Received\$1,800,000 - \$50,000 = \$1,800,000 - \$50,000 = \$1,750,000Divide Adjusted Total Insurance Cost by total clients served. Multiply the Average 6-Month Cost per Client by two to calculate the Average Annual\$1,750,300 = \$5,833 x 2 =

Appendix B: Agreements and Compliance Assurances

FY 2021 Ryan White HIV/AIDS Program ADAP Emergency Relief Funds Awards Agreements and Compliance Assurances

I, the Governor of the State or Territory or his/her 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:

Pursuant to §§ 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.

These funds and services will be allocated and administered in accordance with the *FY* 2021 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: _____