HIV/AIDS Bureau

Division of State HIV/AIDS Programs

AIDS DRUG ASSISTANCE PROGRAM (ADAP) MANUAL

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HRSA
Ryan White HIV/AIDS Program

ADAP Manual – Updated June 2023

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Preface

The Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) AIDS Drug Assistance Program (ADAP) Manual is an informational resource for Ryan White HIV/AIDS Program (RWHAP) ADAP directors, RWHAP Part B directors, and staff. The RWHAP is administered by HAB, which is one of several offices and bureaus within HRSA. HRSA is an agency within the U.S. Department of Health and Human Services (HHS). ADAP is a state/territory-administered program authorized under RWHAP Part B to provide U.S. Food and Drug Administration (FDA)-approved medications to low-income clients with HIV. ADAPs may also use program funds to purchase health care coverage for eligible clients and for services that enhance access to, adherence to, and monitoring of antiretroviral therapy. Each state/territory operates an ADAP as part of the RWHAP Part B, and each ADAP is unique, varying in administrative structure and the mechanisms used to ensure HIV medications are available to eligible individuals with HIV.

The ADAP Manual serves as:

- An orientation guide for new ADAP staff, with sections explaining the purpose of ADAP, how it is structured at the federal and state/territory level, and the key issues and strategies used by ADAPs to ensure access to HIV medications to persons in need;
- A reference document for ADAP staff on legislative and program requirements;
- A tool to guide ADAPs in managing fiscal and program components. Overseeing a ADAP is an ongoing endeavor of refining and reassessing operations to ensure and expand access to HIV medications and pursue cost-saving and cost-cutting strategies within the complex and evolving U.S. and state/territory-specific health care systems; and
- A source for information about where to obtain additional information and technical assistance (TA).

Please note that HRSA HAB's Division of State HIV/AIDS Programs (DSHAP) also publishes the RWHAP Part B Manual, which covers the entire RWHAP Part B. The RWHAP Part B Manual presents an overview of the legislative and programmatic requirements of administering a RWHAP Part B grant, and that information is not repeated in this manual. Thus, the ADAP Manual and RWHAP Part B Manual should be used as companion documents. The RWHAP Part B Manual is available at: https://ryanwhite.hrsa.gov/grants/manage/recipient-resources.

Organization

The ADAP Manual includes sections that start with a general overview and move to specific items. Each section includes a series of chapters that cover related topics. Throughout, information is presented in subsections so ADAP staff can quickly find the information they need.

- The first section is most helpful to those new to ADAP as it presents basic information about the RWHAP, ADAP, and where to find information and assistance. Later sections cover more detailed ADAP management and technical issues.

- Legislative and program requirements are included in the front sections of most chapters, providing ADAP staff with essential information at the outset.
- Information on management of the RWHAP Part B grant is presented in the RWHAP Part B Manual and is not repeated in the ADAP Manual. The ADAP Manual and RWHAP Part B Manual should be used as companion documents. See the RWHAP Part B Manual online at: https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-grants-states-territories.

Summary of Changes

This manual includes the following key changes from the previous version (issued 2016:

- Incorporates requirements set forth in the Office of Management and Budget (OMB)'s release of the Uniform Administrative Requirements codified by HHS in 45 Code of Federal Regulations (CFR) part 75;
- Updates information to reflect HRSA HAB Policy Clarification Notices (PCN) published since the last manual update in 2015;
- Updates language to provide clarification on ADAP-specific issues based on questions received by HRSA HAB since the last manual update.

Routine Updates

HRSA HAB staff will review and update the ADAP Manual periodically and as needed to reflect changes in ADAP requirements and conditions. Recipients are encouraged to share recommendations for future enhancements to the manual or other feedback with their assigned HRSA HAB project officer (PO).

Section I. GENERAL INFORMATION ON THE RWHAP AND ADAP

I. Ch 1. Ryan White HIV/AIDS Program and HRSA

I. 1. A. The Ryan White HIV/AIDS Program

The RWHAP is codified in title XXVI of the Public Health Service (PHS) Act, 42 U.S.C. 300ff-11 et seq., and is the largest federal program focused exclusively on HIV care. The RWHAP awards grants to cities, counties, states/territories, and local community-based organizations for the provision of primary care and support services to more than half a million people with HIV who have no health care coverage (public or private), have insufficient health care coverage, or lack financial resources to get the care and treatment they need for their HIV. The majority of RWHAP funds support core medical services, including Outpatient/Ambulatory Health Services, and essential support services. A smaller but critical portion is used for technical assistance (TA), clinical training, and demonstration projects on innovative models of care.

RWHAP Parts

The RWHAP legislation divides the program into five Parts.

RWHAP Part A – Eligible Metropolitan Areas and Transitional Grant Areas

The RWHAP Part A provides grant funding for HIV core medical and support services to population centers most severely affected by the HIV epidemic, referred to as Eligible Metropolitan Areas (EMAs) and Transitional Grant Areas (TGAs). EMA eligibility requires an area to report more than 2,000 AIDS cases in the most recent five years. TGA eligibility requires an area to report 1,000 to 1,999 AIDS cases in the most recent five years. Both EMAs and TGAs must have a population of at least 50,000 people.

RWHAP Part B – States/Territories

Through authorities established in the RWHAP legislation and the Section 311(c) of the PHS Act, HRSA HAB awards the following grants to states/territories to improve the quality, availability, and organization of HIV health care and support services.

- RWHAP Part B HIV Care Grant Program (Activity Code X07), including:
    - RWHAP Part B Base funds to provide core medical and support services;
    - RWHAP ADAP Base funds to provide FDA-approved medications and purchase of health care coverage for low-income people with HIV with limited or no health coverage from private entities, Medicaid, or Medicare;
    - RWHAP ADAP Supplemental funds for eligible applicants who choose to apply to address a severe need for medication;
    - Emerging Communities (EC) supplemental funds for eligible applicants to enhance a comprehensive array of core medical and supportive services in metropolitan statistical areas (MSAs) reporting between 500 and 999 cumulative AIDS cases over the most recent five years; and

    - Minority AIDS Initiative (MAI) funds to provide education and outreach services to improve minority access to medication assistance programs, including ADAP.
- RWHAP Part B Supplemental Grant Program (Activity Code X08) for recipients with demonstrated need to supplement the HIV care and treatment services provided by the states/territories through the RWHAP Part B, including ADAP.
- ADAP Emergency Relief Funds (ERF) (Activity Code X09) to help states prevent, reduce, or eliminate ADAP waiting lists or implement cost-containment measures.[1]
- Ending the HIV Epidemic in the U.S. — Ryan White HIV/AIDS Program Parts A and B (Activity Code UT8) to help eligible states/territories implement strategies, interventions, approaches, and core medical and support services to reduce new HIV infections in the United States.[2]

RWHAP Part C – Community-Based Programs

The RWHAP Part C provides comprehensive primary health care in an outpatient setting for people with HIV. HRSA awards RWHAP Part C grants that include direct funding to local community-based medical care providers, such as ambulatory medical clinics, to support Outpatient/Ambulatory Health Services (OASHS) and support services through Early Intervention Services (EIS); and grant funding for planning grants to help organizations more effectively deliver HIV care and support services through capacity development.

RWHAP Part D – Women, Infants, Children, and Youth (WICY) with HIV and their Families

The RWHAP Part D provides outpatient, ambulatory, family-centered primary and specialty medical care for women, infants, children, and youth with HIV. Funding also may be used to provide support services to people with HIV and their affected family members.

RWHAP Part F – Demonstration and Training

The RWHAP Part F supports several research, TA, and access-to-care programs, as described below:

> ***The Special Projects of National Significance (SPNS) Program***
> Supports the development of innovative models of HIV care and treatment to respond to emerging needs of clients served by RWHAPs. The SPNS Program advances knowledge and skills in the delivery of health care and support services to underserved populations with HIV and build health information technology (HIT) capacity within the RWHAP community to report client-level data.

[1] Authority for ADAP ERF is 331(c) of the Public Health Service Act.
[2] Authority for Ending the HIV Epidemic is 331(c) of the Public Health Service Act.

The AIDS Education and Training Center (AETC) Program
Supports a network of eight regional centers (and more than 130 local affiliated sites) and two national centers that conduct targeted, multidisciplinary education and training programs for health care providers treating people with HIV. The AETC Program also includes the National HIV Curriculum, a free online curriculum.

Dental Programs
All RWHAP Parts can support the provision of oral health services. However, two RWHAP Part F programs focus on funding oral health care for people with HIV:

- The HIV/AIDS Dental Reimbursement Program (DRP) reimburses dental schools, hospitals with postdoctoral dental education programs, and community colleges with dental hygiene programs for a portion of uncompensated costs incurred by providing oral health treatment to patients with HIV.
- The Community-Based Dental Partnership Program (CBDPP) supports increased access to oral health care services for people with HIV while providing education and clinical training for dental care providers, especially those practicing in community-based settings.

Minority AIDS Initiative

MAI improves access to HIV care and health outcomes for disproportionately affected racial and ethnic minority populations. MAI funds awarded under RWHAP Parts A, C, and D are for services funded under the corresponding Part. MAI funds awarded under RWHAP Part B must be used for education and outreach to improve minority access to medication assistance programs, including ADAP.

For more information on the RWHAP, see **https://ryanwhite.hrsa.gov/about.**

For Congressional appropriations by Part, see **https://ryanwhite.hrsa.gov/about/budget.**

I. Ch 2. HRSA HAB Project Officers

HRSA HAB project officers (POs) are the key point of contact for RWHAP recipients. Each recipient is assigned a PO, with branch chiefs providing oversight to the project officers by region. POs provide guidance on legislative requirements, relevant HRSA HAB policy clarification notices, program letters, and grant requirements. POs also provide TA and can facilitate recipients' access to additional TA and training services. DSHAP also has an ADAP advisor to provide guidance and TA regarding ADAP and a clinical advisor to provide guidance and TA on clinical issues, including clinical quality management.

For more information about HRSA HAB, see the website at https://www.hrsa.gov/about/organization/bureaus/hab/index.html or contact a HRSA HAB PO at 301-443-6745, or visit HRSA HAB at https://ryanwhite.hrsa.gov/about/contacts.

I. Ch 3. RWHAP Legislation, HRSA Requirements, and Expectations

All RWHAP recipients must comply with RWHAP legislation and federal requirements and guidance implementing legislative provisions, as issued by HHS and HRSA. RWHAP recipients are required to follow federal grant requirements found in 2 CFR part 200, adopted by HHS in 45 CFR part 75; the HHS Grants Policy Statement; HRSA HAB policies and program letters; the RWHAP Part B five-year funding cycle Notice of Funding Opportunity (NOFO) guidance and annual Non-Competing Continuation (NCC) Progress Report requirements; and Notices of Award (NoA).

I. 3. A. RWHAP Legislation and ADAP

The latest RWHAP legislation is codified in title XXVI of the PHS Act. The legislation was first enacted in 1990 as the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. It has been amended and reauthorized four times: in 1996, 2000, 2006, and 2009; the authorization for appropriations expired in 2013, but the RWHAP will continue to operate as long as Congress appropriates funding. The RWHAP legislation has been amended with each reauthorization to accommodate new and emerging needs, such as an increased emphasis on funding of core medical services and changes in funding formulas. The RWHAP legislation has included a drug assistance component since its first iteration. The current legislative language for ADAP is:

> *Section 2616. 300ff–26 PROVISION OF TREATMENTS.*
>
> *(a) IN GENERAL.—A State shall use a portion of the amounts provided under a grant awarded under section 2611 to establish a program under section 2612(b)(3)(B) to provide therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.*
>
> *(b) ELIGIBLE INDIVIDUAL.—To be eligible to receive assistance from a State under this section an individual shall—*
>
> *(1) have a medical diagnosis of HIV/AIDS; and*
>
> *(2) be a low-income individual, as defined by the State.*
>
> *(c) STATE DUTIES.—In carrying out this section the State shall—*
>
> *(1) ensure that the therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary under subsection (e) are, at a minimum, the treatments provided by the State pursuant to this section;*
>
> *(2) provide assistance for the purchase of treatments determined to be eligible under paragraph (1), and the provision of such ancillary devices that are essential to administer such treatments;*

(3) provide outreach to individuals with HIV/AIDS, and as appropriate to the families of such individuals;

(4) facilitate access to treatments for such individuals;

(5) document the progress made in making therapeutics described in subsection (a) available to individuals eligible for assistance under this section; and

(6) encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring.

Of the amount reserved by a State for a fiscal year for use under this section, the State may not use more than 5 percent to carry out services under paragraph (6), except that the percentage applicable with respect to such paragraph is 10 percent if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection (a).

(d) DUTIES OF THE SECRETARY.—In carrying out this section, the Secretary shall review the current status of State drug reimbursement programs established under section 2612(2) and assess barriers to the expanded availability of the treatments described in subsection (a). The Secretary shall also examine the extent to which States coordinate with other grantees under this title to reduce barriers to the expanded availability of the treatments described in subsection (a).

(e) LIST OF CLASSES OF CORE ANTIRETROVIRAL THERAPEUTICS.—

For purposes of subsection (c)(1), the Secretary shall develop and maintain a list of classes of core antiretroviral therapeutics, which list shall be based on the therapeutics included in the guidelines of the Secretary known as the Clinical Practice Guidelines for Use of HIV/AIDS Drugs, relating to drugs needed to manage symptoms associated with HIV. The preceding sentence does not affect the authority of the Secretary to modify such Guidelines.

(f) USE OF HEALTH INSURANCE AND PLANS.—

(1) IN GENERAL.—In carrying out subsection (a), a State may expend a grant under section 2611 to provide the therapeutics described in such subsection by paying on behalf of individuals with HIV/AIDS the costs of purchasing or maintaining health insurance or plans whose coverage includes a full range of such therapeutics and appropriate primary care services.

(2) LIMITATION.—The authority established in paragraph (1) applies only to the extent that, for the fiscal year involved, the costs of the health insurance or plans to be purchased or maintained under such paragraph do not exceed the costs of otherwise providing therapeutics described in subsection (a).

(g) DRUG REBATE PROGRAM.—A State shall ensure that any drug rebates received on drugs purchased from funds provided pursuant to this section are applied to activities supported under this subpart, with priority given to activities described under this section.

For more information, see the entire RWHAP legislation at https://ryanwhite.hrsa.gov/about/legislation.

I. 3. B. HRSA HAB Policies

HRSA HAB releases policy notices (PNs) and policy clarification notices (PCNs) to restate or clarify requirements in the RWHAP legislation. HRSA also releases program letters, which provide additional guidance and information. PNs, PCNs and program letters are available at HRSA HAB's website. HRSA HAB also provides additional programmatic implementation guidance in program-specific manuals (e.g., RWHAP Part B and ADAP manuals). Recipients are required to follow HRSA HAB policies and program letters. Recipients are strongly encouraged to review all PNs, PCNs, program letters, and program manuals. Unless otherwise noted, policies relevant to RWHAP Part B are relevant to ADAP as well.

HRSA HAB Policies with Particular Relevance to ADAP

PCN #*	Title
07-02	The Use of RWHAP Funds for HIV Diagnostics and Laboratory Test Policy
07-03	The Use of RWHAP Part B ADAP Funds for Access, Adherence and Monitoring Services
12-02	Part A and Part B Unobligated Balances and Carryover Provisions
13-01	Clarifications Regarding Medicaid-Eligible Clients and Coverage of Services by the RWHAP
13-03	RWHAP Client Eligibility Determinations: Considerations Post-Implementation of the Affordable Care Act
13-04	Clarifications Regarding Clients Eligible for Private Health Insurance and Coverage of Services by the RWHAP
14-01	Clarifications Regarding the RWHAP and Reconciliation of Premium Tax Credits under the Affordable Care Act
15-01	Treatment of Costs under the 10% Administrative Cap for Ryan White HIV/AIDS Program Part A, B, C, and D
15-02	Clinical Quality Management
15-03	Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income
15-04	Utilization and Reporting of Pharmaceutical Rebates
16-01	Clarification of the RWHAP Policy on Services Provided to Veterans
16-02	Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds
18-01	Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance
18-02	The Use of Ryan White HIV/AIDS Program Funds for Core Medical Services and Support Services for People Who Are Incarcerated and Justice-Involved

PCN #*	Title
21-02	Determining Client Eligibility & Payor of Last Resort in the Ryan White HIV/AIDS Program

**Policy Clarification Number (the first number reflects the year the PCN was released or last revised)*

Program Letters with Particular Relevance to ADAPs

Date	Letter Topic
8/10/2000	Ability of use of RWHAP funds for Medicaid beneficiaries if the program does not cover a particular service benefit
4/29/2005	Ability of ADAPs to submit for full rebates on partial payments
11/23/2010	ADAP data sharing with CMS
12/2/2010	Prohibition on use of RWHAP funds for PrEP
2/25/2013	Requirements regarding confirmation of HIV diagnosis
11/18/2014	Reporting of CD4 count tests
2/13/2015	Encouragement to add Hepatitis C medications to ADAP formularies
6/11/2015	RWHAP services in support of the HIV Care Continuum
6/22/2016	The Ryan White HIV/AIDS Program and Pre-Exposure Prophylaxis (PrEP) letter
12/12/2017	Retirement of 11-06 AIDS Drug Assistance Program: Use of Funds, Eligibility and Formulary Parity, Administration, Quality Assurance and Cost-Savings
12/4/2019	ADAP Long-Acting Antiretroviral Guidance
3/23/2023	Medicaid Continuous Enrollment Unwinding for the Ryan White HIV/AIDS Program
4/26/2023	Role of RWHAP in Addressing STIs and Mpox
5/11/2023	ADAP Recipients and Buprenorphine and Naloxone

Retired/Replaced PCNs and Program Letters with Particular Relevance to ADAP

PL/PCN	Topic/Title	Deposition
PL 11/16/12	Use of and Reporting of Rebate Funds	Replaced by PCN 15-04
PCN 07-05	The Use of RWHAP Part B ADAP Funds to Purchase Health Insurance	Replaced by PCN 18-01
PCN 11-06	ADAP: Use of Funds, Eligibility and Formulary Parity, Administration, Quality Assurance and Cost-Savings	Retired December 2017
PCN 13-02	Clarifications on RWHAP Client Eligibility Determinations and Recertifications Requirements (revised 5/1/2019)	Replaced by PCN 21-02
PCN 13-05	Clarifications Regarding Use of RWHAP Funds for Premium and Cost-Sharing Assistance for Private Health Insurance	Replaced by PCN 18-01

PCN 13-06	Clarifications Regarding Use of RWHAP Funds for Premium and Cost-Sharing Assistance for Medicaid	Replaced by PCN 18-01

For more information, see all the HRSA HAB Policies for the RWHAP at https://ryanwhite.hrsa.gov/grants/policy-notices and see all the HRSA HAB Program Letters for the RWHAP at https://ryanwhite.hrsa.gov/grants/program-letters.

I. 3. C. Key HRSA HAB Program Requirements and Expectations

ADAP is a component of the RWHAP Part B grant. There are a number of ADAP-specific requirements for RWHAP Part B recipients—a table summarizing key ADAP requirements can be found in Appendix 1. As of fiscal year 2017, the primary RWHAP Part B HIV Care Grant Program (X07) moved to a five-year funding cycle. For the first fiscal year of the funding cycle, HRSA releases a NOFO to provide instructions to RWHAP Part B recipients for preparing the grant application. For the remaining four years of the funding cycle, the recipients complete an annual Non-Competing Continuation (NCC) Progress Report. The NOFO includes sections on ADAP and ADAP Supplemental funds. The NOFO also outlines the following requirements:

- **Data Reporting:** RWHAP Part B recipients are required to submit an annual data report to HRSA HAB called the ADAP Data Report (ADR). The ADR provides HRSA HAB with information about each ADAP's model, a demographic profile of the clients served, and service and expense data, which is used to describe the program by state/territory and nationwide. More information on the ADR can be found in Section II, Chapter 4.B.
- **Clinical Quality Management and HRSA HAB Performance Measures:** RWHAP Part B recipients are required to have a clinical quality management (CQM) program. HRSA HAB provides policy guidance and TA regarding CQM. HRSA HAB has created performance measures that RWHAP recipients can choose to use to monitor the quality of care provided. The measures can be used at the service provider or system level, in their current format or further modified to meet recipient and subrecipient needs. If an ADAP serves more than 50 percent of a state/territory's RWHAP Part B clients, the recipient is required to identify two performance measures and collect the corresponding performance measure data for ADAP.

  For more information, see the performance measures at: https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio.
- **HIV Treatment Guidelines:** HHS develops treatment guidelines on the appropriate administration of HIV treatments, including antiretroviral therapies and medications for the prevention and treatment of opportunistic infections (HHS treatment guidelines) (https://clinicalinfo.hiv.gov/en/guidelines). These guidelines are regularly updated by expert panels using the latest scientific research findings. ADAPs and other RWHAP recipients that provide medications to treat people with HIV must ensure clients receive medication therapies consistent with current HHS treatment guidelines.

All HHS award recipients are notified of grant requirements in an NoA. The NoA provides the total amount of RWHAP Part B funds awarded for that fiscal year, as well as a breakdown of

funding, including the ADAP Base award and the ADAP Supplemental funding (as relevant). NoAs are issued annually.

For more information, see the latest NOFO via the website at https://www.grants.gov/, or the HHS Grants Policies and Regulations at https://www.hhs.gov/about/agencies/asfr/ogapa/grants/index.html.

I. Ch 4. Key Resources for RWHAP Recipients

In addition to the following information, a table of key resources can be found in Appendix 2.

I. 4. A. Glossary/Definitions and Acronyms

Here are links to glossaries on HIV terms and acronyms, including those used by the RWHAP, ADAP-specific terms, and HIV medication and treatment terms:

- **RWHAP Glossary:** Included here are definitions of RWHAP Parts, federal agencies, and other program terms prepared by HRSA HAB. See the definitions at: https://targethiv.org/library/glossary.
- **RWHAP Service Categories:** Current RWHAP service category definitions can be found in PCN 16-02, "Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds."

  For more information, see the website at https://ryanwhite.hrsa.gov/grants/policy-notices.
- **HIV Medications and Treatments:** Drug database, antiretroviral, and treatment definitions. Maintained by HHS's HIVInfo.NIH.gov. See the glossary at https://clinicalinfo.hiv.gov/en/glossary and the drug database at https://clinicalinfo.hiv.gov/en/drugs.

I. 4. B. National Initiatives

National initiatives and other legislation also have an impact on the RWHAP, including ADAP. Of particular note are:

- **Ending the HIV Epidemic in the U.S (EHE):** In February 2019, the Administration announced a new initiative, Ending the HIV Epidemic in the U.S. (see https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview). This 10-year initiative began in FY 2020 to reduce new HIV infections in the United States by 90 percent by 2030. This level of reduction would mean that HIV transmissions would be rare and would meet the definition of ending the epidemic. Across the United States, the EHE promotes and implements four strategies to substantially reduce HIV transmissions:
  - **Diagnose** all people with HIV as early as possible;
  - **Treat** people with HIV rapidly and effectively to reach sustained viral suppression;
  - **Prevent** new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs); and

    - **Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.
- **National HIV/AIDS Strategy (2022-2025):** The National HIV/AIDS Strategy for the United States (2022-2025) (NHAS) (see https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025) is a roadmap for stakeholders across the United States to accelerate efforts to end the HIV epidemic by 2030. RWHAP promotes robust advances and innovations in HIV health care using NHAS as its framework to end the epidemic. Therefore, to the extent possible, activities funded by RWHAP focus on addressing the following four goals:
    - Prevent new HIV infections;
    - Improve HIV-related health outcomes for people with HIV;
    - Reduce HIV-related health disparities and health inequities; and
    - Achieve integrated and coordinated efforts that address the HIV epidemic among all partners and stakeholders.

  To achieve these shared goals, recipients should, within the parameters of the RWHAP legislation and program guidance, align organizational efforts to ensure that people with HIV are linked to and retained in care, and have timely access to HIV treatment and the supports needed (e.g., mental health and substance use disorder services) to achieve HIV viral suppression.
- **HIV Care Continuum:** The HIV care continuum consists of five stages, including: HIV diagnosis, linked to care, engaged or retained in care, prescribed antiretroviral therapy, and viral suppression.[3] 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 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 HIV surveillance programs, community partners, and other federally funded programs to create a full data set that measures outcomes for people with HIV across the HIV care continuum. Additionally, HRSA recommends using variables (e.g., age, gender, race/ethnicity, and housing status) to stratify the data across the HIV care continuum as a means of identifying those subpopulations less likely to achieve positive health outcomes.

[3] HIV.gov. What is the HIV Care Continuum? https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum Last updated June 21, 2021. Accessed April 2022.

I. 4. C. Technical Assistance for RWHAP Recipients

RWHAP recipients can access many resources to help in managing programs.

- The first point of contact for help is the **HRSA HAB PO**, who can provide TA directly, as well as facilitate access to HRSA HAB-funded training and TA resources.

  The name of your PO and their contact information can be found in your EHBs grant folder.
- **HRSA HAB National Monitoring Standards** (NMS) for RWHAP Part A and Part B recipients is a TA resource to support recipients and subrecipients in meeting federal requirements for program and fiscal management, monitoring, reporting and oversight of the RWHAP Parts A and B, and to improve program efficiency and responsiveness. The NMS consolidates requirements set forth in relevant authorities and outlines suggested "standards" for how recipients and subrecipients can meet those requirements. As such, the NMS does not establish or impose legislative, regulatory, or programmatic requirements; but rather provides guidance on how recipients, lead agency, and consortia can meet requirements and monitor those who have been issued subawards. The standards apply to ADAPs and have particular relevance to with respect to eligibility criteria and CQM. To ensure their programs meet the statutory and funding requirements, recipients are encouraged to implement the RWHAP Part A and Part B NMS at the recipient and service provider/subrecipient levels. TA on compliance with the NMS is available through the HRSA HAB PO.
  For more information, see the NMS website at:
  https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/2022-rwhap-nms-part-b.pdf.
- The **TargetHIV website**, funded by HRSA HAB, collects tools and best practices from HRSA and RWHAP recipients across the country. It also contains information on upcoming trainings and webinars and has archived copies of past webinars on a variety of topics related to the RWHAP.
  Learn more about TA and training for RWHAP recipients at: https://targethiv.org/

I. Ch 5. Introduction to ADAP

I. 5. A. Purpose of the AIDS Drug Assistance Program

By statute and as defined in PCN 16-02, "The AIDS Drug Assistance Program (ADAP) is a state-administered program authorized under RWHAP Part B to provide U.S. Food and Drug Administration (FDA)-approved medications to low-income clients living with HIV who have no coverage or limited health care coverage…ADAPs can also provide access to medications by using program funds to purchase health care coverage and through medication cost sharing for eligible clients. ADAPs must assess and compare the aggregate cost of paying for the health care coverage versus paying for the full cost of medications to ensure that purchasing health care coverage is cost effective in the aggregate. ADAPs may use a limited amount of program funds

for activities that enhance access to, adherence to, and monitoring of antiretroviral therapy with prior approval."

I. 5. B. ADAP within the RWHAP

The RWHAP is the largest source of federal funding specifically directed to provide core medical services and support services for people with HIV. As noted previously, RWHAP Part B funding is used to assist states/territories in developing and/or enhancing access to a comprehensive continuum of high-quality care for low-income people with HIV who have limited or no public or private health care coverage. ADAP is funded through Part B of the RWHAP legislation and is classified as a core medical service.

Through the provision of access to HIV medications, ADAP is a critical component of the continuum of primary care and treatment for people with HIV. Other RWHAP-funded services and recipients work in conjunction with ADAPs to bring people into a system of care and provide them with quality treatment and services.

In addition to ADAP, medications can be paid for by other RWHAP-funded recipients under the following service categories[4]:

- Outpatient/Ambulatory Health Services
- AIDS Pharmaceutical Assistance (which includes Community Pharmaceutical Assistance Program and Local Pharmacy Assistance Program [LPAP])
- Emergency Financial Assistance
- Hospice Services
- Substance Abuse Outpatient Care
- Substance Abuse Services (residential)

Coordination between the ADAP and other RWHAP recipients is crucial to ensure that the most cost-effective method of reaching the maximum number of eligible clients with medication is utilized. See I.5.D. for a comparison of ADAP and LPAP.

For more information, see the ADAP website at https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-adap.

I. 5. C. History of ADAP

ADAP started as a HRSA demonstration project in 1987 to provide low-income individuals with HIV access to azidothymidine (AZT) (zidovudine, Retrovir), the first drug approved by the FDA to treat HIV disease. The annual cost of this drug—at the time about $10,000 per year per person—placed it out of the reach of most people with HIV. Congress responded by approving $30 million in funding under a public health emergency provision, laying the groundwork for

[4] The Health Insurance Premium and Cost Sharing Assistance service category can be used by RWHAP Part B and other RWHAP-funded recipients to pay for cost-sharing, co-payments, and deductibles for clients with health care coverage.

what would be the ADAP. These demonstration projects were rolled into the Ryan White CARE Act in 1990, receiving funding through that program with the 1991 appropriation. The ADAP Base funding was first appropriated as a separate budget line in 1996.

ADAPs have expanded considerably in terms of numbers of enrolled clients, program resources, and the complexity of program management and operations since Congress first appropriated funds for RWHAP in 1991 and first permitted ADAP to pay for health care coverage costs in 2000.

For more information, see the ADAP website at: https://ryanwhite.hrsa.gov/about/history.

I. Ch 6. ADAP Funding

Most ADAPs are funded through a range of local, state/territory, and federal resources. All funds allocated to ADAP, regardless of source, are subject to the RWHAP statute as well as HRSA HAB policies, program guidance, and grant requirements.

I. 6. A. ADAP-Specific Funding

There are four separate grant awards under RWHAP Part B: the RWHAP Part B HIV Care Program, including ADAP (Activity Code X07); RWHAP Part B Supplemental (Activity Code X08); ADAP Emergency Relief Funds (Activity Code X09); and Ending the HIV Epidemic in the U.S. — Ryan White HIV/AIDS Program Parts A and B (Activity Code UT8); each is applied for and awarded separately. Funding is determined through formula and demonstrated need, depending on the grant. The following summarizes grant funding that is ADAP-specific (i.e., is intended solely for ADAP-fundable services) and how the funds are applied for and determined. Please note that RWHAP Part B MAI funding, while ADAP-related, cannot be used to purchase medications or health care coverage. RWHAP Part B MAI is covered in the next chapter.

- **ADAP Base**: The primary source of federal funding for ADAP is through the ADAP Base award component within the RWHAP Part B HIV Care Grant Program (X07) award. RWHAP ADAP Base funding is distributed using a funding formula based on the number of reported living cases of HIV/AIDS cases in the state or territory in the most recent calendar year as confirmed by CDC. The ADAP Base award can only be expended for allowable costs related to the ADAP service category and ADAP administrative, planning and evaluation, and clinical quality management costs. These funding restrictions continue when the ADAP Base funds are carried over into a future budget period. The RWHAP Part B HIV Care Grant Program (X07) award is, as of FY 2017, funded on a five-year cycle. States/territories are required to submit an application prior to the first year of an X07 award, and then submit an NCC Progress Report prior to receiving funding in years two through five.
- **ADAP Supplemental**: The X07 award also includes the ADAP Supplemental award, which is distributed using a funding formula to states/territories that meet the eligibility criteria as outlined in the RWHAP statute and that choose to apply for additional funding

to address a severe need for medications as part of the X07 application or NCC Progress Report. Section 2618(a)(2)(F)(ii) of the PHS Act states that 5 percent of the ADAP appropriation will be reserved as supplemental funding to purchase medications for states/territories with demonstrated severe need. The X07 NOFO and the NCC Progress Report instructions outline the ADAP Supplemental eligibility criteria.

- **ADAP Emergency Relief Funds (ERF)**: The ADAP ERF (X09) is a competitive grant intended for states/territories that can demonstrate the need for additional resources to prevent, reduce, or eliminate ADAP waiting lists, including through cost-containment measures (i.e., "cost-cutting" and/or "cost-saving"). An Objective Review Committee (ORC) reviews and scores the applicant's responses to criteria published in the annual X09 NOFO, and gives priority to addressing waiting lists.

I. 6. B. Non-ADAP-Specific RWHAP Part B Funding:

- **RWHAP Part B Base:** In addition to the ADAP Base component of the X07 award, recipients can choose to use RWHAP Part B Base funds from the X07 award for ADAP.
- **RWHAP Part B Supplemental:** The RWHAP Part B Supplemental (X08) grant is a competitive award for states/territories that demonstrate the need for additional RWHAP Part B funds using quantifiable data. RWHAP Part B recipients can choose to apply for funding and, if awarded, can use these additional grant funds for their ADAP. An Objective Review Committee (ORC) reviews and scores the applicant's responses to criteria published in the annual X08 NOFO.
- **Ending the HIV Epidemic in the U.S. — Ryan White HIV/AIDS Program Parts A and B:** The HAB EHE award is meant to help eligible states/territories implement strategies, interventions, approaches, and core medical and support services to reduce new HIV infections in the United States. States that receive an EHE (UT8) award may choose to use some of the award to cover the medication and health care coverage costs of clients brought into the ADAP through EHE efforts.

I. 6. C. Other Funding:

Recipients can choose to allocate other funding to ADAP, including federal, state/territory, and local resources. ADAP-generated program income and rebates can also be allocated to the ADAP, since they must be used for RWHAP Part B allowable services, with (for rebates) priority given to ADAP. See Section I, Chapter 7 below for more information on the use of program income and rebates within ADAP.

I. 6. D. ADAP and LPAP

An LPAP allows an RWHAP Part A or Part B recipient to provide ongoing assistance to HIV/AIDS medications to eligible clients outside of an ADAP. An LPAP is similar to ADAP in many of its requirements but is implemented by the RWHAP Part A or Part B recipient (or its subrecipients) outside of the ADAP. As defined in PCN 16-02, "A Local Pharmaceutical Assistance Program (LPAP) is operated by a RWHAP Parts A or B (non-ADAP) recipient or subrecipient as a supplemental means of providing ongoing medication assistance when an ADAP has a restricted formulary, waiting list and/or restricted financial eligibility criteria."

RWHAP Parts A or B recipients using the LPAP to provide AIDS pharmaceutical assistance must establish the following:

- Uniform benefits for all enrolled clients throughout the service area;
- A recordkeeping system for distributed medications;
- An LPAP advisory board;
- A drug formulary that is approved by the local advisory committee/board and consists of HIV-related medications not otherwise available to the clients due to the elements mentioned above;
- A drug distribution system;
- A client enrollment and eligibility determination process that includes screening for ADAP and LPAP eligibility with rescreening at minimum of every six months;
- Coordination with the state's ADAP (a statement of need should specify restrictions of the ADAP and the need for the LPAP); and
- Implementation in accordance with requirements of the HRSA 340B Drug Pricing Program, including the Prime Vendor Program.

LPAP funds are not to be used for emergency or short-term financial assistance, including providing medications while awaiting ADAP eligibility determination. The Emergency Financial Assistance service category may assist with short-term assistance for medications.

For more information, see the website at PCN 16-02, "Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds."

I. Ch 7. Rebates and Program Income

Pharmaceutical rebates and program income can be generated through the provision of ADAP services. This manual covers information about the generation of pharmaceutical rebates and program income through ADAP. The RWHAP Part B Manual covers information about the generation of program income through RWHAP Part B-funded services and rules about the expenditure and tracking of both program income and rebates.

All revenues directly generated by a federal dollar, whether as program income or rebates, are subject to federal expenditure rules. RWHAP Part B recipients should proactively project the receipt of rebates and program income and develop a budget and expenditure plan that incorporates all available funds, including federal funds, program income, and rebate funds. HRSA HAB encourages recipients to explore funding services allowable under RWHAP core and support service categories that address unmet need and service gaps identified in planning processes as a part of ongoing RWHAP Part B development efforts.

I. 7. A. Rebates

HRSA HAB provides guidance on rebates in PCN 15-04, "Utilization and Reporting of Pharmaceutical Rebates." An ADAP that purchases medications through a retail pharmacy

network at a price higher than the 340B price can submit claims to drug manufacturers for rebates on full-pay medications or medication co-payments, coinsurance, or deductibles to achieve cost savings comparable to those received by an ADAP that directly purchases medications at the 340B price.[5]

The RWHAP legislation states: "A State shall ensure that any drug rebates received on drugs purchased from funds provided pursuant to this section *[ADAP]* are applied to activities supported under this subpart *[RWHAP Part B]*, with priority given to activities described under this section *[ADAP]*" (section 2616(g) of the PHS Act (42 U.S.C. 300ff–26 (g)). As such, all 340B rebates directly generated by a federal dollar are subject to HRSA HAB's rebate policies and rules for expenditure. All rebates generated through ADAP must be used for RWHAP Part B activities, with priority given to ADAP. Recipients do not need prior approval from HRSA to use rebates for an allowable expense, even in cases where the use of grant funds would require approval (e.g., purchasing a vehicle).

Recipients are required to track and account for all pharmaceutical rebates in accordance with 45 CFR §75.302(b)(3).

For more information, see the RWHAP Part B Manual.

I. 7. C. Program Income

Program income means the gross income earned by the non-federal entity that is directly generated by a supported activity or earned as a result of the federal award during the period of performance (or budget period for grants that have a multiyear period of performance), except as provided in 45 CFR §75.307(f). Except as otherwise provided in federal statutes, regulations, or the terms and conditions of the federal award, program income does not include pharmaceutical rebates, credits, discounts, and interest earned on any of them. In the context of the ADAP, program income is most commonly generated by billing third-party insurance the usual and customary cost for medications sold to ADAP clients for medications purchased at 340B pricing.

PCN 15-03, "Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income," provides guidance on the use of program income derived from RWHAP-funded services, including ADAP, to further eligible project or program objectives and/or to cover program costs. PCN 15-03 also includes the requirements of expenditure of program income.

For more information, see PCN 15-03, "Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income," and the RWHAP Part B Manual.

[5] Please note: ADAPs may have access to sub-340B pricing for certain medications through the ADAP Crisis Task Force or other negotiations. Please see Section IV, Chapter 1.

I. Ch 8. RWHAP Part B Minority AIDS Initiative (MAI)

The RWHAP legislation states that MAI funds awarded to RWHAP Part B recipients are: "for grants used for supplemental support education and outreach services to increase the number of eligible racial and ethnic minorities who have access to treatment through (ADAP)" (section 2693(b)(2)(B) of the PHS Act (42 USC 300ff-121)). The legislation states that racial and ethnic minorities include: "African Americans, Alaska Natives, Latinos, American Indians, Asian Americans, Native Hawaiians, and Pacific Islanders." The amount of the RWHAP Part B MAI award is determined by a formula based on the number of reported living racial/ethnic minority HIV/AIDS cases for the most recent calendar year as confirmed by CDC.

The parameters for the use of RWHAP Part B MAI outlined in the legislation are narrow—Part B MAI funds can only be used for education and outreach services for the specific purpose of increasing racial/ethnic minority enrollment in ADAP. Recipients must design MAI-funded services that meet this specific intent along with other funding requirements. The state/territory provides an MAI Plan Narrative that describes the planned education and outreach services in the RWHAP Part B HIV Care Grant Program (X07) full grant application at the start of the five-year period of performance and the NCC Progress Report at the start of each budget period during years two through five of the period of performance. The state/territory also submits an MAI Annual Plan that provides more specific information, including deliverables, geographic locations of and types of agencies and staff to provide services, coordination with existing services and service providers, and the involvement of targeted minority populations in implementation of the plan.

Increasing Racial/Ethnic Minority Enrollment in ADAP

Given the legislative intent of the RWHAP Part B MAI funding to increase racial/ethnic minority enrollment in ADAP, the recipient must be able to assess the effectiveness of the RWHAP Part B MAI-funded activity on minority enrollment into ADAP or another medication assistance program. To improve the effectiveness of RWHAP Part B MAI-funded activities, recipients should use data to identify specific racial/ethnic minority groups or sub-groups who are experiencing disparities in access to medications or disparities in HIV health, and design activities or services for them.

Three Key Components of RWHAP Part B MAI-funded services:

- Targeted Activities
- Targeted Audiences
- Assessment of Effectiveness

Education and Outreach

As noted, the only allowable services for RWHAP Part B MAI listed in the legislation are education and outreach. The terms "education" and "outreach" should be interpreted in light of the legislative intent of RWHAP Part B MAI funds to increase racial/ethnic minority participation in ADAP or another medication assistance program. Recipients may find it helpful to think of allowable RWHAP Part B MAI services in terms of "education about HIV

medications and treatment adherence" and "outreach for enrollment and re-engagement in ADAP." With these parameters in mind, recipients may fund a variety of outreach and education activities or services to meet the legislative intent of the funding. These activities may include community and public awareness activities that provide information about ADAP and are targeted to minority communities of interest. All activities funded with RWHAP Part B MAI funds must be assessed for effectiveness.

I. Ch 9. Access, Adherence, and Monitoring Services (Flexibility Policy)

The RWHAP legislation includes the state/territory's responsibility under ADAP to provide outreach, to facilitate access to treatment, and to support adherence. While ADAP funds are largely devoted to paying for HIV medications and health care coverage, a limited amount of funds can, with approval from HRSA HAB, be used to improve access to medications, increase adherence to medication regimens, and help clients monitor their progress in taking HIV-related medications.

I. 9. A. Legislation, HRSA HAB Program Requirements, and Expectations

The RWHAP legislation states the following regarding outreach, access, adherence, and monitoring:

> *Section 2616(c) STATE DUTIES.—In carrying out this section the State shall—…*
>
> *(3) provide outreach to individuals with HIV/AIDS, and as appropriate to the families of such individuals;*
>
> *(4) facilitate access to treatments for such individuals;…*
>
> *(6) encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring.*
>
> *Of the amount reserved by a State for a fiscal year for use under this section, the State may not use more than 5 percent to carry out services under paragraph (6), except that the percentage applicable with respect to such paragraph is 10 percent if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection (a).*

PCN 07-03, "The Use of Ryan White HIV/AIDS Program, Part B ADAP Funds for Access, Adherence, & Monitoring Services," provides further guidance that states/territories may request use of up to 10 percent in "extraordinary circumstances."

States/territories that want to use ADAP funds under the Flexibility Policy must request permission to do so in the ADAP Flexibility section of the RWHAP Part B HIV Care Grant Program (X07) application, NCC Progress Report, or through a prior authorization request in the Electronic Handbooks (EHBs) during the budget period. As a component of the request, states/territories must provide a narrative description that includes the proposed RWHAP service

categories to be funded to support access, adherence, and/or monitoring; the cost for each service; and the number of clients who will directly benefit from each of the proposed services. Complete instructions are provided each year in the RWHAP Part B HIV Care Grant Program (X07) NOFO or NCC Progress Report instructions. If a state/territory is requesting permission to use ADAP funds under the Flexibility Policy through the prior authorization process, the Flexibility Policy activities can be used for allowable RWHAP services that exceed what was included in the state's X07 implementation work plan. Recipients are notified of approval to use ADAP funds under the Flexibility Policy in the RWHAP Part B HIV Care Grant Program (X07) NoA. If permission is granted after the final X07 NoA has been released, a revised NoA will be released to reflect this permission.

I. 9. B. Access, Adherence, and Monitoring Services

As noted, the only allowable uses under the Flexibility Policy listed in the legislation are to "encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring." The legislation does not further define adherence and monitoring, but HRSA HAB PCN 07-03 provides a description of allowable services. Monitoring services can include relevant laboratory tests.

HRSA HAB recognizes that a range of allowable RWHAP services can support access to ADAP and medication adherence and monitoring. RWHAP Part B recipients requesting the use of the Flexibility Policy are not limited to which RWHAP service categories they could choose to fund if they demonstrate how each service category supports one or more of the allowable uses of the Flexibility Policy.

Although funded through ADAP Base dollars, Flexibility Policy services are not reported on the ADAP Data Report (ADR).

I. 9. C. Conditions for the Use of Funding for ADAP Flexibility

As required in the legislation and clarified in PCN 07-03, ADAP funds may be used for access, adherence, and monitoring services if the following conditions are met:

- *The state/territory "demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection 2616(a) of the PHS Act."*
- *"There are no current limitations to accessing ADAP in the state/territory, including: 1) no client waiting list or limits on client enrollment; 2) no restrictions or limitations on HIV medications, such as caps on the number of prescriptions or cost to the client (such as co-pays), except for purposes of clinical quality assurance or the prevention of fraud and abuse; and 3) administrative support is maintained (e.g., administrative support and eligibility staff)."*
- *"There is current, comprehensive coverage of antiretroviral and opportunistic infection (OI)/preventive therapies including: 1) an ADAP formulary that includes a full complement of PHS recommended antiretroviral medications; and 2) medication necessary for the prophylaxis and treatment of opportunistic infections."*

Section II. ADAP ADMINISTRATIVE STRUCTURE AND RECIPIENT RESPONSIBILITIES

II. Ch 1. Introduction

RWHAP ADAP is a component of RWHAP Part B and, as such, exists in each state/territory. State/territorial ADAPs have much in common, as each must adhere to the same federal legislative and program requirements; however, administrative structures and operations vary. The size of the program's budget, the number of people with HIV, and other state/territory medication programs (e.g., Medicaid) are often the most significant factors in the design of the ADAP administrative and service delivery systems.

II. Ch 2. Key Administrative Requirements

II. 2. A. ADAP Staffing

HRSA HAB requires that recipients have sufficient staffing, whether employees or contractual, to provide ADAP services in compliance with legislative and programmatic requirements. Any senior ADAP staff (e.g., ADAP director/administrator) hired under the grant must be approved by the HRSA HAB PO through the prior approval process in the EHBs.

II. 2. B. ADAP Policies and Procedures

HRSA HAB requires that recipients have appropriate guidelines and controls in place to ensure compliance with legislative and programmatic requirements. This is most often demonstrated through a collection of written policies and procedures that provide guidance and direction.

II. 2. C. Financial Oversight and Monitoring

HRSA HAB requires that recipients have appropriate financial systems and controls in place to ensure the appropriate use and reporting of federal awards. While most states have accounting and auditing departments to handle overall health spending, some ADAPs have fiscal staff who focus specifically on ADAP. Their role typically involves use of an accounting system that documents recipient and subrecipient budgets, records program expenditures, tracks rebate and back-billing recoveries, projects positive and negative line-item variances, and generates ADAP reports for submission to HRSA.

II. Ch 3. RWHAP Part B ADAP Subawarding and Required Monitoring

II. 3. A. Introduction

This chapter provides guidance on HRSA HAB's expectations for a recipient when it subawards ADAP-related services.[6] Recipients may choose to subaward some or all of the ADAP operations. Subawards may be provided through any form of a legal agreement, including a contract, Memorandum of Understanding (MOU), or Memorandum of Agreement (MOA). Most frequently, ADAPs contract with other organizations to provide pharmacy benefit management) services for clients.

II. 3. B. Procurement and Contracting

According to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR part 75), state/territory and local government recipients must use the same documented procurement procedures that are used for procurement from non-federal funds. Procurement procedures must also conform to applicable federal laws and the standards identified in the requirements, including 45 CFR §75.331 (procurement of recovered materials) and the inclusion of contract provisions contained in Appendix II. Contracts must also contain the clauses necessary to ensure that all requirements under the RWHAP Part B award will be satisfied, including reporting requirements. States/territories must maintain oversight to ensure that contractors perform in accordance with the terms, conditions, and specifications of their contracts.

RWHAP Part B recipients must ensure that subrecipients follow written procurement procedures that conform to the standards identified in 45 CFR §§75.327 through 75.335.

II. 3. C. Required Components of a Subaward

In addition to the requirements specified in 45 CFR §75.352, ADAP-related subawards (including contracts or MOU/MOA, or other legal funding mechanisms) must contain the following components:

- **Scope of Work:** The scope of work, or the activities to be performed, must be specified. The scope of work must include clear performance goals, indicators, milestones, and assessment criteria. Funding agencies must clearly describe performance measures that will be used to determine successful or unsuccessful implementation of the services to be delivered.
- **Operating Budget:** The subaward should include a budget that establishes the financial obligation of the funding agency. A budget can set the funding agency's maximum obligation, even when the service provider draws down funds from a pool, based on fee-for-service or unit cost accounting systems. If the service provider is using multiple

[6] For more information on the determination of appropriate use of the terms subrecipient, contractor and subaward, see the RWHAP Part B Manual or the HHS Uniform Administrative Requirements (45 CFR §75.351).

funding streams to support a particular service, the budget should clearly indicate the other funding sources and specify which line items are supported by each funding source.

- **Fiscal Assurances:** Fiscal assurances include policies, limits, or requirements regarding financial controls, independent audits, allowable expenditures, payor of last resort requirements, administrative costs, liability/risk insurance, collections from third-party payors, and other fiscal matters. Fiscal assurances should be spelled out in a manner that ensures each party's ability to satisfy federal, state/territory, and local regulations.
- **Program Assurances (including Service Standards):** The funding agency must require subrecipients to comply with the requirements included in the RWHAP legislation, HHS Uniform Administrative Requirements, and related policies regarding record maintenance, client confidentiality, standards of care, or client eligibility restrictions and protections. A written subaward must include a commitment to follow HRSA HAB and state/territory program policies.
- **Reporting Requirements:** Every ADAP subaward must include expectations about providing data as needed by the recipient, including that needed for the recipient to successfully submit the ADR.

II. 3. D. Subaward Monitoring and Management

Under RWHAP Part B, subrecipient monitoring is the responsibility of the state/territory recipient and includes both financial and performance monitoring activities. Subrecipient monitoring and management processes must comply with the requirements outlined in 45 CFR §75.352. HRSA HAB's National Monitoring Standards give guidance on how monitoring can be done to ensure compliance with requirements.

In cases where the RWHAP Part B recipient has contracted ADAP administration to an organization or state/territory agency (e.g., the state Medicaid office), the RWHAP Part B recipient may delegate monitoring functions to this agency. However, the RWHAP Part B recipient is legally responsible for ensuring that all RWHAP Part B legislative and programmatic requirements and all federal policies and guidance are met and that there is appropriate oversight and monitoring of the contract. As was noted earlier, the liability for improperly used RWHAP funds or delivered services is the responsibility of the RWHAP Part B recipient. ADAPs must be careful to avoid conflicts of interest when assigning tasks related to program and fiscal monitoring, including the involvement of other agencies that are also contracted service providers. Contracted service providers have an inherent conflict of interest when they are involved in monitoring their own contracts.

The National Monitoring Standards provide RWHAP Part B recipients with the requirements for managing federal RWHAP grant funds and guidance on how to ensure compliance with legislative and program requirements. These documents include standards and corresponding performance measures/methods along with recipient and subrecipient/service provider responsibilities that are tied to each standard and measure.

For more information, see the HRSA HAB National Monitoring Standards at: https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/2022-rwhap-nms-part-b.pdf.

II. Ch 4. Data and Reporting

There are three types of reporting associated with the RWHAP Part B funds: programmatic reports, which are reviewed and approved by the HRSA HAB PO(e.g., the Program Terms Report); fiscal reports, which are reviewed and approved by a Grants Management Specialist (GMS) in the Division of Grants Management Operations (e.g., the FFR); and data reports, which are reviewed by HRSA HAB's Division of Data and Policy and by DSHAP (e.g., RSR and ADR). As components of the RWHAP Part B HIV Care Grant Program (X07) award, ADAP Base funds and ADAP Supplemental funds are included in all programmatic and fiscal reporting required for the X07 award. The ADAP ERF (X09) and any RWHAP Part B Supplemental (X08) funds used for ADAP are included in the programmatic and fiscal reporting for those specific grants. The ADR encompasses all ADAP services and clients, regardless of the source of funding used for the ADAP service.

II. 4. A. Confidentiality and Privacy of Client Data

HRSA HAB requires RWHAP recipients to establish and maintain a process for protecting client confidentiality. ADAPs must utilize security and administrative controls to protect client information and should work with the state's legal counsel to determine the appropriate language to be included to enable communication with clinical providers, insurance companies, and pharmacies.

II. 4. B. Purpose of ADAP Data Reporting

ADAP services nearly a quarter of all people with HIV in the United States. Therefore, it is critical that HRSA HAB and RWHAP Part B recipients be able to describe the demographics of the people with HIV served by the program, the services provided, the operations of the ADAPs, and the cost-containment strategies used by the program. ADAP data reports are used by HRSA HAB to help answer questions from other entities including HHS, congressional lawmakers, and others.

II. 4. C. ADAP Data Reporting Responsibilities

ADAP Data Report (ADR)

As a condition of the grant award, HRSA HAB requires all RWHAP B recipients to report ADAP programmatic and client-level data using the ADR. The ADR was developed and implemented in 2013. The ADR enables HRSA HAB to evaluate the impact of the ADAP on a national level and allows HRSA HAB to characterize the individuals using the program, describe the ADAP-funded services being used, and delineate the costs associated with these services. The ADAP client-level data is used to:

- Monitor the clinical outcomes of clients receiving medication assistance through ADAP;
- Monitor the use of ADAP funds in addressing the HIV epidemic in the United States;
- Monitor the support provided by ADAP to the most vulnerable communities, especially minorities;

- Address the data needs of Congress and the Department of Health and Human Services (HHS) concerning the HIV epidemic and the RWHAP; and
- Monitor progress toward the national goals to end the HIV epidemic.

The ADR includes two components: 1) the Recipient Report, and 2) the Client Report (i.e., client-level data). The Recipient Report contains information on the ADAP's administration, medication purchasing mechanisms, funding, expenditures, and formulary**.** The Client Level Data Report contains records of all clients enrolled in ADAP during the calendar year and provides information on client demographics, service utilization, and clinical outcomes. The ADR must be submitted in a specific file format (.xml), and all client-level data are de-identified. The web-based system includes built-in validations and warnings to assure that the data is internally consistent.

All RWHAP B recipients are responsible for:

- Ensuring the submission of required ADR client-level data annually;
- Ensuring accuracy of ADR data prior to submission; and
- Cooperating in verification of data following submission.

Instructions for completing the ADR can be found in the ADR Instruction Manual at https://targethiv.org/library/adr-instruction-manual. HRSA HAB supports TA providers and provides tools that can assist both recipients and subrecipients to address issues related to the ADR.

HRSA HAB publishes the RWHAP ADAP Annual Client-Level Data Report. The most recent report presents data for clients reported to the ADR data system for calendar years 2016 through 2020.

For more information, see RWHAP data support resources at https://hab.hrsa.gov/program-grants-management/data-reporting-requirements-and-technical-assistance.

II. Ch 5. ADAP Planning

RWHAP Part B recipients are responsible for conducting planning in order to guide decisions about the use of RWHAP Part B funds, including funds being used within the ADAP. HRSA HAB strongly encourages RWHAP Part B recipients to have advisory bodies to provide recommendations to the RWHAP Part B recipient on the use of RWHAP funds on at least an annual basis. Additional ADAP planning takes place in response to NOFOs and NCC Progress Report instructions issued by HRSA, as well as by ADAP advisory committees that provide guidance and recommendations on ADAP operations. Committees focus on areas such as modifications to the ADAP formulary and eligibility criteria, assessments of potential ADAP cost-effectiveness strategies, and feedback and guidance on the ADAP's clinical quality management plan.

II. 5. A. Legislative and Programmatic Requirements

A detailed description of the legislative and program requirements for planning for RWHAP Part B (including ADAP) can be found in the RWHAP Part B Manual. Two key planning requirements for RWHAP Part B recipients relate to the development of the Statewide Coordinated Statement of Need (SCSN) and a comprehensive plan:

> *SEC. 2617. [42 U.S.C. 300ff–27] (b)(6) an assurance that the public health agency administering the grant for the State will periodically convene a meeting of individuals with HIV/AIDS, members of a Federally recognized Indian tribe as represented in the State, representatives of grantees under each part under this title, service providers, and public agency representatives for the purpose of developing a statewide coordinated statement of need;*
>
> *(b)(7) an assurance by the State that—(A) the public health agency that is administering the grant for the State engages in a public advisory planning process, including public hearings, that includes the participants under paragraph (6), and the types of entities described in section 2602(b)(2), in developing the comprehensive plan under paragraph (5) and commenting on the implementation of such plan;*

HRSA and CDC encourage RWHAP and HIV prevention programs at the local and state/territory levels to integrate planning activities. TA for coordinated planning is available through HRSA and CDC. Recipients should talk to their HRSA HAB and/or CDC PO for more information.

For more information, see the Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2022- 2026, dated June 30, 2021, as well as the Dear Colleague Letter and Frequently Asked Questions and Responses on HRSA HAB's website.

II. 5. B. ADAP-Specific Areas of Planning

Because RWHAP Part B recipients are responsible for conducting planning to guide decisions about the use of RWHAP Part B funds, including funds being used within the ADAP, ADAPs should consider planning for the following key areas:

- ADAP eligibility criteria;
- The scope of ADAP services;
- ADAP budgeting;
- ADAP client capacity;
- ADAP formulary;
- Cost-effectiveness of health care coverage assistance; and
- Clinical quality management.

A key focus of planning is the impact of the expansion of Medicaid in some states and options to purchase insurance through the health insurance Marketplace. ADAP planning can occur under

RWHAP Part B planning structures as well as through ADAP Advisory Committees, including Formulary Committees.

II. 5. C. ADAP Advisory Committees

The RWHAP legislation does not mandate an ADAP-specific advisory committee; however, most states convene one as a best practice. Below are common characteristics of ADAP advisory committees. Operating processes are influenced by RWHAP planning as carried out under other RWHAP Parts, as well as state/territory-specific regulations on functioning of advisory bodies. Key aspects of ADAP advisory committees include:

- **Composition:** ADAP advisory committees are typically comprised of clinicians, pharmacists, service providers, people with HIV, representatives from other RWHAP Parts, health department staff, and state Medicaid program staff. The intent of this diversity is to ensure the group has a breadth of expertise on key issues of concern to ADAPs, including financing, clinical care, consumer needs, and systems issues for public and private sector programs.
- **Meetings and Frequency:** The ADAP advisory committee may meet in person, by conference call, or electronically. ADAP advisory committees' meeting frequency varies across recipients, depending on the role of the committee and the needs of the ADAP.
- **Roles:** The recipient can assign the ADAP advisory committee with responsibilities ranging from the review of ADAP policies, regulations, functions, quality management issues, and budgets, to making recommendations on formulary management, utilization management, or program eligibility.

II. Ch 6. Clinical Quality Management (CQM)

In order to assess whether RWHAP-funded services are delivering high-quality HIV care and improving health outcomes, the RWHAP legislation requires that recipients have a CQM program. By evaluating services for their impact on health outcomes, patient care, and client satisfaction, and employing quality improvement methods, CQM programs help recipients develop and improve systems of care.

ADAP, as part of the overall RWHAP Part B, must be included in the RWHAP Part B CQM program. Some recipients may choose to have a separate ADAP CQM program, while others may choose to integrate the ADAP CQM activities into the RWHAP Part B CQM program. Either is an acceptable model as long as ADAP-specific CQM activities are included.

Performance measurement is the process of collecting, analyzing, and reporting data regarding client care, health outcomes on an individual or population level, and patient satisfaction. HRSA HAB requires that RWHAP-funded service categories (including ADAP) where greater than or equal to 50 percent of the recipients' eligible clients receive at least one unit of service need to have at least two identified performance measures, and recipients should collect the corresponding performance measure data.

For more information, see the HRSA HAB performance measures and Frequently Asked Questions (FAQ) at https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio.

HRSA HAB issued PCN 15-02, Clinical Quality Management Policy Clarification Notice, to clarify CQM program expectations for RWHAP recipients. PCN 15-02 sets the minimum requirements for RWHAP Part A, Part B, Part C, and Part D, and details the necessary components of a CQM program. It should serve as the guiding reference for establishing and implementing the CQM program. The RWHAP Part B Manual provides a detailed description of the requirements for a CQM program, including ADAP, and the TA resources available.

II.Ch 7. Emergency Preparedness

Preparedness is defined by the Federal Emergency Management Agency (FEMA) as, "a state of readiness to respond to a disaster, crisis or any other type of emergency situation." Given the critical nature of access to HIV medications, HRSA HAB expects every ADAP to have an emergency preparedness plan in place that demonstrates a state of readiness to respond to an emergency situation. The ADAP emergency plan should include, at minimum: a Continuity of Operations Plan (COOP) to ensure timely and continued access to HIV medications and other ADAP services in the case of an emergency; coordination of key suppliers and partners; and integration with the individual state/territory's larger disaster plan.

NASTAD has produced, as a deliverable in the ADAP technical assistance cooperative agreement with HRSA HAB, an ADAP Emergency Preparedness Guide "to assist AIDS Drug Assistance Programs (ADAP) that function within state health or social service departments to prepare emergency plans in response to possible disasters; in particular, the guide's provisions are intended to ensure continued access to HIV medications for individuals served by ADAP."

For more information, see the guide on the TargetHIV website at https://targethiv.org/library/adap-emergency-preparedness-guide.

Section III. ADAP OPERATIONS

III. Ch 1. ADAP Eligibility

ADAPs are required to determine eligibility for all enrolled clients per the RWHAP legislation based on HIV status, low-income status (as defined by the recipient), and residency (also defined by the recipient). PCN 21-02 gives further details on the expectations for determining client eligibility for RWHAP services, including ADAP. HRSA HAB expects all RWHAP recipients and subrecipients to establish, implement, and monitor policies and procedures to determine client eligibility based on each of these three factors, including documentation requirements.

The eligibility assessment process is determined by each ADAP and entails review of an application, verification of information and documentation provided, a determination of eligibility, and client notification. Some ADAPs handle eligibility determination centrally while others have clients apply locally through local health department or other agency case managers, eligibility workers, and clinical staff. Regardless of the specific criteria used by the ADAP, the requirement is that eligibility criteria must be consistently applied across the state/territory to anyone applying for the ADAP. As such, all RWHAP Part B recipients must devise, implement, and rigorously monitor the use of consistent eligibility standards across all entities involved in ADAP eligibility determination. In addition, HRSA HAB's expectation is that all therapeutic treatments and ancillary devices included on the recipient's approved ADAP formulary and all ADAP-funded services must be equitably and consistently available to all eligible enrolled individuals throughout the state/territory.

HRSA HAB outlines expectations for client eligibility determinations in the context of the changing healthcare landscape in PCN 13-03, "Ryan White HIV/AIDS Program Client Eligibility Determinations: Considerations Post-Implementation of the Affordable Care Act."

III. 1. A. Legislation, HRSA HAB Program Requirements, and Expectations

The legislative provisions for ADAP eligibility are:

> *Section 2616 (b) ELIGIBLE INDIVIDUAL.—To be eligible to receive assistance from a State under this section an individual shall—*
> *(1) have a medical diagnosis of HIV/AIDS; and*
> *(2) be a low-income individual, as defined by the State.*

PCN 21-02, "Determining Client Eligibility & Payor of Last Resort in the Ryan White HIV/AIDS Program.

III. 1. B. Initial Eligibility

At the time of initial enrollment, an ADAP must provide a complete assessment of an individual's eligibility for ADAP. The eligibility standards used must be consistently applied to all applicants across the state/territory. While it is up to the state/territory to determine what

information and documentation it requires for eligibility, it should ensure that it is collecting sufficient information to meet the data reporting requirements for ADAP (see Section II, Chapter 4 for more information).

PCN 21-02 states: "RWHAP recipients and subrecipients are expected to develop protocols to facilitate the rapid delivery of RWHAP services, including the provision of antiretrovirals for those newly diagnosed or re-engaged in care." The HHS treatment guidelines state: "In order for persons with HIV to benefit from early diagnosis, the Panel recommends that ART be started immediately or as soon as possible after diagnosis to increase the uptake of ART, decrease the time required to achieve linkage to care and virologic suppression for individual patients, reduce the risk of HIV transmission, and improve the rate of virologic suppression among persons with HIV." While ADAPs are not required to provide rapid delivery of services prior to eligibility determination, where and when it is feasible for ADAPs to do so, a protocol should be in place.

III. 1. C. Eligibility Requirements

As mentioned earlier, PCN 21-02 includes the eligibility criteria for RWHAP services, i.e., HIV status, low-income status, and residency. ADAPs typically meet these components of eligibility through the following:

- **Medical eligibility,** i.e., HIV status. HIV status is most often a diagnosis of HIV infection based upon diagnostic testing. All states/territories must require proof of diagnosed HIV infection for ADAP enrollment. HRSA HAB does not have any requirements as to what specific documentation a state/territory must collect as proof of diagnosed HIV infection.
- **Financial eligibility,** which is usually determined as a percentage of the Federal Poverty Level (FPL). The income cap for each ADAP is set by the state/territory. While HRSA HAB is not prescriptive on how financial eligibility is determined, it encourages RWHAP recipients to consider aligning RWHAP financial eligibility determination requirements to reduce the burden on clients and to support coordination with the eligibility determination processes for insurance affordability programs. See PCN 13-03 for more information.
- **Residency** in the jurisdiction. It is up to the state/territory as to how it defines residency, including for transient populations (e.g., the homeless, students, migrant workers, etc.).

The Federal Poverty Level is a measure of low-income status. The FPL is updated annually in the Federal Register by the U.S. Department of Health and Human Services (HHS) under the authority of section 673(2) of the Omnibus Budget Reconciliation Act of 1981. The updated FPL is usually available in late January. See the most recent Federal Poverty Guidelines at: https://aspe.hhs.gov/poverty-guidelines.

For a list of ADAP eligibility criteria by state/territory, please refer to the most recent version of the NASTAD National RWHAP Part B and ADAP Monitoring Project Annual Report on the NASTAD website.

For more information, see the most recent annual report on the NASTAD website at: https://nastad.org/.

Providing temporary assistance to ADAP-eligible clients while eligibility is determined for Medicaid or other insurance (i.e., "provisional status") is allowed, with the clear understanding that the ADAP will submit for retroactive reimbursement if there is another payment source.

III. 1. E. Confirming Eligibility

PCN 21-02 outlines HRSA HAB's expectations regarding confirming client eligibility. HRSA HAB does not define specific parameters around conducting "timely" eligibility confirmations but expects RWHAP recipients and subrecipients to define a reasonable timeframe in their policies and procedures regarding their eligibility confirmation process. In establishing this timeframe, recipients and subrecipients should consider the frequency and manner of monitoring changes to clients' income and residency status and apply this standard consistently to all clients.

III. 1. F. Provision of Services During Eligibility Determination Process

PCN 21-02 also includes guidance to facilitate rapid delivery of services during eligibility determination. Recipient policies and procedures need to include a formal eligibility determination process that includes the timeframe and reconciliation process to ensure that RWHAP funds are only used for allowable costs for eligible clients.

III. Ch 2. ADAP Formulary

III. 2. A. Legislation and HRSA HAB Program Requirements

The RWHAP legislation addresses the ADAP formulary as follows:

> *Section 2616(c) of the Public Health Service Act (42 U.S.C. 300ff-26(c)). STATE DUTIES.—In carrying out this section the State shall—*
>
> *(1) ensure that the therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary under subsection (e) are, at a minimum, the treatments provided by the State pursuant to this section;*
>
> *(2) provide assistance for the purchase of treatments determined to be eligible under paragraph (1), and the provision of such ancillary devices that are essential to administer such treatments;*

III. 2. B. Formulary Requirements

The RWHAP legislation and HRSA HAB have established the following requirements for ADAP formularies:

- An ADAP formulary must include at least one drug from each class of HIV antiretroviral medications.
- RWHAP funds may only be used to purchase medications approved by the FDA and the devices needed to administer them.

- An ADAP formulary must be consistent with the most recent HHS treatment guidelines.
- All therapeutic treatment and ancillary devices (e.g., syringes to administer an ADAP formulary medication) included on the ADAP formulary and all ADAP-funded services must be equally and consistently available to all eligible enrolled individuals throughout the state/territory.

Within this framework, each ADAP determines the composition of its medication formulary, which may also include vaccines and medications for the prevention and treatment of opportunistic infections, and for the treatment of chronic medical and mental health conditions, including co-morbidities such as hepatitis. Medications that require infusion can be covered, so long as the infusion is outpatient, and the medication is FDA-approved. The December 2019 program letter provides guidance on the use of ADAP funds for the medical costs associated with provider administration of an antiretroviral medication on the ADAP formulary, including the cost of an office visit exclusively for medication administration. Also, for clients with health care coverage, ADAPs can cover the client's cost-sharing related to that visit. This guidance on ADAP formulary supersedes preceding guidance.

III. 2. C. Formulary Management Strategies

ADAPs manage the medications on their ADAP formulary with consideration to a variety of factors, including RWHAP legislative requirements, standards of care, maximizing access to those in need, costs, funding, and availability of medications from other payors and programs. The following are examples of strategies used by ADAPs to manage their formularies:

- **Purchasing Medications at Best Price Available:** The most effective way for ADAPs to maximize what they offer under formularies is to secure the "best price available" (i.e., lowest cost) for all the products offered. See Section IV for more information on drug purchasing.
- **Advisory Committee Input:** ADAP advisory committees typically make decisions or recommendations about formulary changes. Advisory committees are normally comprised of clinicians, people with HIV, and others well positioned to provide expert guidance on changes to formularies. Members often discuss advances in HIV treatment and assist ADAP staff in determining the cost-effectiveness of adding new treatments to formularies. Although not statutorily required, advisory committees can also play an important role when ADAPs face serious budgetary constraints and choose to implement cost containment mechanisms to decrease program costs.
- **Prioritizing Drugs Based on Clinical Indications:** Some ADAPs prioritize categories of drugs based on clinical indications, with considerations such as: severity of the clinical condition and frequency in the HIV population; toxicity; cost; available alternatives; and potential for unintended use.
- **Prioritizing Based on Cost:** When considering adjustments to their formularies, ADAPs often assess the financial impact prior to adding or removing a medication. Cost assessments can take various forms (e.g., drug-to-drug cost comparison, review of costs in relation to

potential improvements in patient care). Cost considerations might include mandated use of lower-cost generics.

- **Prior Authorization:** Some ADAPs manage formularies by use of a prior authorization process before certain medications can be approved for dispensing to ADAP clients. Prior authorization is typically used for high-cost drugs that have narrow clinical indications. Prior authorization models vary but often entail these steps:
    - A medical provider completes an application with clinical information;
    - The application is reviewed, using objective criteria (e.g., lab test results);
    - Decisions are communicated back to medical providers (approval and disapproval); and
    - ADAP monitors utilization (e.g., to determine if additional patients can access the medication) and process (e.g., to determine if the approval/disapproval process is working).

III. Ch 3. Payor of Last Resort

The payor of last resort requirement is defined in the RWHAP legislation (see below). It is incumbent upon the ADAP to assure that eligible individuals are expeditiously enrolled in other programs (e.g., Medicaid, Medicare, health insurance) and that RWHAP funds are not used to pay for any costs covered by other programs. The exceptions to the payor of last resort requirement for Department of Veterans Affairs (VA) and Indian Health Service (IHS) clients are covered in III.3.E below.

Recipients who subcontract ADAP and/or ADAP eligibility determination must ensure that RWHAP funds remain the payor of last resort. Contractors with the authority to conduct ADAP eligibility must also perform insurance verification and make every effort to identify primary payor verifications. The RWHAP Part B recipient is responsible for monitoring compliance of contractors (and sub-contractors) regarding payor of last resort.

III. 3. A. Legislation, HRSA HAB Program Requirements, and Expectations

RWHAP funds are intended to fill gaps in care and serve as the payor of last resort. This means that RWHAP resources can only be used to pay for allowable costs when there is no other public or private payor, or when the costs are not covered by other public and private payors.

Section 2617(b)(7)(F) of the RWHAP legislation states:

> *SEC. 2617. STATE APPLICATION. (b) DESCRIPTION OF INTENDED USES AND AGREEMENTS.—The application submitted under subsection (a) shall contain— (7) an assurance by the State that— (F) the State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service—*
>
> *(i) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or*

(ii) by an entity that provides health services on a prepaid basis (except for a program administered by or providing the services of the Indian Health Service);

For more information, see PCN 21-02, "Determining Client Eligibility & Payor of Last Resort in the Ryan White HIV/AIDS Program," which provides guidance on complying with the payor of last resort requirement, and PCN 13-03, "Ryan White HIV/AIDS Program Client Eligibility Determinations: Considerations Post Implementation of the Affordable Care Act," which provides expectations on efforts to enroll eligible clients in available health care coverage.

III. 3. B. Ensuring Compliance with Payor of Last Resort

In order to ensure compliance with the payor of last resort requirement, ADAPs must have policies and procedures in place that identify other payors and ensure eligible individuals are expeditiously enrolled in other programs for which they are eligible and that the ADAPs coordinate with other payors.

PCN 18-02 outlines HRSA HAB policy on the use of RWHAP funds in state and federal prison facilities. The guidance included in PCN 18-02 maintains the payor of last resort requirement while ensuring eligible clients receive services to the extent allowed under the RWHAP statute. The restrictions included in PCN 18-02 apply to the provision of ADAP services in federal or state prison systems.

For more information, see PCN 18-02.

"Vigorously Pursue" Health Care Coverage

PCN 18-01 includes expectations for pursuing health care coverage for clients to maximize finite RWHAP grant resources.

PCN 13-01 clarifies that recipients and subrecipients are expected to vigorously pursue Medicaid enrollment for individuals likely eligible for Medicaid.

PCNs 13-01 and 13-04 set expectations for recipients regarding establishing and implementing policies and procedures to ensure that enrollment in health care coverage is maximized. The expectations apply to subrecipients and contractors as well. Recipients are permitted to, and encouraged to, continue providing services funded through RWHAP to a client who remains unenrolled in Medicaid or health care coverage "after extensive documented efforts on the part of the grantee to enroll the client."

For more information, see PCNs 13-01 and 13-04.

Coordination with Other Payors

ADAPs are expected to work with other payors and programs to provide clients with access to HIV medications and a continuum of care. As the level of expenditures and the number of individuals needing HIV services continues to increase, coordination among these programs is

necessary to ensure that gaps in service are addressed and that program overlaps are minimized. Depending on eligibility requirements and funding levels, other programs can serve as an alternative source of coverage and/or can supplement ADAP.

Coordination with other payors and programs can be implemented in many ways, as follows:

- **Understanding Other Payors and Programs:** RWHAP programs, including ADAPs, are required to coordinate services and seek payment from other sources before RWHAP funds are used. This makes RWHAP the "payor of last resort," meaning that funds are to fill gaps in care not covered by other resources. Major payors include Medicaid, Medicare, Children's Health Insurance Program (CHIP), private health insurance, and state and/or federal health insurance Marketplace plans.
- **Planning:** ADAPs can engage in planning and assessments (through ADAP advisory groups and RWHAP Part B planning processes) to determine optimal means for coordinating with other systems of care. In particular, implementation of the Affordable Care Act (ACA) represented opportunities for access to Medicaid, ADAP expenditures counting toward True Out of Pocket (TrOOP) Expenditures for Medicare Part D, and participation in state or federal health insurance Marketplaces.
- **Eligibility Screening:** Some ADAPs have coordinated enrollment processes with other programs (like other RWHAP Parts and Medicaid) and/or have engaged with a service provider to electronically check for an applicant's enrollment in Medicaid and other third-party insurance.

Back-billing Medicaid

As noted, PCN 13-01 states that recipients and sub-recipients "are expected to vigorously pursue Medicaid enrollment for individuals who are likely eligible for coverage." PCN 13-01 also requires that recipients and subrecipients "seek payment from Medicaid when they provide a Medicaid-covered service for Medicaid beneficiaries, and back-bill Medicaid for RWHAP-funded services provided for all Medicaid-eligible clients upon determination." For ADAPs, this is often encountered if a state Medicaid back-dates eligibility to the date of application to Medicaid, which may overlap with a period in which the ADAP provided medication to a client. ADAPs must have a process in place to attempt to recoup these funds from the state Medicaid.

ADAP Coverage of Medicare Part D Costs: TrOOP

Medicare Part D is an optional Medicare program specifically designed to address the prescription drug needs of eligible individuals. Depending on the benefit type, Medicare Part D plans can include premiums, deductibles, co-payments, and/or co-insurance. Individuals' TrOOP, the amount a beneficiary must spend in a calendar year on Medicare Part D covered drugs in order to reach the Medicare Part D catastrophic coverage threshold, vary according to when various levels of spending on prescription drugs are reached. The gap in Medicare Part D coverage, called the "donut hole," starts when total drug costs reach a designated level and ends when expenditures for medications (TrOOP) reach the "catastrophic coverage" threshold. ADAP

funds can be used to cover the costs of Medicare D premiums, deductibles, co-payments, and the costs of ADAP formulary drugs during the "donut hole."

For more information, see ADAP and Medicare Part D information on the website at https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/adaptroop-itr-10-2011.pdf and also PCN 18-01, "Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance."

III. 3. C. Exceptions to the Payor of Last Resort Requirement

As per PCN 16-01, RWHAP recipients may not deny services, including prescription drugs, to an individual receiving benefits through the VA who is otherwise eligible for RWHAP services, even if they could obtain services and medications through the VA. As per PCN 07-01, Native Americans and Alaska Natives can also access RWHAP services, including prescription drugs, even if those services are available through Indian Health Service, tribal, or urban Indian health programs. Individuals who are eligible for VA or Indian Health programs still need to seek health care coverage in accordance with the RWHAP Part B, including ADAP, and the recipient's policies and procedures; the recipient's requirements to vigorously pursue are also applicable.

For questions regarding exceptions to the payor of last resort requirement, consult your HRSA HAB PO.

III. Ch 4. Overview of Cost Containment Strategies

ADAPs are responsible for managing resources in the most efficient and effective manner possible. Over the years, ADAPs have experienced greater demand for services due to:

- Increased HIV testing, resulting in more people learning their HIV status;
- HHS treatment guidelines for earlier treatment of infected individuals;
- People living longer with HIV;
- More intensive use of HIV drugs by long-term survivors;
- Economic conditions;
- Increased cost of medications and insurance; and
- Reductions in state/territory funding for other programs.

Throughout their history, ADAPs have devised and implemented a variety of cost containment strategies, including cost-saving and cost-cutting strategies. HRSA HAB defines them as follows.

- **Cost-Saving Measures:** Any measures taken to improve the cost-effectiveness of ADAP operations. Cost-saving strategies are required to improve and/or maximize available resources. Examples of "cost-saving" measures include:

- RWHAP Part B structural or operational changes, such as expanding health care coverage assistance;
- Strategies to increase enrollment in health care coverage;
- Improved systems and procedures for the collection of rebates from drug manufacturers; and
- Data-sharing agreements, including agreements with CMS for Medicare Part D.

- **Cost-Cutting Measures:** Any measures taken that restrict or reduce enrollment or benefits. These measures are instituted out of necessity due to insufficient resources and/or to avoid implementing a waiting list. 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 to ADAP-funded health care coverage assistance eligibility criteria.
  Some ADAPs manage utilization (and control costs) by setting limitations on client access to and use of medications. Common methods include:
  - **Caps:** These are monthly or annual limitations on the amount of money ADAPs will spend for prescriptions for each client.
  - **Supply Limits:** Some ADAPs limit prescriptions to 30-day supplies, limit the way that refills are handled, or limit the quantity of medications they will cover for a given client. This limits waste in several areas, such as when a client's regimen changes (unused drugs must be disposed of); when a client's eligibility changes (and the client should be getting coverage by another payor); or when a client loses medications.
  - **Prior Authorization:** For certain medications and regimens, ADAPs may choose to cover the cost only after formal ADAP authorization. This is used in cases where drugs are costly and/or there are narrow clinical indications for the drug.

III. Ch 5. Waiting Lists

Despite appropriation increases, there have been instances in the past when the steady growth in the number of eligible clients combined with rising costs of complex HIV treatments resulted in states/territories experiencing greater demand for ADAP services than available resources could cover. As a last resort, an ADAP waiting list may be implemented when adequate funding is not available to provide medications to all eligible persons requesting enrollment and after all other feasible cost containment strategies have been utilized.

HRSA HAB defines a waiting list as a register of individuals who have applied for and been deemed eligible for a state/territory's ADAP, but who the state cannot immediately serve due to insufficient resources. In situations when an ADAP is proposing to implement a waiting list, HRSA HAB reviews the ADAP's budget forecasting to ensure that a waiting list is an appropriate response. The ADAP is required to actively monitor the eligibility status of those on the waiting list and to arrange for medication assistance until an enrollment slot opens for the individual on the ADAP.

HRSA HAB strongly discourages the use of a waiting list as a cost containment strategy, unless determined to be absolutely necessary. Establishment of a waiting list will result in increased

monitoring of the RWHAP Part B grant by the HRSA HAB PO and routine reporting to HRSA on the status of the waiting list.

Section 2617(b)(2)(A) of the RWHAP legislation affirms that a RWHAP Part B recipient is not eligible to request a waiver from the requirement to allocate 75 percent of funds on core medical services if has an ADAP waiting list.

III. 5. A. Requirements Regarding Waiting Lists

As noted, as a term on the RWHAP Part B HIV Care Program grant (X07) NoA, HRSA HAB has the following requirements regarding ADAP waiting lists:

- **Rationale for Establishing a Waiting List:** An ADAP must be able to clearly demonstrate to HRSA HAB the need for a waiting list prior to establishing one.
- **Policies and Procedures:** An ADAP must have written policies and procedures for managing a waiting list that include:
  - Criteria that are fair and equitable;
  - Compliance with state/territory laws and regulations that impact establishment of a waiting list;
  - A means for public input and communications to the public;
  - Methods for monitoring the waiting list to ensure that the policies and procedures are consistently followed across the state/territory; and
  - A revisions and appeals process.
- **Eligibility Determination:** An ADAP must assess each applicant for ADAP eligibility prior to placing the individual on an ADAP waiting list.
- **Monitoring Process:** An ADAP must, according to a schedule outlined in a waiting list policy and procedure, reassess eligibility on a pre-established basis. An ADAP must prioritize individuals by a pre-determined criterion, and bring clients into the program as soon as funding becomes available.
- **Reporting**: An ADAP with a waiting list is required to report data on the waiting list to HRSA HAB, as determined by HRSA HAB.
- **Client Communication:** Clients on waiting lists should be provided with information about:
  - Why a waiting list is necessary;
  - Waiting list criteria;
  - The estimated length of time one might remain on the waiting list;
  - Options for securing medications in the interim that include:
    - Recommendations or requirements for clients to work with a case manager;
    - Patient Assistance Programs (PAPs) applications and assistance in applying;
    - Other options available, e.g., RWHAP Part A LPAP; and
    - Continuous assistance for applying and re-applying, as necessary, for other programs).

Section IV. ADAP MEDICATION ASSISTANCE

IV. Ch 1. Introduction

The purchase of FDA-approved medications for low-income individuals with HIV who have limited or no coverage from private health care coverage, Medicaid, or Medicare is the core historical component of RWHAP ADAP. ADAPs have developed a variety of drug purchasing and dispensing systems to respond to the needs of individual populations and build on local systems and strengths. Please note that the payment of medication deductibles, co-payments, and co-insurance costs are considered a health care coverage assistance cost and are covered in the next section.

The design of an ADAP's medication purchasing and dispensing system is influenced by a number of factors, including:

- **Infrastructure:** ADAPs use variable staffing structures to manage purchasing and dispensing operations. It is at the discretion of the ADAP to assess which individual or combination of models is most effective for its program. Many ADAPs use Pharmacy Benefits Managers (PBMs) to handle tasks such as accessing medications and processing of drug manufacturer rebates.
- **Purchasing Options:** ADAPs may pay for medications by directly purchasing medications from the manufacturer or a wholesaler, by reimbursing pharmacies for medications disbursed to ADAP clients, or some combination of these strategies. Regardless of approach, the primary requirement for an ADAP is to secure medications at the best price available to maximize the availability of HIV treatment to the most people. This is most effectively accomplished through participation in the 340B Drug Pricing Program, which provides enrolled ADAPs and other RWHAP recipients with discounted pricing on certain drugs.
- **Additional Cost Savings:** ADAPs may seek additional discounts on any drug purchased through the 340B Program. For example:
  - The 340B Prime Vendor Program (PVP) is an optional program for 340B covered entities that directly purchase medications that is operated by a contractor of the HRSA Healthcare Systems Bureau (HSB), Office of Pharmacy Affairs (OPA). The prime vendor's role is to secure sub-ceiling discounts on outpatient drug purchases and discounts on other pharmacy-related products and services for participating covered entities electing to join the PVP. Purchasing pharmaceuticals through the 340B PVP may result in additional discounts of 20 to 50 percent of drug market prices.

    For more information, visit the PVP website at: https://www.340bpvp.com/controller.html.
  - The ADAP Crisis Task Force negotiates reduced drug prices or price freezes with all manufacturers of antiretrovirals for all ADAPs. More information about the ADAP Crisis Task Force can be found on the NASTAD website at https://www.nastad.org/.

- ADAPs may receive additional wholesaler discounts due to prompt payment of other offers negotiated directly with wholesalers.
- ADAPs may also be able to procure discounted medical products, including vaccines and medical supplies excluded from the 340B Drug Pricing Program, through membership in the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), a national cooperative group purchasing organization (GPO) for government facilities that provide healthcare services.

IV. Ch 2. 340B Drug Pricing Program

As a federally funded program, RWHAP ADAP recipients are required to acquire drugs "in the most economical manner feasible" (42 CFR part 50, subpart E). The 340B Drug Pricing Program (340B Program) is a federal drug pricing program, administered by HRSA OPA, that provides federally designated entities (including ADAPs and other RWHAP recipients) with access to discounted medications. The 340B Program enables eligible entities to stretch scarce federal resources, allowing them to reach more eligible patients and provide more comprehensive services. Manufacturers that choose to participate in Medicaid must participate in the 340B Program, offering participating "covered entities" covered outpatient drugs at or below the statutorily defined ceiling price. The 340B ceiling price is based on quarterly pricing data reported to the Centers for Medicare & Medicaid Services (CMS) and is calculated by subtracting the Unit Rebate Amount (URA) from the Average Manufacturer Price (AMP).

IV. 2. A. Definition of Covered Outpatient Drugs

Participating covered entities may purchase covered outpatient drugs, which are defined in section 1927(k) of the Social Security Act. Covered outpatient drugs generally include:

- A drug that can only be dispensed upon prescription;
- A prescribed biological product other than a vaccine;
- Insulin; and
- An over-the-counter drug if it is prescribed by a person authorized to prescribe such a drug under state/territory law.

A covered outpatient drug does not include any drug or product that is used when there is no medically accepted indication.

For more information, see a list of drug manufacturers participating in 340B at https://www.hrsa.gov/opa/manufacturers/index.html

IV. 2. B. Legislation, 340B Program Requirements, and Expectations

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service (PHS) Act "Limitation on Prices of Drugs Purchased by Covered Entities," codified at 42 USC 256b.

Key provisions, which relate to basic concepts of drug pricing and procurement, are described below. For a comprehensive list of 340B Program requirements, see the website at https://www.hrsa.gov/opa/program-requirements.

Who Has Access to 340B Prices: Covered Entities

Eligible covered entity types are defined in section 340B(a)(4) of the PHS Act. RWHAP recipients are among the statutorily defined covered entity types eligible for 340B pricing. An entity eligible for the 340B Program must first register for the 340B Program and receive a unique 340B identification number in order to purchase and use 340B drugs for its patients. Specific 340B Program registration requirements for all covered entities are available at: https://www.hrsa.gov/opa/registration/index.html.

ADAPs are unique in that they are the only entities that can choose to receive a 340B rebate from a drug manufacturer.

Key Requirements for Covered Entities

When an eligible entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities are encouraged to develop a 340B compliance plan. Key requirements for covered entities include:

- **Prohibition on Duplicate Discounts (Medicaid and 340B Drug Purchases)**: A drug purchased under the 340B Program cannot also be subject to a Medicaid rebate under section 1927 of the Social Security Act. An ADAP must indicate its Medicaid billing status when it enrolls in the 340B Program and ensure the 340B Medicaid Exclusion File correctly reflects the ADAP's Medicaid billing status at all times.

  For more information, see the website at http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html.

  Related to the prohibition on duplicate discounts, a drug purchased under the 340B Program by a covered entity cannot also be claimed for a 340B rebate by an ADAP. This is informally referred to as "double dipping."
- **Prohibition on Diversion of 340B Drugs**: Drugs purchased under the 340B Program can only be utilized by the individuals who are defined as "patients" of the covered entity. As such, individuals meeting an ADAP's financial and medical eligibility criteria and enrolled as active ADAP clients are deemed "patients" of the ADAP for the purposes of the 340B Program guidelines.
  For more information, see Patient Definition Guidelines: 61 Fed. Reg. 55156 (October 24, 1996) at https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf

ADAPs can avoid drug diversion to ineligible patients by implementing administrative controls that carefully track enrollees (in terms of eligibility requirements, initial enrollment, and recertification of eligibility), as well as drug purchases and inventory (including when and to whom drugs are dispensed).

- **Audits**: The covered entity must permit the HHS Secretary to audit covered entity records, in accordance with procedures established by the Secretary, to assure compliance with all 340B Program requirements. Drug manufacturers may audit any covered entity, including ADAPs, to ensure that duplicate discounts and diversion have not occurred. Covered entities are encouraged to perform self audits and to have an annual independent audit.

  For more information, see the OPA audit process at: https://www.hrsa.gov/opa/program-integrity.
- **Maintenance of Auditable Records:** Covered entities (e.g., participating ADAPs) must retain all records related to compliance with 340B Program requirements including, but not limited to, drug purchases and patient eligibility. This is critical documentation in the event of a manufacturer or HHS audit.
- **Violations of Statutory Requirements**: The covered entity must offer repayment to affected manufacturers for any violations of the prohibitions on duplicate discounts/rebates or diversion.

IV. Ch 3. Accessing 340B Prices

ADAPs who have registered as 340B covered entities can secure 340B pricing through a point of purchase discount (direct purchase), through a pharmacy network/rebate model, or both. All 340B covered entities may use a direct purchase model to access 340B prices. However, an ADAP may choose to pursue rebates from manufacturers for drug costs when the ADAP has paid for all or any part (i.e., partial pay) of the cost of the prescription, including cost sharing or co-payments. ADAPs should conduct a cost-benefit analysis to determine the most cost-effective mechanism (or mechanisms) for purchasing medications. The analysis should include the costs of medications and all administrative costs and fees associated with purchasing and distribution.

IV. 3. A. Direct Purchase Model

Under the direct purchase model, a covered entity pays a discounted price (i.e., 340B minus any additional discounts, including ADAP Crisis Task Force negotiated discounts) for each drug at the point of purchase. Participation in a direct purchase model may be administratively easier for states/territories that centrally purchase and dispense medications. ADAPs that use the direct purchase model may purchase drugs directly from manufacturers, wholesalers, or through a purchasing agent (e.g., a PBM). Drugs may be dispensed through a central pharmacy or contracted pharmacy service providers. In all cases, the covered entity must maintain ownership of the drugs.

For ADAPs utilizing the direct purchase option, dispensing fees charged by a contracted pharmacy and other administrative costs may impact the final cost of the drug. These costs may

be assigned on top of drug purchases or may be accounted for through different mechanisms. These operational cost factors should be considered when assessing the cost-effectiveness of the drug purchasing, dispensing, and administrative system used by the ADAP.

The 340B Program does not prohibit covered entities from seeking deeper discounts beyond the 340B ceiling price on any given drug. ADAPs have the discretion to work with a purchasing agent of its choice to access the most cost efficient options for purchasing medications. The 340B Program PVP is available to covered entities to assist with drug distribution and to have access to sub-ceiling 340B prices (https://www.340bpvp.com/controller.html).

As noted earlier, an ADAP, as a 340B covered entity, is prohibited from obtaining 340B pricing (either through a rebate or through direct purchase) on a drug purchased by another covered entity at or below the 340B ceiling price.

IV. 3. B. Pharmacy Network/Rebate Model

In 1998, the 340B Program published guidelines permitting ADAPs to use a rebate model (63 Fed. Reg. 35239, June 29, 1998). Under the pharmacy network/rebate option, ADAPs submit claims to drug manufacturers for rebates on medications that were purchased through a retail pharmacy network at a price higher than the 340B price. ADAPs using the rebate option on full pay medications or medication co-payments, coinsurance, or deductibles achieve cost savings comparable to those received by ADAPs that directly purchase medications at the 340B price.

The 340B Program requirements described above apply to all covered entities, including ADAPs participating in the pharmacy network/rebate option. ADAPs must submit claims to drug manufacturers to receive rebates on 340B drugs. An ADAP must not submit a claim for a 340B rebate if the drug is also subject to a Medicaid rebate. As noted earlier, an ADAP may not submit a claim for a 340B rebate if the drug was purchased under the 340B Program by another covered entity (i.e., “double dipping”).

The RWHAP legislation requires that rebates collected on ADAP medication purchases be applied to the RWHAP Part B program with a priority, but not a requirement, that the rebates be placed back into ADAP. More information on the utilization and reporting of drug rebates can be found in PCN 15-04.

Distribution Systems Used Under the ADAP 340B Rebate Option

ADAPs that make medications available under a rebate model have formal agreements with a network of retail pharmacies, a mail-order pharmacy, a PBM, and/or a state Medicaid program or other state-sponsored pharmacy network. Utilizing a network of retail pharmacies can provide the following benefits:

- Multiple, convenient pharmacies for improved client access;
- Increased ability of clients to have immediate access to pharmacy services;

- Increased coordination through the utilization of an existing network of pharmacies that have contracted with and are certified through the state Medicaid program or other state-sponsored pharmacy program (e.g., benefits program for the elderly); and
- The opportunity to provide ADAP clients with access to a face-to-face pharmacist/patient relationship (e.g., patient counseling services).

Submitting 340B Rebates Claims

HRSA has provided guidance that standard business practices, such as those reflected in the Medicaid Rebate Program, should be utilized for the 340B rebate claim process. ADAPs should engage in a thorough cash flow analysis to determine the timing of rebate recoveries and availability of grant funds and other resources. This can ensure a continuous cash flow to the program to prevent the potential for cash shortages and program service delivery disruption.

To submit a rebate to a drug manufacturer, the ADAP provides the information required by the manufacturer. Individual manufacturers have different requirements for information, including on an invoice, ranging from aggregate National Drug Code (NDC), the drug name, the drug form, the quantity of the drug prescriptions dispensed, quantity of units reimbursed, and amount reimbursed to claim level data. ADAPs need to keep supporting records for all submitted claims and make them available to manufacturers, if necessary, to resolve disputes.

IV. 3. C. Contract Pharmacy Services Mechanism

The 340B Program guidelines acknowledge that an ADAP (and other covered entities) may contract with one or more pharmacy(ies) to dispense 340B drugs. 340B Program guidelines state that the ADAP must purchase and retain ownership of drugs procured through the 340B Program. A contract pharmacy may order drugs on behalf of a covered entity as long as the ADAP is billed for the drugs and ensure that the medications are dispensed to eligible patients of the ADAP. The ADAP may also use a purchasing agent as long as the drugs are shipped to the dispensing/contracted pharmacy and the ADAP is billed for the purchased drugs. In addition, the ADAP should take steps to ensure that the 340B Program requirements for preventing drug diversion and duplicate discounts/rebates are met by the contract pharmacy. All contract pharmacy arrangements must meet the requirements specified in contract pharmacy guidelines (75 Fed. Reg. 10272, March 5, 2010), including the registration of each contract pharmacy and having a written contract in place.

For more information, see the website at http://www.hrsa.gov/opa/implementation/contract/index.html.

IV. 3. D. Dispute Resolution

Due to the complexity of the rebate submissions and claims process, manufacturers may raise questions about certain rebates being requested. ADAPs are encouraged to respond and attempt to resolve any questions raised by a manufacturer within 30 days of the manufacturer's request. The ADAP may amend its rebate claim to correct any agreed-upon errors.

If the manufacturer is late in its payment to the ADAP, it is recommended that any initial or minor problems be resolved using normal business procedures to collect overdue payments. NASTAD can provide technical assistance to support ADAPs as they reach out to and coordinate with manufacturers. If a major problem of nonpayment or late payment develops, an ADAP should request assistance from OPA to resolve the problem.

ADAPs should consult OPA's website (https://www.hrsa.gov/opa) for current information on the intent, scope, and process for the 340B dispute resolution process.

Free technical assistance is available to participating covered entities through the contracted 340B PVP at https://www.340bpvp.com/controller.html.

IV. 3. E. Drug Safety Chain Security Act Compliance

The Drug Quality and Security Act, signed into law in November 2013, contains provisions in Title II, known as the Drug Supply Chain Security Act (DSCSA), that are intended to enhance the safety of pharmaceuticals as they make their way from the manufacturer to the patient. Chief among those provisions are: 1) a new system to track and trace drugs as they move across the supply chain, and 2) new licensure and oversight requirements for wholesalers. At the end of 2014, the Food and Drug Administration (FDA) finalized guidance documents implementing the act, enforcement for which was slated to begin in 2015. The act and related guidance can be found on FDA's website at https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

Section V. ADAP HEALTH CARE COVERAGE ASSISTANCE

V. Ch 1. Introduction

The RWHAP legislation allows RWHAP ADAP the option of purchasing or maintaining health care coverage for ADAP clients instead of paying solely for HIV medications, and HRSA HAB encourages recipients to "consider assisting clients by paying for premium and/or cost-sharing, if cost-effective" (PCN 18-01). Many RWHAP Part B recipients have health care coverage purchasing programs through the RWHAP Part B HIV Care Grant Program (X07), including through ADAP. Within ADAP, these programs can pay for health care coverage premiums as well as medication cost-sharing (deductibles, co-payments and/or co-insurance).

V. Ch 2. Legislation, HRSA HAB Program Requirements, and Expectations

The RWHAP legislation defines ADAP health care coverage assistance as follows:

> *Section 2616. 300ff–26 Provision of Treatments.*
>
> *(f) USE OF HEALTH INSURANCE AND PLANS.—*
>
> *(1) IN GENERAL.—In carrying out subsection (a), a State may expend a grant under section 2611 to provide the therapeutics described in such subsection by paying on behalf of individuals with HIV/AIDS the costs of purchasing or maintaining health insurance or plans whose coverage includes a full range of such therapeutics and appropriate primary care services.*
>
> *(2) LIMITATION.—The authority established in paragraph (1) applies only to the extent that, for the fiscal year involved, the costs of the health insurance or plans to be purchased or maintained under such paragraph do not exceed the costs of otherwise providing therapeutics described in subsection (a).*

PCN 18-01, "Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance," provides guidance and expectations on the use of RWHAP funds for health care coverage.

V. Ch 3. Requirements for Purchase of Health Care Coverage

As noted in PCN 18-01, ADAP funds can be used to purchase private health insurance, Medicaid, and Medicare coverage that meets HRSA HAB's requirements. In order to use ADAP funds for health care coverage, the RWHAP Part B recipient must indicate in the RWHAP Part B HIV Care Grant Program (X07) application or NCC Progress Report that the program intends to utilize ADAP funds for a health care coverage assistance program in the coming budget period. The ADAP must have conducted an analysis to: 1) assure that it is buying health care coverage

that meets minimum formulary and coverage requirements; and 2) assess and compare the cost of providing medications through a health care coverage purchasing program versus the existing ADAP. HRSA does not specify the type of health care coverage plan that must be purchased or where it is purchased from, as long as the plan meets the criteria outlined in this chapter.

V. 3. A. Minimum Coverage Standard

The RWHAP legislation stipulates that an ADAP can only pay for health care coverage that includes both:

1) **Primary Care Services:** Section 2616(f)(1) of the PHS Act states that the primary care services must be "appropriate." HRSA HAB PCN 18-01 further clarifies that: "Private health insurance plans must, at a minimum, provide comprehensive primary health care services, deemed adequate by the state."
2) **HIV Treatments:** The RWHAP legislation states that the health care coverage must include "a full range of such therapeutics." HRSA HAB's guidance in PCN 18-01 clarifies that the health care coverage purchased must include "at least one U.S. Food and Drug Administration (FDA) approved medicine in each drug class of core antiretroviral medicines" outlined in the HHS treatment guidelines (i.e., the minimum formulary requirement for ADAP).

An ADAP cannot pay a premium for health care coverage that does not include a pharmacy benefit. For example, an ADAP cannot pay for a stand-alone dental or vision insurance policy, as these plans do not provide pharmacy benefits.

As per PCN 18-01, ADAP funds may be used to pay for Medicare premiums and medication cost sharing when the criteria listed in the PCN are met.

V. 3. B. Cost-Effectiveness Assessment

The RWHAP legislation states that an ADAP can purchase health care coverage if, "for the fiscal year involved, the costs of the health insurance or plans to be purchased or maintained…do not exceed the costs of otherwise providing therapeutics." PCN 18-01 clarifies that the ADAP must "determine the cost of paying for the health care coverage is cost-effective in the aggregate versus paying for the full cost for medications." The required cost comparison is in the aggregate for all clients. NASTAD can provide technical assistance to support ADAPs as they evaluate the cost-effectiveness of health care coverage plans.

Example of Aggregate Cost-Effectiveness Calculation

An example of a simple formula to evaluate and measure the aggregate cost-effectiveness of the ADAP purchasing health insurance coverage is: [cost of the monthly premium x 12 months] = [annual premium cost for an insurance policy or plan + (annual out-of-pocket maximum) or (stop loss amount)] versus the annual average per client expenditure for medicines by the ADAP.

For example, if a policy or plan costs [$300 x 12] = [$3,600 + ($2,000 out-of-pocket maximum)], then the annual cost is $5,600. The ADAP would then compare the $5,600 insurance policy or plan cost to its average annual cost of providing medications per client.

Client	Cost of Purchasing Drugs Through ADAP	Cost of Health Insurance
A	$10,000	$12,000
B	$10,000	$8,000
C	$10,000	$7,500
Aggregate Total:	$30,000	$27,500

Since cost neutrality is required for the aggregate cost of the health care coverage, not for each participating individual, although the cost of health care coverage for Client A exceeds the cost of purchasing drugs directly, the total cost of purchasing health insurance is less than the cost of purchasing drugs through the ADAP.

V. 3. C. Aspects of Cost-Effectiveness within ADAP

PCN 13-01, "Clarifications Regarding Medicaid-Eligible Clients and Coverage of Services by the Ryan White HIV/AIDS Program," includes information on the allowability of RWHAP funds, including ADAP funds, being used to purchase health care coverage for Medicaid-eligible clients. PCN 18-01, " Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance," gives further guidance on the use of RWHAP funds for premium and cost sharing assistance for the purchase and maintenance of private health insurance, Medicaid, and Medicare coverage.

An ADAP is allowed to pay past-due premiums for policies that meet the minimum coverage standard so long as doing so remains cost-effective; however, RWHAP funds cannot be used to pay any fines or penalties (e.g., late fees) (see 45 CFR §75.441). The payment of a past-due premium for coverage months outside of the client's ADAP eligibility period is allowable as long as the client is eligible on the date of the service (i.e., the payment of the premium). Prospective health care coverage premium payments that exceed the client's current eligibility

period can be made if a health care coverage plan requires that a payment be made for a period of time that exceeds the eligibility period.

While HRSA HAB requires that the health care coverage plans purchased by an ADAP are cost-effective, the issue of cost-effectiveness does not override the RWHAP requirement to be payor of last resort. The client's existing health care coverage must always be utilized as the primary payor while it is active, even if it is not deemed cost-effective. HRSA HAB does not allow an ADAP to purchase health care coverage for a client who concurrently has health care coverage (e.g., through the workplace), regardless of the cost effectiveness of the health care coverage. If a client is able to and chooses to "opt out" of their employer-sponsored plan, RWHAP funds could be used to purchase health care coverage for that individual once they are no longer covered by the employer-sponsored plan.

V. Ch 4. Health Insurance Assistance and Premium Tax Credits

Many RWHAP clients with incomes between 100 to 400 percent of the FPL may be eligible for a premium tax credit to offset the cost of purchasing a qualified health plan through the Marketplace. Since premium tax credits make health insurance premiums more affordable, recipients must vigorously pursue them, as they can be reasonably expected to help pay for health insurance premiums. An individual may choose to have some or all of the estimated premium tax credit paid in advance directly to the insurance company as an advance payment of the premium tax credit (APTC) to lower the individual's monthly premium, or can wait to get all of the premium tax credit when the individual files a tax return at the end of the year.

If an individual receives an APTC that is less than the actual premium tax credit for which the individual is eligible, the excess amount of premium tax credit will reduce any tax liability of the individual and may result in a refund. Similarly, if the individual received APTC that exceeds the actual premium tax credit for which the individual is eligible, the individual will owe that amount back to the Internal Revenue Service (IRS).

PCN 14-01 and the related Frequently Asked Questions (FAQs) outline certain opportunities and obligations for ADAPs (and other RWHAP recipients) regarding premium tax credits:

- **"Vigorously Pursue" Premium Tax Credit Refunds:** Recipients that use RWHAP program funds to purchase health care coverage in the Marketplace must establish appropriate mechanisms to vigorously pursue any excess premium tax credit a client receives from the IRS. Recipients and subrecipients must document the steps that were taken to pursue these funds from clients. Recovered excess premium tax credits are considered insurance refunds, not program income, and must be used for services allowable under the ADAP service category in the grant year when the refund is received by the recipient or subrecipient.
- **Payment of Tax Liability:** Recipients may use RWHAP funds to pay the IRS any additional tax liability a client may owe to the IRS solely based on reconciliation of the premium tax credit.

For more information, see HRSA HAB's Policy Clarification Notices at: https://ryanwhite.hrsa.gov/grants/policy-notices.

V. Ch 5. Health Care Coverage Assistance: Medication Cost-Sharing

An ADAP can choose to use resources to pay for medication cost-sharing (deductibles, co-payments and/or co-insurance costs) for ADAP enrolled clients who have another payor. Non-medication-related cost-sharing (e.g., medical visit deductibles, co-payments and/or co-insurance) is not an allowable expense under ADAP health care coverage assistance, with the exception that an ADAP can cover the cost of a client's cost-sharing related to an office visit exclusively for administering an antiretroviral medication on the ADAP formulary.[7] Cost-sharing is only allowed for services allowable under the RWHAP. Non-medication-related cost-sharing can be covered by the RWHAP Part B recipient through the Health Insurance Premium and Cost-Sharing Assistance service category.

Medication cost-sharing is considered by HRSA HAB to be health care coverage assistance, not medication assistance. As such, medication deductibles, co-payments and/or co-insurance services and expenditures should be reported to HRSA HAB on RWHAP Part B programmatic reports and on the ADR as an ADAP health insurance assistance service, not as an ADAP medication service.

[7] An ADAP can choose to request permission to cover non-medication-related cost-sharing under the Flexibility Policy, using the service category Health Insurance Premium and Cost-Sharing (see Section I, Chapter 8 for more information on the Flexibility Policy).

Section VI. THIRD-PARTY ADMINISTRATORS

Many ADAPs utilize a third-party administrator (TPA), such as a PBM or insurance benefits manager (IBM) to assist with program operations.

VI. Ch 1. Oversight and Monitoring of Third-Party Administrators

As noted in Section II, Chapter 3, "RWHAP Part B ADAP Subawarding and Required Monitoring" of this manual, the recipient is responsible for ensuring that all legislative, programmatic, administrative, and fiscal requirements are met and that there is appropriate oversight and monitoring of RWHAP funds, regardless of what ADAP-related services a recipient subawards. Subrecipient monitoring and management processes must comply with the requirements outlined in 45 CFR §75.352. Guidance on how to meet the requirements is outlined in HRSA HAB's Part B National Monitoring Standards. The liability for improperly used RWHAP funds or delivered services is a responsibility of the RWHAP Part B recipient.

Please refer to Section II, Chapter 3 for a more detailed overview of required oversight and monitoring.

VI. Ch 2. Third-Party Administrator Administrative Fees

TPAs may charge a per transaction administrative fee, depending on the number and extent of services that the TPA is contracted to perform. The fees, if any, are dependent on the contract terms negotiated between the ADAP and TPA. ADAPs that contract with a TPA could pay a dispensing fee, per claim administrative fee, or an administrative fee as part of an overall contract fee. The costs of a TPA are considered a "direct service" and do not count against a RWHAP Part B recipient's 10 percent administrative cost cap. HRSA HAB PCN 15-01, "Treatment of Costs under the 10% Administrative Cap for Ryan White HIV/AIDS Program Parts A, B, C, and D," provides clarification on what costs count toward the administrative cap.

VI. Ch 3. Pharmacy Benefits Managers (PBMs)

ADAPs can choose to utilize a PBM to provide administrative and pharmacy claim adjudication services. NASTAD created, through its cooperative agreement with HRSA HAB, a PBM toolkit as a TA resource for ADAPs.

VI. 3. A. PBM Administrative Functions

A PBM can provide a wide range of administrative and drug utilization services that can benefit an ADAP. Administrative functions typically include the following:

- Establish and maintain a network of providers (i.e., recruiting and managing a network of pharmacies that fill prescriptions for RWHAP ADAP clients, negotiating prices and payment terms, contracting with pharmacies, and monitoring/auditing performance);
- Centrally process claims in real time, claim adjudication, record keeping and reports to clients, payment to providers and fiscal intermediaries (e.g., processing of co-payments, deductibles for medications; tracking data required to receive rebates; performing electronic split billing at pharmacy point of service, paying pharmacy invoices, and billing ADAP; managing rebates and discounts with pharmaceutical companies; serving as electronic data transfer agent to meet all requirements related to Medicare TrOOP payments; and paying health care coverage co-payments and deductibles);
- Assist with benefit design and business rules (e.g., covered drugs, exclusions, cost-sharing provisions [differential co-payments for generic or preferred drugs], mail-order dispensing);
- Information management (e.g., risk assessment, profiling);
- Continuous electronic health care coverage eligibility checking; and
- Pharmacoeconomic studies.

VI. 3. B. PBM Drug Use Control Functions

In addition, PBMs perform a variety of drug utilization functions. These services generally involve managing drug utilization to reduce costs and maintain or improve quality. These functions include policies and programs to affect prescribing and dispensing patterns and are targeted toward pharmacists, patients, and prescribers. The range of drug utilization functions that a PBM can offer include:

- Formulary and formulary-related activities (e.g., rebate management, prior authorization therapeutic interchange);
- Drug use review (e.g., retrospective-drug utilization review (DUR), prospective-DUR, DUR interventions, "academic detailing," and provider education);
- Disease management (therapeutic outcomes management); and
- Patient compliance (patient education, e.g., newsletters; phone reminders).

VI. Ch 4. Insurance Benefits Managers (IBMs

ADAPs can choose to utilize an IBM to provide administrative support, including management of premium and co-insurance payments for health care coverage.

VI. 4. A. IBM Administrative Functions

IBMs can provide a range of administrative services that can benefit an ADAP. Administrative functions typically include:

- Enrollment in ADAP health care coverage assistance and maintenance of eligibility;
- Management of a timely health care coverage premium payment process;
- Development of relationships with third-party payors to facilitate payment of premiums;

- Understanding of health care coverage plan options available;
- Determination of health care coverage and compliance with RWHAP coverage requirements; and
- Claim reimbursement.

Section VII. TECHNICAL ASSISTANCE FOR ADAP

The following resources are available to guide ADAPs in managing programs.

- Within HRSA HAB's Division of State HIV/AIDS Programs (DSHAP), the PO and the ADAP Advisor work closely to provide TA directly as well as facilitate access to HRSA-funded training and TA resources. The ADAP Advisor can also provide clarity on ADAP requirements and ADAP-related policies.

  For more information, contact the HRSA HAB PO; contact information for the PO can be found in the EHBs grant folder or by calling the DSHAP main number at (301) 443-6745.

  Contact the ADAP Advisor at (301) 443-6745.
- HRSA HAB has a cooperative agreement with the NASTAD to provide TA to RWHAP Part B/ADAPs in the following areas:
  - Strengthening ADAP administrative structures, including:
    - Building the capacity of RWHAP Part B recipients to incorporate ADAP into the state/territory's comprehensive systems of HIV care, integrated planning processes, and continuous quality improvement programs;
    - Assessing and building the capacity of ADAPs' staffing, policies and procedures, and financial oversight and monitoring systems;
    - Strengthening ADAP staffing through the effective on-boarding of new ADAP staff, development of succession planning, and use of peer mentors; and
    - Building the capacity of ADAPs to develop emergency preparedness plans that demonstrate a state of readiness to ensure access to HIV medications in emergency situations.
  - Strengthening ADAP operations, including:
    - Expanding and enhancing current tools and providing support regarding the ongoing utilization of ADAP financial forecasting;
    - Strengthening ADAP effectiveness in the generation, tracking, and utilization of ADAP-generated program income and drug manufacturer rebates; and
    - Evaluating the effectiveness and utilization of cost-containment strategies (both cost-cutting and cost-saving).
  - Strengthening the capacity of ADAPs to implement and administer medication assistance and health care coverage assistance programs to optimize client health outcomes:
    - Expanding and enhancing current tools and creating new tools as necessary to analyze the cost-effectiveness of health care coverage plans to assist ADAPs in ensuring compliance with RWHAP legislative requirements;
  - Conducting ongoing assessment of RWHAP Part B recipients' TA needs related to ADAP and adapting TA to changing needs.

    More information on NASTAD's services is found at: https://www.nastad.org/.

- The TargetHIV website, funded by HRSA, collects tools and best practices from HRSA and RWHAP recipients across the country. It also contains information on upcoming trainings and webinars and has archived copies of past webinars on a variety of topics related to the RWHAP and ADAPs.

  For more information, see TA and training for ADAPs on the website at https://targethiv.org/.

Section VIII. APPENDICES

Appendix 1: RWHAP ADAP Requirements Table

Topic	Sub-Topic	Require-ment	Best Practice	Source Document
Formulary	Minimum formulary	X		Section 2616(c)(1) of PHS Act PCN 18-01
	FDA-approved medication	X		Section 2616(c)(1)(e) of PHS Act PCN 16-02
	Consistent with HHS treatment guidelines	X		PCN 18-01 PCN 16-02
	Advisory body input on formulary		X	AM p. 31
Eligibility Determination and Confirmation	ADAP has eligibility criteria for clients (as determined by the recipient) that includes the three required elements: HIV status, low-income and residency.	X		Section 2616 of the PHS Act PCN 21-02
	ADAP eligibility is supported through documentation (as determined by the recipient).	X		PCN 21-02
	ADAP eligibility is determined and clients are provided access to ADAP services in a timely way.	X		Section 2618 of the PHS Act PCN 21-02
	The eligibility criteria is applied consistently across all entities involved in certifying ADAP eligibility and confirming eligibility.	X		Section 2618 of the PHS Act PCN 21-02
	If ADAP services are initiated prior to eligibility being established, the ADAP conducts a formal eligibility determination within a reasonable timeframe and ensures that RWHAP funds are not used for individuals ultimately deemed ineligible for ADAP.	X		PCN 21-02
	ADAP has a policy and procedure for the timely confirmation of eligibility of ADAP clients.	X		PCN 21-02
	Confirmation of eligibility for clients enrolled in ADAP follows the schedule	X		PCN 21-02

Topic	Sub-Topic	Require-ment	Best Practice	Source Document
	established in the ADAP policies and procedures.			
Best Pricing	Acquire drugs "in the most economical manner feasible."	X		42 CFR part 50, subpart E
	Compliance with 340B Program rules (i.e., prohibitions on diversion, duplicate discounts and "double dipping").	X		NoA
Payor of Last Resort	Assure that service providers make reasonable efforts to secure non-RWHAP funds whenever possible for services to individual clients.	X		Section 2617(b)(7)(F) of PHS Act PCN 13-03
	Vigorously pursue expeditious enrollment into health care coverage for which clients may be eligible (recipients and subrecipients).	X		PCN 13-01 PCN 13-03 PCN 13-04 PCN 18-01
	Regarding Vigorously Pursue: • Maintain policies regarding the required process for pursuit of enrollment for all clients. • Document the steps during their pursuit of enrollment for all clients. • Continue to provide services through ADAP if the client remains unenrolled in Medicaid or health care coverage after extensive documented efforts on the part of the recipient to enroll client.	X X	X	PCN 13-01 PCN 13-04
	Back-bill other payors and reimburse the ADAP when clients are determined to be eligible for other programs that provide prescription drugs	X		PCN 13-01
Rebates (if applicable)	Rebates must be applied to Part B activities, with priority given to ADAP	X		Section 2616(g) of PHS Act PCN 15-04
	Rebates must be spent in the grant year in which they are received and prior to drawing down grant funds.	X		PCN 15-04

Topic	Sub-Topic	Require-ment	Best Practice	Source Document
	Recipients must track and account for all rebate funds and must be able to account for the rebate funds in any A-133 audit.	X		PCN 15-04
	Prohibition on sharing ADAP rebates with any other entities.	X		PCN 15-04
Drug Distribution	All ADAP-funded services must be equally and consistently available to all eligible enrolled individuals throughout the state/territory.	X		Section 2616(b) of the PHS Act PCN 21-02
Health Care Coverage Assistance (if applicable)	RWHAP recipients are strongly encouraged to use RWHAP funds to help clients purchase and maintain health care coverage, if cost-effective and in accordance with RWHAP policy.		X	PCN 13-04
	Health care coverage purchased by ADAP must include a full range of "such therapeutics" and appropriate primary care services. Clarification that health care coverage includes at least one drug in each class of core ARV as well as appropriate HIV outpatient/ambulatory health services.	X X		Section 2616(f)(1) of the PHS Act PCN 18-01
	Cost-Effectiveness The cost of purchasing health care coverage cannot exceed the cost of otherwise providing drugs. States must be able to document for HRSA HAB, upon request, the methodology used by the state to determine cost neutrality.	X		Section 2616(f)(2) of the PHS Act PCN 18-01 PCN 16-02
	Must establish appropriate mechanisms to vigorously pursue an excess premium tax credit, including: • Establishing and maintaining policies and procedures for the pursuit of excess premium tax credit from individual clients; • Documenting the steps taken to pursue these funds from clients;	X		PCN 14-01

Topic	Sub-Topic	Require-ment	Best Practice	Source Document
Flexibility Policy (if applicable)	• 5 percent cap (10 percent in "extraordinary circumstances"); • Used only for: access, adherence and/or monitoring • Requested services are "essential"; • No current limitations to accessing ADAP in the state; • Request to use the Flexibility Policy submitted annually through grant application or prior authorization.	X		Section 2616(c) of the PHS Act PCN 07-03
ADR	Submit recipient and client-level data in required format annually.	X		NoA
CQM	Part B: As a component of the Part B grant, Part B CQM requirements apply to ADAP. Part B QM program must: • Have a statewide QM plan with annual updates; • Establish processes for ensuring that services are provided in accordance with PHS treatment guidelines & standards of care; and • Incorporate quality-related expectations into RFPs and contracts.	X		Section 2618(b)(3)(E) of the PHS Act PCN 15-02
	ADAP-specific: Document progress in making drugs available.	X		Section 2616(c)(5) of the PHS Act
	Use of HRSA HAB ADAP Performance Measures		X	HPM
Waiting List (if applicable)	Establishment of Waiting List Policies and Procedures, including waiting list criteria and methods for monitoring the list.	X		NoA
One Program/ One Set of Rules	One program/one set of rules/expectation: All funds allocated to ADAP are subject to HRSA HAB ADAP expectations.	X		Section 2616(b) of the PHS Act PCN 21-02

PHS Act = Public Health Service Act (the Ryan White HIV/AIDS Program and 340B legislation)
PCN = HRSA HAB Policy Clarification Notice
PL = Program Letters (also referred to as 'Dear Grantee Letters')

AM = ADAP Manual
NoA = Notice of Award
HPM = HRSA HAB Performance Measures

Appendix 2: Key Resources Table

Key Resources	Web Links and Phone Contacts
HRSA and RWHAP	
HRSA HIV/AIDS Bureau	https://ryanwhite.hrsa.gov/ - (301) 443-6745 or https://ryanwhite.hrsa.gov/about/contacts
HRSA HAB Project Officers	(301) 443-6745 or https://directory.psc.gov/employee.htm
RWHAP Legislation	https://ryanwhite.hrsa.gov/about/legislation
HRSA HAB Policies	https://ryanwhite.hrsa.gov/grants/policy-notices
HRSA HAB Program Letters	https://ryanwhite.hrsa.gov/grants/program-letters
Reporting/Monitoring	
ADR Data Reporting	https://ryanwhite.hrsa.gov/grants/manage/reporting-requirements
National Monitoring Standards	https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/2022-rwhap-nms-part-b.pdf
Performance Measures	https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio
Grants Management	
HRSA Electronic Handbooks	https://grants.hrsa.gov/2010/WebEPSExternal/Interface/common/accesscontrol/login.aspx?TgtURL=grants3.hrsa.gov/2010/WebEPSExternal/Interface/common/accesscontrol/login.aspx&RefURL=
HHS Grants Policies and Information	https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html
Technical Assistance and Training	
HRSA Office of Pharmacy Affairs (OPA)	https://www.hrsa.gov/opa/ or (301) 594-4353 or (800) 628-6297
Prime Vendor Program	https://www.340bpvp.com/about-340b-and-pvp
Technical Assistance and Training for RWHAP	TargetHIV: https://targethiv.org/

Key Resources	
HHS HIV/AIDS Treatment Guidelines	https://hivinfo.nih.gov/home-page
HRSA HAB Clinical Protocols	https://ryanwhite.hrsa.gov/grants/clinical-care-guidelines-resources
Affordable Care Act	https://www.healthcare.gov/
National HIV/AIDS Strategy	https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025