

HIV/AIDS Bureau

Division of State HIV/AIDS Programs



AIDS DRUG ASSISTANCE PROGRAM (ADAP) MANUAL

2016

5600 FISHERS LANE, ROCKVILLE, MARYLAND 20857 301-443-6745

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HRSA HAB Preface

The AIDS Drug Assistance Program (ADAP) Manual is for ADAP Directors and staff, Ryan White HIV/AIDS Program (RWHAP) Part B Program Directors and staff, and others interested in ADAP.

An ADAP is a State/Territory-administered program authorized under Part B of the Ryan White HIV/AIDS Program that provides FDA-approved medications to low-income individuals with HIV disease who have limited or no coverage from private insurance, Medicaid, or Medicare. Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments. Each State and Territory operates an ADAP, and each is unique. ADAPs vary in their administrative structures and the mechanisms they use to ensure HIV medications are available to eligible individuals living with HIV.

With this in mind, the Manual—an update from the 2012 version—is designed to serve 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 broaden 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 their fiscal and program components. Overseeing a State/Territory ADAP is an ongoing endeavor of refining and reassessing operations in order 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.

The Health Resources and Administration's (HRSA) HIV/AIDS Bureau (HAB) prepared this version of the ADAP Manual. HRSA is an Operating Division within the U.S. Department of Health and Human Services (HHS) and administers the RWHAP at the Federal level, along with other health programs for underserved populations.

How This Manual is Organized

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 clearly labeled subsections so that 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 program, 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 in one place. Many chapters

then present highlights (e.g., best practices, resources) on ways to address these requirements.

- 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. A revised RWHAP Part B Manual was released in early 2015. *See the RHWAP Part B Manual online: <http://hab.hrsa.gov>*

Routine Updates to the ADAP Manual

The ADAP Manual is reviewed regularly and will be updated online as needed to reflect changes in ADAP requirements and conditions. HRSA Project Officers will keep recipients informed about update releases. For further assistance, contact your HRSA Project Officer at 301-443-6745. *See the ADAP Manual online: <http://hab.hrsa.gov>*

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 Ryan White HIV/AIDS Program (RWHAP) is codified in Title XXVI of the Public Health Service (PHS) Act and is the largest Federal program focused exclusively on HIV care. The RWHAP awards grants for the provision of primary care and support services to people living with HIV who have no health insurance (public or private), have insufficient health care coverage, or lack financial resources to get the care they need. As such, the RWHAP provides access to care and fills gaps in care not covered by other funding sources. The RWHAP awards grants to cities, States/Territories, and local community-based organizations to provide HIV-related services to more than half a million people each year. The majority of RWHAP funds support core medical services, including outpatient/ ambulatory medical services, and essential support services. A smaller but critical portion is used for technical assistance, clinical training, and research on innovative models of care.

RWHAP Parts

The RWHAP legislation has “Parts” which are focused on meeting the needs of communities and populations affected by HIV. The focus and recipients (formerly referred to as “grantees”) by Part are as follows:

- **RWHAP Part A** provides emergency assistance to cities (Eligible Metropolitan Areas (EMAs) and Transitional Grant Areas (TGAs)) that are most severely affected by the HIV epidemic. The RWHAP Part A grant may also include a Part A Supplemental award and Minority AIDS Initiative (MAI) funding;
- **RWHAP Part B** provides grants to States and Territories to improve the quality, availability, and organization of HIV health care and support services. Within the RWHAP Part B grant there is: a Base grant for core medical and support services; the AIDS Drug Assistance Program (ADAP) award; the ADAP Supplemental award for eligible entities that choose to apply; the Part B Supplemental award for recipients with demonstrated need that choose to apply; Minority AIDS Initiative funding for education and outreach to improve minority access to medication assistance programs, including ADAP; and supplemental grants to States with “emerging communities”. Since 2010, funds have also been available through the ADAP Emergency Relief Funds (ERF) to help States/Territories prevent, reduce or eliminate ADAP waiting lists or implement cost-containment measures;
- **RWHAP Part C** provides grants to community-based organizations to provide comprehensive primary health care in an outpatient setting for people living with HIV. The RWHAP Part C grant may include Minority AIDS Initiative (MAI) funding;
- **RWHAP Part D** provides grants to community-based organizations to provide family-centered, outpatient, ambulatory comprehensive HIV care and support services to women, youth, children, and infants. The RWHAP Part D grant may include Minority AIDS Initiative (MAI) funding ; and

- **RWHAP Part F** provides funds for a variety of programs, including Special Projects of National Significance (SPNS), the AIDS Education and Training Centers (AETC), dental programs and the Minority AIDS Initiative (MAI) program.

Learn more: <http://hab.hrsa.gov/abouthab/aboutprogram.html>

I.1.B. Health Resources and Services Administration HIV/AIDS Bureau Project Officers

The Ryan White HIV/AIDS Program is administered at the Federal level by the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB). HRSA is the primary Federal agency for improving access to health care services for people who are uninsured or underinsured.

HRSA HAB Project Officers are the key-point-of-contact for RWHAP recipients (formerly referred to as “grantees”). Each recipient is assigned a Project Officer, with Branch Chiefs providing oversight to the Project Officers by region. Project Officers provide guidance on legislative requirements, relevant HRSA policies, and grant requirements. Project Officers also provide technical assistance and can facilitate recipients’ access to additional technical assistance and training services. The Division of State HIV/AIDS Programs (DSHAP) also has an ADAP Advisor to provide guidance and technical assistance regarding ADAP and a Clinical Consultant to provide guidance and technical assistance on clinical issues and clinical quality management.

Learn more about HRSA HAB:

<http://www.hrsa.gov/about/organization/bureaus/hab/index.html>

Contact your HRSA Project Officer: 301-443-6745 or <http://directory.psc.gov/employee.htm>

Contact HRSA HAB: <http://hab.hrsa.gov/manageyourgrant/contacts.html>

I. Ch 2. RWHAP Legislation, HRSA Requirements, and Expectations

I.2.A. Introduction

All RWHAP recipients must comply with the RWHAP legislation, Federal requirements and guidance in order to implement legislative provisions, as issued by the U.S. Department of Health and Human Services (HHS) and HHS’s Health Resources and Services Administration (HRSA). Requirements and guidance are contained within annual Funding Opportunity Announcements (FOAs) and include policies, program letters, and requirements covering areas such as adherence to Federal HIV/AIDS treatment guidelines, data reporting requirements, and quality management.

I.2.B. RWHAP Legislation and ADAP

The latest RWHAP legislation is codified at Title XXVI of the Public Health Service (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 adjusted 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.

See the entire RWHAP legislation at <http://hab.hrsa.gov/abouthab/legislation.html>

I.2.C. HRSA HAB Policies

HRSA HAB develops policies that implement the RWHAP legislation, providing guidance to recipients in understanding and implementing legislative requirements. These policies are available at HAB's website, along with program letters that provide additional guidance for recipients. Recipients are strongly encouraged to review all policy notices, policy clarification

notices (PCNs), program letters and Frequently Asked Questions (FAQs). Unless otherwise noted, ADAP-relevant policies are issued as RWHAP Part B recipient policies.

HRSA HAB Policies with particular relevance to ADAPs include:

<u>PCN #*</u>	<u>Title</u>
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
07-05	The Use of RWHAP Part B ADAP Funds to Purchase Health Insurance
11-06	ADAP: Use of Funds, Eligibility and Formulary Parity, Administration, Quality Assurance and Cost-Savings
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
13-02	Clarifications on RWHAP Client Eligibility Determinations and Recertifications Requirements
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
13-05	Clarifications Regarding Use of RWHAP Funds for Premium and Cost-Sharing Assistance for Private Health Insurance
13-06	Clarifications Regarding Use of RWHAP Funds for Premium and Cost-Sharing Assistance for Medicaid
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	Eligible Individuals & Allowable Uses of Funds for Discretely Defined Categories of Services

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

Program letters with particular relevance to ADAPs include:

<u>Date</u>	<u>Letter Topic</u>
8/10/00	Ability of use of RWHAP funds for Medicaid beneficiaries if the program does not cover a particular service benefit
4/29/05	Ability of ADAPs to submit for full rebates on partial payments
11/23/10	ADAP data sharing with CMS
12/2/10	Prohibition on use of RWHAP funds for PrEP

<u>Date</u>	<u>Letter Topic</u>
11/16/12	Use of and Reporting of Rebate Funds Replaced by PCN 15-04
2/25/13	Requirements re: Confirmation of HIV Diagnosis
11/18/14	Reporting of CD4 count tests
2/13/15	Encouragement to Add Hepatitis C Medications to ADAP Formularies

See all the HRSA HAB Policies and Program Letters for the RWHAP at <http://hab.hrsa.gov/manageyourgrant/policiesletters.html>

I.2.D. Key HRSA 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**. Each fiscal year, HRSA releases a Funding Opportunity Announcement (FOA) (previously called ‘program guidance’) to provide instructions to RWHAP Part B recipients for preparing their Fiscal Year grant application. The FOA includes sections on ADAP and ADAP Supplemental funds. The FOA also outlines the following requirements:

- **HRSA HAB National Monitoring Standards.** HRSA HAB has issued the National Monitoring Standards for RWHAP Part A and Part B recipients. The Standards apply to RWHAP Part B ADAPs and have particular relevance to ADAPs with respect to: eligibility criteria, six -month ADAP client recertification, and clinical quality management. Recipients are required to implement the RWHAP Part A and B National Monitoring Standards at the recipient and service provider/sub-recipient levels. Technical assistance on compliance with the monitoring standards is available through the HRSA HAB Project Officers.

See the National Monitoring Standards: <http://hab.hrsa.gov/manageyourgrant/granteebasics.html>

- **Data Reporting.** RWHAP Part B recipients are required to submit an annual data report to HRSA called the ADAP Data Report (ADR). The ADR provides HAB with 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 and nationwide. More information on the ADR can be found in Section II.4.B.
- **Clinical Quality Management and HRSA HAB Performance Measures.** RWHAP Part B recipients are required to have a clinical quality management (CQM) program. HAB provides policy guidance and technical assistance regarding CQM. HAB has created performance measures that RWHAP recipients can use to monitor the quality of care they provide. 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.

See the Measures: <http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html>

- **HIV/AIDS Treatment Guidelines.** HHS develops Federal guidelines on the appropriate administration of HIV/AIDS treatments, including antiretroviral therapies, and medications for the prevention and treatment of opportunistic infections. The Guidelines are regularly updated using the latest scientific research findings by expert panels. ADAPs and other RWHAP recipients that provide HIV/AIDS medications must ensure that clients receive medication therapies consistent with current Federal HIV/AIDS treatment guidelines.

Access HHS treatment guidelines: <http://aidsinfo.nih.gov>

- **HIV/AIDS Clinical Protocols.** HRSA maintains a series of HIV/AIDS care protocols, based upon HHS guidelines, to provide detailed information to HIV/AIDS agencies on the delivery of HIV/AIDS care—for overall primary medical care as well as key areas such as HIV/AIDS services to women, Hepatitis C treatment, and nutrition.

*Access HRSA HIV/AIDS care protocols:
<http://hab.hrsa.gov/deliverhivaidscares/clinicalguidelines.html>*

Access the latest FOA via Grants.gov website: <http://www.grants.gov/search/basic.do>

Access HHS Grants Policies and Regulations: <http://dhhs.gov/asfr/oqapa/aboutoq/>

Upon award, all HHS award recipients are notified of grant requirements in a Notice of Award (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).

I. Ch 3. Key Resources for RWHAP Recipients

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

I.3.A. Glossary/Definitions and Acronyms

This chapter presents Web links to glossaries on HIV terms and acronyms, including those used by the Ryan White HIV/AIDS Program (RWHAP), ADAP-specific terms, and HIV medication and treatment terms. Information is regularly updated online.

- **RWHAP Glossary.** Included here are definitions of RWHAP Parts, Federal agencies, and other program terms. Prepared by HRSA’s HIV/AIDS Bureau.
- **RWHAP Service Categories.** Current RWHAP Service Category definitions can be found in the Ryan White Service Report (RSR) manual and in Policy Notice 10-02, “Eligible Individuals & Allowable Uses of Funds for Discretely Defined Categories of Services”.

Updated RWHAP service category definitions that will go into effect as of FY 2017 can be found in PCN 16-02.

See: <http://hab.hrsa.gov/manageyourgrant/pinspals/>

- **HIV Medications and Treatments.** Drug database, antiretroviral, and treatment definitions. Maintained by HHS's AIDSInfo.

See the glossary: <http://www.aidsinfo.nih.gov/education-materials/glossary>

See the drug database: <http://www.aidsinfo.nih.gov/drugs>

I.3.B. National Initiatives

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

- **Patient Protection and Affordable Care Act of 2010 (ACA).** As part of the Affordable Care Act (ACA), the health care law enacted in 2010, several significant changes have been made in the health insurance market that expand options for health care coverage, including those options for Persons Living with HIV (PLWH). The ACA creates new State-based health care coverage marketplaces, also known as exchanges, and a federally-facilitated health care coverage marketplace to offer millions of Americans access to affordable health insurance coverage. Under the ACA individuals with incomes between 100 to 400 percent of the Federal Poverty Level (FPL) may be eligible to receive advance payments of premium tax credits and/or cost-sharing reductions to help pay for the cost of enrolling in qualified health insurance plans and for coverage of essential health benefits. In States that choose to expand Medicaid, non-disabled adults with incomes of up to 133 percent of FPL (138% FPL inclusive of the 5% income set-aside) become eligible for the program, providing new coverage options for many individuals who were previously ineligible for Medicaid. In addition, the law requires health plans to cover certain recommended preventative services without cost-sharing making health care more affordable and accessible for Americans. Collectively, these changes represent new opportunities for ADAPs to provide access to HIV medications through health insurance mechanisms.

Learn more: <https://www.healthcare.gov/>

- **The National HIV/AIDS Strategy (NHAS).** Released in 2010 and updated in 2015, the Strategy is the Federal plan for addressing HIV in the United States. Its three primary goals are: 1) reducing the number of people who become infected with HIV, 2) increasing access to care and optimizing health outcomes for people living with HIV and 3) reducing HIV-related health disparities. ADAP has an important role in all three goals due to the relationship between low viral load and reduced HIV transmission, to the positive health outcomes for people consistently on HIV medications, and to the reduction of health disparities.

The NHAS states that more must be done to ensure that new prevention methods are identified and that prevention resources are more strategically utilized. Further, the NHAS recognizes the importance of getting people with HIV into care early after infection to protect their health and reduce their potential of transmitting the virus to others. HIV disproportionately affects people who have less access to prevention and treatment services and, as a result, often have poorer health outcomes. Therefore, the NHAS advocates adopting community-level approaches to reduce HIV infection in high-risk communities and reduce stigma and discrimination against people living with HIV.

States and Territories have used RWHAP Part B grant funds to develop and/or expand systems of care to meet the needs of PLWH in their jurisdictions. This includes efforts by HAB and recipients to estimate and assess Unmet Need and the number of individuals who are unaware of their HIV status and to ensure that essential core medical services have been adequately addressed when setting priorities and allocating funds. At the same time, the CDC has ongoing initiatives that may identify significant new numbers of PLWH who will be seeking services. This requires careful reassessment of how States/Territories will ensure access to primary care and medications as well as the provision of critical support services necessary to maintain individuals in systems of care.

CDC estimates that of the 1.2 million adults and adolescents at the end of 2012 living with HIV, nearly 13 percent of infected persons do not know their HIV status. The ultimate NHAS goal is to inform all HIV positive persons of their status and bring them into care in order to improve their health status, prolong their lives and slow the spread of the epidemic in the U.S. through enhanced prevention efforts. The RWHAP Part B Early Identification of Individuals with HIV/AIDS (EIIHA) legislative requirement calls for recipients to identify HIV positive individuals who are unaware of their HIV status and bring them into care.

HRSA/HAB and CDC, Division of HIV/AIDS Prevention support integrated data sharing, analysis, and use for the purposes of program planning, needs assessments, unmet need estimates, reports, quality improvement, the development of the HIV Care Continuum, and public health action. HRSA HAB strongly encourages RWHAP Part B recipients to follow the principles and standards in the Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action. HRSA HAB strongly encourages establishing data sharing agreements between surveillance and program to ensure clarity about the process and purpose of the data sharing and use. Integrated HIV data sharing and use approaches by local, state and territorial health departments can help further progress in reaching the goals of the NHAS and improving outcomes on the HIV Care Continuum.

Learn more: <https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update>

I.3.C. Technical Assistance for the RWHAP Community

RWHAP recipients can access many resources to guide them in managing their programs.

- The first point-of-contact for help is the HAB Project Officer, who can provide technical assistance directly as well as facilitate access to HRSA-funded training and technical assistance resources.

Contact your HRSA Project Officer: 301-443-6745 or <https://directory.psc.gov/employee.htm>

- 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.

Learn more about TA and training for RWHAP programs: <https://targethiv.org>

I. Ch 4. Introduction to ADAP

I.4.A. Purpose of ADAP

An AIDS Drug Assistance Program (ADAP) is a State/Territory-administered program authorized under Part B of the Ryan White HIV/AIDS Program (RWHAP) that provides FDA-approved medications to low-income individuals with HIV disease who have limited or no coverage from private insurance, Medicaid, or Medicare. Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments.

HIV drugs are costly, and many Persons Living with HIV (PLWH) in the U.S. are unable to pay for the medications without assistance through ADAP. The number of individuals on ADAP assistance has grown significantly in recent years due to: increased HIV testing, resulting in more people learning their HIV status; PHS guidelines indicating the need for early treatment of infected individuals; people living longer with HIV; more intensive use of HIV drugs from long-term survivors; economic conditions; increased cost-sharing associated with health insurance; increased cost of medications and insurance; and reductions in State/Territory funding for other programs.

I.4.B. ADAP within the RWHAP

The RWHAP is the largest source of Federal funding specifically directed to provide primary care and support services for PLWH. As noted, RWHAP Part B funding is used to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality care for low-income and uninsured/underinsured individuals living with HIV. This

continuum includes a range of core medical services and support services. 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, ADAPs are a critical component of the continuum of primary care and treatment for PLWH. Other RWHAP programs work in conjunction with State/Territory ADAPs to bring people into a system of care and provide them with quality treatment and services. In addition to ADAP, medications can be purchased by RWHAP funded recipients under the following allowable service categories:

Outpatient/Ambulatory Health Services, AIDS Pharmaceutical Assistance (which includes Community Pharmaceutical Assistance Program and Local Pharmacy Assistance Program (LPAP)), and Emergency Financial Assistance¹. Coordination between the ADAP and the 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 ADAPs and LPAPs.

Learn more about ADAP: <http://hab.hrsa.gov/abouthab/partbdrug.html>

I.4.C. History of ADAPs

ADAP started as a HRSA demonstration project to provide low-income individuals with access to Azidothymidine (AZT) (zidovudine, Retrovir), the first drug approved by the Food and Drug Administration (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 PLWH. Congress responded by approving \$30 million in funding under a public health emergency provision, and later enacted Public Law 100-71 authorizing the establishment of ADAPs nationwide.

As HIV treatment advances occurred and as resources permitted, States/Territories expanded their programs to cover multiple categories of antiretroviral drugs. States/Territories also added therapeutics beneficial in the treatment and prevention of many of the opportunistic infections (OIs) that characterize HIV disease. When ADAP became part of the 1990 Ryan White CARE Act, States/Territories had the option to cover any FDA-approved drugs to treat HIV disease or prevent the serious deterioration of health due to HIV.

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

Learn more about the history of ADAP: <http://hab.hrsa.gov/livinghistory/programs/Part-B.htm>

¹ Medications can also be purchased as a component of Hospice Services, Substance Abuse Outpatient Care, Substance Abuse Services (residential).

I. Ch 5. ADAP Funding

There are three separate grant awards under the RWHAP Part B Program—the RWHAP Part B (X07), RWHAP Part B Supplemental (X08), and ADAP Emergency Relief Funds (X09)—each of which is applied for and awarded separately. Funding is determined through formula and demonstrated need, depending on the grant. The following summarizes which grant funding 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 Minority AIDS Initiative (MAI) funding, while ADAP-related, cannot be used to purchase medications or health insurance. RWHAP Part B MAI is covered in the next chapter.

I.5.A. ADAP-Specific Funding:

- **ADAP Base:** The primary source of Federal funding for ADAPs is through the ADAP Base (formerly referred to as “earmark”) award component within the RWHAP Part B Formula (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. States/Territories are required to submit an annual application prior to receiving an X07 award.
- **ADAP Supplemental:** The “X07” award also includes the ADAP Supplemental award, which is for those 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 their X07 annual application. Section 2618(a)(2)(F)(ii) of the PHS Act states that five percent of the ADAP appropriation will be reserved as supplemental funding to purchase medications for States and Territories with demonstrated severe need. The annual X07 Funding Opportunity Announcement (FOA) outlines 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 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 X09 Funding Opportunity Announcement (FOA), and gives priority to addressing waiting lists.

I.5.B. Non-ADAP-Specific RWHAP Part B Funding:

- **RWHAP Part B Base:** Recipients can choose to use Part B Base (X07) funds for ADAP. The only component of the X07 award that must be used for ADAP is the ADAP Base award.
- **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 to use within their ADAP. An Objective Review Committee (ORC) reviews and

scores the applicant's responses to criteria published in the X08 Funding Opportunity Announcement (FOA).

I.5.C. Other Funding:

Recipients can choose to allocate other funding to ADAP, including State/Territory, local and Federal resources. ADAP-generated program income and rebates can also be allocated back to the ADAP, since they must be used for RWHAP Part B allowable services, with (for rebates) priority given to ADAP. All funds allocated to ADAP are subject to HRSA HAB ADAP program expectations.

I.5.D. Rebates

HRSA defines a 'rebate' as a return of a part of a payment. ADAPs who purchase 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 copayments, coinsurance, or deductibles to achieve cost savings comparable to those received by ADAPs that directly purchase medications at the 340B price. HRSA provides guidance on rebates in Policy Clarification Notice 15-04, "Utilization and Reporting of Pharmaceutical Rebates".

The RWHAP legislation states "A State shall ensure that any drug rebates received on drugs purchased from funds provided pursuant to this section (*i.e.* ADAP) are applied to activities supported under this subpart (*i.e.* RWHAP Part B), with priority given to activities described under this section (*i.e.* ADAP)" (Section 2616. 300ff–26 (g)). As such, any rebates received on drugs purchased with ADAP funds must be used for RWHAP Part B allowable activities, with *priority* given to ADAP. Rebates are not part of the recipient's RWHAP Part B award, and are not subject to the 10% administrative cost cap or the requirement to spend 75% on core medical services.

Federal regulations require that rebate funds are spent prior to drawing down grant funds from the Payment Management System (PMS) (45 CR 92.21 (f)(2)). HRSA has determined that recipients can spend rebate funds in the grant year in which they are received and prior to drawing down grant funds; the regulations do not require that rebate funds be spent in the year in which they are generated. If rebates are received at the end of a grant year, PCN 15-04 states that recipients can spend those rebates in the subsequent grant year, prior to the expenditure of new RWHAP funds.

See Section II.4. "Data and Reporting" for information on the appropriate reporting of rebates.

I.5.E. Program Income

PCN 15-03, "Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income", defines program income as "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 grant year) except as provided in 45 CFR § 75.307(f)." In the context of the ADAP, program income is most commonly generated billing third party insurance for medications purchased at 340B pricing. Program income in this case would be the difference

between the insurance reimbursement for 340B drugs and the cost of this medication.

PCN 15-03 outlines HRSA policy on the generation, use and reporting of program income. Program income must be used for the purposes for which the award was made, and may only be used for allowable costs under the award. Key requirements include:

- Program income should be spent in the grant year in which they are received, not generated.
- Program income should be spent prior to drawing down grant funds.
- The statutory exemption from Unobligated Balance (UOB) penalties for Part B recipients that expend rebate dollars before requesting additional grant RWHAP funds does not extend to UOBs accrued as a result of expending program income.
- Program income received at the end of the grant year can be spent in the subsequent grant year, but must be spent prior to the expenditure of new RWHAP funds.

I.5.F. ADAP and LPAP

A Local Pharmaceutical Assistance Program (LPAP) allows a RWHAP Part A or Part B recipient to provide on-going 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. If a jurisdiction determines there is a need for medication assistance and decides to allocate funds to the LPAP service category, it must demonstrate that the decision was based on information identified through a needs assessment process. The needs assessment must determine that the State/Territory's ADAP does not adequately address the medication assistance needs of clients in the jurisdiction (e.g. existence of an ADAP waiting list, restrictive ADAP financial eligibility criteria, or a limited ADAP formulary). The needs assessment must also demonstrate that other resources are inadequate to meet the medication needs of clients residing in the jurisdiction.

Implementation of an LPAP involves the development of a drug distribution system that includes, but is not limited to: a client enrollment and eligibility determination process that includes screening for ADAP and LPAP eligibility with rescreening, at minimum, every six months; an LPAP advisory board; uniform benefits for all enrolled clients; compliance with RWHAP requirement of payer of last resort; and a drug formulary approved by the LPAP advisory board. **An LPAP may not be used to provide short-term or emergency medication assistance, including providing medications while awaiting ADAP eligibility determination.** Recipients should refer to the National Monitoring Standards for a complete list of LPAP requirements.

I. Ch 6. RWHAP Part B Minority AIDS Initiative (MAI)

The RWHAP legislation states that Minority AIDS Initiative (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)” (Sec. 26939(b)(2)(B))*. 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 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—it can only be used for education and outreach services for the specific purpose of increasing minority enrollment in ADAP, and only for the racial and ethnic minorities indicated in the legislation. Recipients must design MAI funded services that meet the specific intent and parameters of the funding. The State provides an MAI Plan Narrative in their annual RWHAP Part B (X07) application that describes the planned education and outreach services, and 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 Minority Enrollment in ADAP

Given the legislative intent of the RWHAP Part B MAI funding to increase minority enrollment in ADAP, the recipient must be able to trace the RWHAP Part B MAI activity to the client’s enrollment into ADAP or another medication assistance program.

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

- Targeted Activities
- Targeted Audiences
- Traceable Clients

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’ must be interpreted in light of the legislative intent of the funds to increase minority participation in ADAP. As such, it can be helpful to think of allowable MAI services in terms of ‘outreach for ADAP’ and ‘education about HIV medications’. MAI services should be targeted activities with targeted audiences, not general HIV education or outreach. In FY 2013, 37% of RWHAP Part B MAI funds were used for education and 63% for outreach services.

I. Ch 7. Access, Adherence, and Monitoring Services (ADAP Flex)

I.7.A. Introduction

The RWHAP legislation includes the States/Territories responsibility 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 insurance, a limited amount of funds can, with approval from 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.7.B. Legislation, HRSA 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).

HAB Policy Notice 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’. PCN 07-03 states that extraordinary circumstances may include such factors as demonstrated exceptionally low compliance and adherence rates among targeted segments of the clients receiving ADAP medications (e.g. active substance users, persons with serious mental illnesses, etc.), or significant new numbers of clients entering ADAP who are new recipients of drug therapies (as a result of other outreach activities) that necessitate devoting added resources to these activities.

States/Territories who 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 Base (X07) application. States/Territories provide in that section a narrative description that includes the proposed services to be funded, 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 Base (X07) Funding Opportunity Announcement (FOA). Recipients are notified of approval to use ADAP funds under the Flexibility Policy in their annual RWHAP Part B Base (X07) Notice of Award.

I.7.C. Access, Adherence and Monitoring Services

As noted, the only allowable uses of ADAP Flex 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 Policy Notice 07-03 provides the following description of allowable services: 1) enabling

eligible individuals to gain access to drugs; (2) supporting adherence to the drug regimen necessary to experience the full health benefits afforded by the medications; and (3) services to monitor the client's progress in taking HIV-related medications. Monitoring services can include relevant laboratory tests.

In FY15, 11 RWHAP Part B recipients requested permission to use ADAP Flex for a range of services within the legislative parameters. These services included medication adherence programs, medical and non-medical case management, client re-engagement programs, and laboratory monitoring costs,

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

I.7.D. 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 only if the following conditions are met:

- 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 2616(a) of the PHS Act.
- There are no current limitations to accessing ADAP in the State, including: (1) no client waiting list or limits on client enrollment; (2) no restrictions or limitation 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. Compliance with formulary coverage may be adjusted or modified based on the State's alternative methods of providing comprehensive pharmacy coverage (e.g., health insurance, or Stated-funded pharmacy assistance program).

Section II. ADAP Administrative Structure and Responsibilities

II. Ch 1. Introduction

ADAPs are a component of RWHAP Part B and, as such, exist in each State and Territory. ADAPs have much in common, as each must adhere to the same Federal legislative and program requirements; however, their administrative structures and operations vary. The size of the program's budget, the number of people living 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 requires that recipients have sufficient staffing, whether employees or contractual, to provide ADAP services in compliance with legislative and programmatic requirements.

II.2.B. ADAP Policies and Procedures

HRSA 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 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 that focus specifically on ADAP. Their role typically involves use of an accounting system that documents recipient and sub-recipient 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's expectations for a RWHAP Part B program when it subawards ADAP-related services². RWHAP Part B recipients may choose to subaward some, or in some cases all, of their ADAP operations. Subawards may be provided through any form of a

² 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 Guidance (45 CFR §75.351).

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 (PBM) services for their clients. States/Territories must follow the same documented procurement processes that they use for procurements from non-Federal funds. The procedures must also conform to the requirements in the HHS Uniform Guidance (45 CFR part 75). In addition to the information specified in the HHS Uniform Guidance, ADAP-related subawards must specify the scope of work, methods, budget, deadlines, deliverables and oversight responsibility. Regardless of what ADAP-related services a RWHAP Part B recipient subawards, 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. The liability for improperly used RWHAP funds or delivered services is a responsibility of the RWHAP Part B recipient.

II.3.B. Procurement and Contracting

According to the HHS Uniform Guidance (45 CFR part 75), state and local government recipients must use the same documented procurement procedures that they use for procurement from their non-Federal funds. Their procurement procedures must also conform to applicable Federal laws and the standards identified in the HHS Uniform Guidance, 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 their subrecipients follow their written procurement procedures that conform to the standards identified in 45 CFR §§75.327 through 75.335. The standards include:

- Proper pre-award considerations, award management and oversight;
- Standards of conduct covering conflicts of interest and governing the actions of parent organizations and/or employees involved in the selection, award, and administration of contracts;
- Cost effectiveness and efficiency considerations;
- Use of full and open competition;
- Procurement methods based on dollar thresholds;
- Use of minority and women's business enterprises and labor surplus are firms; and
- Recordkeeping and retention.

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 Memorandum of Understanding/ Agreement (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 funds down from a pool, based on fee-for-service or unit cost accounting systems. If the service provider is using multiple 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, payer of last-resort requirements, administrative costs, liability/risk insurance, collections from third party payers, 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 Guidance, 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 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 ADAP Data Report (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 and meet HRSA's Monitoring Standards.

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 guidances are met and that there is appropriate oversight and monitoring of the contract. 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 Fiscal and Program Monitoring Standards provide RWHAP Part A and Part B recipients with the requirements for managing their Federal RWHAP grant funds and complying 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.

See HRSA HAB Monitoring Standards:

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

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 DSHAP Project Officer, (e.g. 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. Federal Financial Report (FFR)); and data reports, which are reviewed by HAB's Division of Data and Policy and DSHAP (e.g. RSR and ADR). As a component of the RWHAP Part B Formula (X07) award, ADAP Base funds and ADAP Supplemental funds are included in all programmatic and fiscal reporting required for the X07 award. The ADAP Emergency Relief Funds (ERF) (X09) and any RWHAP Part B Supplemental (X08) used for ADAP are included in the programmatic and fiscal reporting for those specific grants. The ADAP Data Report (ADR) encompasses all ADAP services and clients, regardless of the source of funding used for the ADAP service.

II.4.A. Purpose of ADAP Data Reporting

The ADAP services over 250,000 PLWH, nearly a quarter of all PLWH in the United States. Therefore, it is critical that HRSA and ADAPs be able to describe the demographics of the PLWH served by the program, the operations of the ADAPs, and the cost-saving strategies used by the program. ADAP data reports are used by HRSA to help answer these questions for other entities including HHS, Congressional lawmakers and others.

II.4.B. ADAP Data Reporting Responsibilities

ADAP Data Report (ADR)

As a condition of their grant awards, RWHAP Part B recipients are required to report client level data on clients enrolled, services provided, and expenditures on an annual basis through the ADAP Data Report (ADR). Data collection began in 2012 for the ADR, for submission in 2013. RWHAP Part B recipients formerly provided information on their ADAP through the ADAP Quarterly Report (AQR), which was an aggregate data report. The AQR was retired at the end of Fiscal Year 2013, and HAB no longer requires recipient submission of this report. The ADR enables HRSA HAB to evaluate the impact of the ADAP on a national level, inclusive of client demographics, what ADAP-funded services are being utilized, and the associated costs of these services.

The ADR is comprised of two components: the **Grantee Report** and the **Client Report** (i.e. client-level data). The ADR must be submitted in a specific file format (.xml) to HAB. The web-based system includes built-in validations and warnings to assure that the data is internally consistent. Each year, HRSA's Division of Policy and Data (DPD) releases an ADR Instruction Manual and an ADR Client Data Dictionary to provide guidance to ADAPs on the successful submission of required data.

Learn more about ADAP Reporting and Reporting Deadlines:

<http://hab.hrsa.gov/manageyourgrant/reportingrequirements.html>

<https://targethiv.org/library/topics/adap-data-report-adr>

II.4.C. Reporting of Rebates

HRSA defines a 'rebate' as a return of a part of a payment. As noted earlier, 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 copayments, coinsurance, or deductibles achieve cost savings comparable to those received by ADAPs that directly purchase medications at the 340B price. Rebates generated by an ADAP are not considered to be Federal funds or program income, and are reported in some recipient reports and not others. Rebates should not be included in any X07, X08 or X09 program reports since they are not federal funds. For example, rebates should not be included in the Planned Allocations table of the Program Terms Report or the Final Expenditure Table.

Rebates are reported in specific ways on the Federal Financial Report (FFR). Rebates should not be included anywhere on line 10 of the FFR, unless they are counted as part of the recipient's required State match under "Recipient Share" section of line 10. ADAP rebates are not considered program income, and should not be reported as such on an FFR. They also should never be recorded as an unobligated balance on the FFR. Rebates are reported in two places on the FFR: the "Ryan White Rebate Funding" section and the "comments" section. HRSA is prescriptive on how this information should be reported. First, in the "Ryan White Rebate Funding" section, recipients report two amounts: the Expended Rebate Amount and the Expended rebate amount to be used to reduce UOB. The second place recipients report on rebates is in the "Comments" section. There, recipients must provide information on rebates received during the grant period, rebates expended during the grant period, and any remaining balance. If a recipient has an unobligated balance greater than 5% directly due to the receipt and expenditure of rebate funds, they must inform HRSA of this in order to not be penalized. For more information, see PCN 15-04 "Utilization and Reporting of Pharmaceutical Rebates".

II.5.A. Introduction

RWHAP Part B programs are responsible for conducting planning in order to guide decisions about use of RWHAP Part B funds, including funds being used within the AIDS Drug Assistance Program (ADAP). HRSA HAB strongly encourages RWHAP Part B programs 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 also takes place in response to annual FOAs 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 quality management plan.

II.5.B. 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 a statewide coordinated statement of need and a comprehensive plan:

SEC. 2617. [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 the CDC encourage RWHAP and HIV prevention programs at the local and state levels to integrate planning activities. See HRSA HAB Program letters dated June 19, 2015 and September 30, 2015 on HAB's website for more information.

II.5.C. Required ADAP-Specific Areas of Planning

HRSA HAB requires ADAPs to engage in planning for key aspects of ADAP structure and operations, including:

- ADAP eligibility criteria,
- The scope of ADAP services,
- ADAP budgeting,

- ADAP client capacity,
- ADAP formulary,
- Cost effectiveness of health insurance assistance, and
- Clinical Quality Management.

A current key focus of planning is the implication of the implementation of the Affordable Care Act, particularly in relation to Medicaid expansion in some states, and options to purchase insurance under State or Federal Health Insurance Marketplaces. ADAP planning can occur under RWHAP Part B planning structures as well as through ADAP Advisory Committees, including formulary committees.

II.5.D. 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; their operating processes are influenced by RWHAP planning as carried out under other RWHAP Parts as well as State-specific regulations on functioning of advisory bodies. Key aspects of ADAP Advisory Committees include:

- **Composition**
State ADAP Advisory Committees are typically comprised of clinicians, pharmacists, service providers, consumers, 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 advisory committee may meet in person, by conference call or electronically. ADAP Advisory Committees' meeting frequency varies from State to State, 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

II.6.A. Introduction

The RWHAP Part B Program awards grants to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality HIV care and treatment for low-income people living with HIV (PLWH). 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 clinical quality management (CQM) program. By evaluating compliance with guidelines and protocols and employing quality improvement methods, CQM programs help recipients develop and improve their systems of care, which is demonstrated by the improved health outcomes of PLWH. ADAPs, as part of the overall Ryan White Part B program, need to be included in the CQM program.

II.6.B. Legislative Background

Section 2618(b)(3)(E) of the PHS Act requires that “Each State that receives a grant under section 2611 shall provide for the establishment of a clinical quality management program to assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infection, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services.”

Additional language under Section 2618 “Administrative Expenses” sets limits on the amounts to be expended for CQM, but states that the CQM costs do not count towards the 10% administrative cap:

“(ii) USE OF FUNDS-

- (I) IN GENERAL- From amounts received under a grant awarded under section 2611 for a fiscal year, a State may use for activities associated with the clinical quality management program required in clause (i) not to exceed the lesser of--
 - (aa) 5 percent of amounts received under the grant; or
 - (bb) \$3,000,000.

(II) RELATION TO LIMITATION ON ADMINISTRATIVE EXPENSES- The costs of a clinical quality management program under clause (i) may not be considered administrative expenses for purposes of the limitation established in subparagraph (A).”

II.6.C. HAB Program Expectations

The complexity of HIV care and the RWHAP’s commitment to equal access to quality care for all PLWH require systematic efforts to ensure that all RWHAP-funded services are delivered efficiently and effectively. The RWHAP legislative requirements for CQM apply to all RWHAP-funded core medical and support services, whether provided by a direct recipient or a subrecipient/contractor. The ADAP must be included in the CQM program as well. 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.

RWHAP Part B CQM programs should use tested quality management concepts in developing and implementing their programs. CQM programs coordinate activities that aim to improve patient care, health outcomes and patient satisfaction. In order to be effective, CQM programs require specific aims based in health outcomes, leadership support, accountability for CQM

activities, dedicated resources and use of data and measurable outcomes. CQM activities should be continuous and fit within and support the framework of grant administration functions.

At a minimum, RWHAP Part B recipient quality management program must have:

- Appropriate and sufficient infrastructure to make the CQM program successful and sustainable.
- Performance measurement to appropriately assess outcomes.
- Quality improvement activities aimed at improving patient care, health outcomes and patient satisfaction.

The expectations of a RWHAP Part B recipient's CQM program are outlined in Policy Clarification Notice 15-02. The requirements to implement a CQM program are covered in Section D of HAB's RWHAP Part B National Monitoring Standards. DSHAP monitors recipient compliance with CQM requirements through questions in funding opportunity announcements, progress reports, monthly monitoring calls and site visits. States must sign assurances in their annual applications attesting that appropriate quality management programs are in place.

II.6.D. Infrastructure

Appropriate and sufficient infrastructure is needed to make the CQM program a successful and sustainable endeavor. Infrastructure is needed to plan, implement, and evaluate CQM program activities. Utilization of RWHAP grant funds to establish an appropriate infrastructure for a CQM program is allowed. An ideal infrastructure consists of leadership, CQM committee, dedicated staffing, dedicated resources, a quality management plan, consumer involvement, stakeholder involvement and evaluation of the CQM program. Although the infrastructure will vary in scope among recipients, the inclusion of all these elements creates a strong foundation for the CQM program.

II.6.E. Performance Measurement

Performance measurement is the process of collecting, analyzing, and reporting data regarding patient care, health outcomes on an individual or population level, and patient satisfaction. In order to appropriately assess outcomes, measurement must occur. Measures should be selected that best assess the services the recipient is funding. A sound performance measure portfolio is reflective of RWHAP funded services, local HIV epidemiology, and identified needs of PLWH. Recipients are strongly encouraged to include HRSA HIV/AIDS Bureau and HHS measures that align with the National HIV/AIDS Strategy (updated July 2015). Recipients should have an identified process to regularly collect and analyze performance measure data which would occur more frequently than data collection for reporting (i.e., the annual Ryan White HIV/AIDS Service Report). It is also important for recipients to collect and analyze performance measure data that allows for inspection and improvement of health disparities across different target populations. All funded service categories need to have at least one performance measure. For each highly utilized and highly prioritized RWHAP-funded service category, such

as ADAP, recipients should identify two performance measures and collect the corresponding performance measure data.

II.6.F. Quality Improvement

Quality improvement entails the development and implementation of activities to make changes to the program in response to the performance data results. To do this, recipients are required to implement quality improvement activities aimed at improving patient care, health outcomes, and patient satisfaction.³ Recipients are expected to implement quality improvement activities using a defined approach or methodology (e.g., model for improvement⁴, Lean⁵, etc.). Quality improvement activities should be implemented in an organized, systematic fashion. As a result, the recipient is able to understand if specific changes or improvements had a positive impact on patient health outcomes or were indicative of further necessary changes in RWHAP funded services. All quality improvement activities should be documented in the quality management (QM) plan.

II.6.G. References, Links, and Resources

Clinical Quality Management Policy Clarification Notice

This PCN clarifies HRSA RWHAP expectations for CQM programs.

<http://hab.hrsa.gov/manageyourgrant/clinicalqualitymanagementpcn.pdf>

HIV/AIDS Bureau Performance Measures

List of performance measures and Frequently Asked Questions (FAQ):

<http://hab.hrsa.gov/deliverhivaidscore/habperformmeasures.html>

National Quality Center (NQC)

The purpose of NQC is to provide no-cost, state-of the-art technical assistance to all Ryan White HIV/AIDS Program funded recipients to improve the HIV/AIDS care and the services they provide. NQC aims to build capacity for quality improvement across all Parts.

<https://targethiv.org/cqii>

NQC Quality Academy – An internet-based modular learning program on quality improvement, accessible 24/7 and free of charge. The currently available tutorials stress quality improvement theories and methodologies, real world examples from other HIV service providers, and methods for applying this information in HIV programs.

<https://targethiv.org/cqii>

³ See §§ 2604(h)(5), 2618(b)(3)(E), 2664(g)(5), and 2671(f)(2) of the PHS Act.

⁴ Institute for Healthcare Improvement. Model for Improvement. Accessed at <http://www.ihc.org/resources/Pages/HowtoImprove/ScienceofImprovementHowtoImprove.aspx>

⁵ Lean Enterprise Institute. What is Lean? Accessed at <http://www.lean.org/WhatsLean/>

HRSA Quality

HRSA's primary goal is to "Improve Access to Quality Health Care and Services" and has a longstanding commitment to improve the quality of healthcare for people who are uninsured, isolated or medically vulnerable the in the United States. HRSA is active in improving quality at the Federal, State and local levels and at the point of care. The HRSA Quality website (<https://targethiv.org/library/ecqm>) provides a centralized source of information and technical assistance for HRSA recipients and the safety net population.

Agency for Health Research and Quality

AHRQ is the lead Department of Health and Human Services (HHS) agency supporting research to improve quality of care, reduce costs, and increase access to essential services. Website: <http://www.ahrq.gov>

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 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 larger State disaster plan.

The National Alliance of State and Territorial AIDS Directors (NASTAD) has produced 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." The guide can be found on NASTAD's website: <https://www.nastad.org/>.

Section III. ADAP Operations

III. Ch 1. ADAP Initial Eligibility Determination and Recertification

III.1.A. Introduction

ADAPs are required to determine initial eligibility and to conduct annual certification and six-month recertification of all enrolled clients to verify whether individuals remain eligible for ADAP. The RWHAP legislation states that an individual must have a diagnosis of HIV and “be a low-income individual as defined by the State.” More specific eligibility for ADAP enrollment is determined at the State/Territory level and includes residency in the jurisdiction. The eligibility assessment process entails review of applications, verification of information, approval/disapproval, and client notification. Some ADAPs handle this 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 State/Territory ADAP, the requirement is that eligibility criteria and covered treatments for anyone enrolled in the ADAP must be consistently applied across the State/Territory.

In Policy Notice 13-03, HRSA outlines expectations for client eligibility determinations in the context of Affordable Care Act implementation. The PCN reviews the coverage options that are available to many people living with HIV, recommends that recipients standardize RWHAP financial eligibility determinations with the eligibility process for these coverage options, and describes RWHAP recertification requirements.

Confidentiality and Privacy of Client Data.

Client information compiled by ADAPs contains protected health information (PHI) and is often considered part of a client’s medical record. This makes the information subject to privacy and confidentiality standards, including HIPAA. ADAPs must utilize security and administrative controls to protect client information. ADAPs should work with their legal counsel to determine the appropriate language to be included to enable communication with clinical providers, insurance companies, and pharmacies.

HIPAA is the Health Insurance Portability and Accountability Act of 1996, which established a set of national standards for the protection of certain health information, including HIV status. A major goal of HIPAA is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public’s health and well being. For more information, see

<http://www.hhs.gov/ocr/privacy/index.html>

III.1.B. Legislation, HRSA Program Requirements, and Expectations

The legislative provisions for 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.

HRSA Policy Clarification Notice (PCN) 11-06 states that “All therapeutic treatments and ancillary devices included on the recipient’s approved ADAP formulary and all ADAP-funded services...must be equally and consistently available to all eligible enrolled individuals throughout the State/Territory”.

PCN 11-06 also states that “All Part B grantees must devise, implement, and rigorously monitor the use of consistent eligibility standards across all entities involved in certifying and recertifying ADAP eligibility”.

PCN 13-02 states “HAB expects all RWHAP grantees to establish and monitor procedures to ensure that all funded service providers verify and document client eligibility”.

III.1.C. Initial Eligibility and Annual Certification

At the time of initial enrollment, and on an annual basis thereafter, an ADAP must provide a complete assessment of an individual’s eligibility for the AIDS Drug Assistance Program. The eligibility standards used must be consistently applied to all applicants across the State/Territory. As per PCN 13-02, ADAPs must ensure that client eligibility is documented, whether through paper client files or electronically. It is HRSA’s expectation that ADAP enrollment, certification and recertification processes are designed to allow clients access to medications in a timely manner. The HAB HIV Performance Measures for ADAP include one for “Application Determination” that measures the percent of ADAP applications approved or denied for new ADAP enrollment within 14 days (two weeks) of ADAP receiving a complete application.

III.1.D. Eligibility Requirements

As mentioned earlier, the RWHAP legislation states that eligibility criteria must include, at minimum, an HIV diagnosis and “low-income” status. 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 HIV positive status for ADAP enrollment.

Financial eligibility, which is usually determined as a percentage of the Federal Poverty Level (FPL). One method for calculating an ADAP applicant’s income is Modified Adjusted Gross Income (MAGI), which is used to determine eligibility for

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: <http://aspe.hhs.gov/poverty>

lower costs in the Marketplace and for Medicaid and CHIP. While HRSA HAB is not prescriptive on how financial eligibility is determined, it encourages RWHAP grantees to consider aligning their RWHAP financial eligibility determination requirements with MAGI to reduce the burden on clients and to support coordination with the eligibility determination processes for incusurance affordability programs. See Policy Clarification Notice 13-03 for more information.

Additional eligibility for ADAP enrollment is determined at the State/Territory level. Criteria typically used by ADAPs include the following:

- **Residency** in the jurisdiction.
- **Lack of other sources** to pay for prescribed HIV medications, or documented gaps in third party payment for the medications—to ensure compliance with payer of last resort requirements.

For a list of ADAP eligibility criteria by State/Territory, please refer to the most recent version of the NASTAD National ADAP Monitoring Project Annual Report on the NASTAD website. The 2015 annual report is at: <https://www.nastad.org/resource/national-adap-monitoring-project-2015-annual-report>.

III.1.E. Prohibition on Presumptive Eligibility

The ADAP section of the RWHAP legislation states that “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” (Section 2616. 300ff–26 (b)). HRSA has interpreted the legislation to mean that an individual must be determined eligible for ADAP prior to receiving services. As such, it is unallowable for an ADAP to provide services before a client has been determined to meet the ADAP’s eligibility criteria (i.e. “presumptive eligibility”). Expedited enrollment (i.e. “emergency enrollment”) is allowed if the process ensures that clients have been determined eligible prior to services being provided. 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.F. Six Month Recertification Requirement

ADAPs are required to recertify client eligibility every 6 months, and must meet HRSA’s minimum requirements for recertification. ADAPs often use a process similar to their application process to determine clients’ continuing eligibility. Recipients are given flexibility as to whether they recertify all clients at the same time or have a “rolling” recertification based on some other factor (e.g. original enrollment date, birth date, etc.). Recipients should design recertification processes that meet the requirements but do not create additional barriers to care.

Self-attestation

Self-attestation of eligibility criteria may be utilized during a six month recertification process if it fulfills the State/Territory's requirements for verifying an individual's income status, residency status, and insurance status. If the client reports any changes to eligibility criteria, the recipient must obtain documentation of the changes, and their impact on the client's continued eligibility for the ADAP.

Prohibition on Grace Periods

Since HRSA requires eligibility to be redetermined every 6 months and does not allow ADAP to provide services before a client has been determined to meet that ADAP's eligibility criteria, it is also unallowable for a client to receive ADAP service after their 6 month eligibility period has expired and before they recertify their eligibility. If a client does not recertify by the date specified by the recipient, the client is ineligible for the program as of that date; there is no allowable grace period or "cushion". ADAPs are strongly encouraged to evaluate their recertification processes to ensure they are providing sufficient time frames and supports for clients to recertify by the required date. ADAPs are encouraged to work with their other RWHAP Part A, B, C and D colleagues to identify ways to cover medication costs for individuals who did not recertify for ADAP on time.

III. Ch 2. ADAP Formulary

III.2.A. Legislation and HRSA Program Requirements

The RWHAP legislation addresses the ADAP formulary as follows:

Section 2616(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 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 Adolescent and Adult HIV/AIDS Treatment Guidelines published by the Department of Health and Human Services.
- All therapeutic treatment and ancillary devices 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. This guidance on ADAP formulary supercedes preceding guidances.

III.2.C. Formulary Management Strategies

Financial resources largely determine the variations in ADAP formularies whereby some States/Territories have large formularies while others are limited. Other factors influencing formulary design are cost containment strategies, input from an ADAP Advisory Committee, and availability of medications from other payers and programs.

ADAPs manage their formularies with primary attention to RWHAP legislative requirements, determining which medications to include in the ADAP formulary with consideration to a variety of factors, including standards of care, maximizing access to those in need, costs, and availability of medications from other payers and programs. These factors are summarized below.

- **Purchasing Medications at Best Price Available**
The most effective way for ADAPs to maximize what they offer under their formularies is to secure the 'best price available' (i.e. lowest cost) for all the products they offer. 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, consumers, 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, based on considerations like: 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 their 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. Half of all ADAPs use prior authorization processes. Their 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).
- 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. Payer of Last Resort

III.3.A. Introduction

The payer 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 payer of last resort requirement for Veteran’s Administration (VA) and Indian Health Service (IHS) clients is covered in III.3.E below.

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

III.3.B. Legislation, HRSA Program Requirements, and Expectations

RWHAP funds are intended to fill gaps in care and serve as the payer 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 payer or when the costs are not covered by other public and private payers.

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);

Policy Clarification Notice 13-03 states:

“Grantees must assure that funded service providers make reasonable efforts to secure non-RWHAP funds whenever possible for services to individual clients. Grantees and their contractors are expected to vigorously pursue enrollment into health care coverage for which their clients may be eligible (e.g., Medicaid, CHIP, Medicare, state-funded HIV/AIDS programs, employer-sponsored health insurance coverage, and/or other private health insurance) to extend finite RWHAP grant resources to new clients and/or needed services. Grantees and subgrantees must assure that individual clients are enrolled in health care coverage whenever possible or applicable, and are informed about the consequences for not enrolling. Please note that the RWHAP will continue to be the payer of last resort and will continue to provide those RWHAP services not covered, or partially covered, by public or private health insurance plans.”

III.3.C. Ensuring Compliance with Payer of Last Resort

In order to ensure compliance with the payer of last resort requirement, ADAPs must ensure eligible individuals are expeditiously enrolled in other programs for which they are eligible and that the ADAPs coordinate with other payers.

“Vigorously Pursue” Health Care Coverage

As stated in PCN 13-05, recipients and their contractors “are expected to vigorously pursue enrollment into health care coverage for which their clients may be eligible (e.g., Medicaid, CHIP, Medicare, state-funded HIV/AIDS programs, employer-sponsored health insurance coverage, and/or other private health insurance) to extend finite RWHAP grant resources to new clients and/or needed services.” Recipients and sub-recipients must also assure that clients are informed about the consequences (i.e. the fee called the ‘individual shared responsibility payment’) for not enrolling in health care coverage for which they are eligible.

PCNs 13-01 and 13-04 state that recipients are required to have policies regarding the required process for pursuit of enrollment of health care coverage for all clients, and that they need to document the steps taken during their pursuit of enrollment for all clients. This requirement applies to sub-recipients and contractors as well. Recipients are permitted to, and encouraged to, continue providing services funded through RWHAP to a client that remains unenrolled in

Medicaid or health care coverage “after extensive documented efforts on the part of the grantee to enroll the client”. See PCN 13-01 and 13-04 for more information.

Coordination with Other Payers

ADAPs are expected to work with other payers 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 payers and programs can be implemented in many ways, as follows:

- **Understanding Other Payers and Programs.** RWHAP programs, including ADAPs, are required to coordinate their services and seek payment from other sources before RWHAP funds are used. This makes RWHAP the “payer of last resort,” meaning that funds are to fill gaps in care not covered by other resources. Major payers include: Medicaid, Medicare, the Children’s Health Insurance Program (CHIP), private health insurance, and as of 2014, State and/or Federal Health Insurance Marketplace. The next section summarizes key public and private programs.
- **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 represents new opportunities for access to Medicaid, ADAP expenditures counting towards 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 Medicaid) and/or have engaged with a service provider to electronically check for and applicant’s enrollment in Medicaid and other third party insurance.

III.3.D. Other Payers and Programs

This section outlines potential other payers and programs that may cover a PLWH’s costs for medication.

A. Medicaid

Accounting for both Federal and State funds, Medicaid is the largest payer of health care for PLWH, including prescription drug costs. The level of cooperation between ADAPs and State Medicaid programs varies significantly across States. State Medicaid programs have been strongly encouraged by CMS to coordinate with RWHAP recipients (see “State Medicaid Director” letter dated November 25, 1998). HRSA HAB strongly encourages ADAPs to develop a very high level of collaboration with Medicaid on multiple issues. At a minimum, ADAPs need

to ensure the level of interface needed between the program and Medicaid to transition ADAP clients to Medicaid and to establish back billing processes. For example:

- In States that have chosen to expand Medicaid through the ACA, ADAP clients who previously did not meet Medicaid income or disability eligibility requirements may now be Medicaid eligible.
- Clients may transition back and forth from ADAP to Medicaid during Medicaid spend-down periods. (Spend-down refers to the process of incurring medical expenses that are subtracted from income so that the individual becomes Medicaid eligible based on income).
- An individual covered under ADAP may receive retroactive Medicaid eligibility status, and the ADAP must have a process in place to back-bill Medicaid for ADAP funds expended during the retroactive coverage period.
- An individual's health or financial circumstances may change rapidly, potentially resulting in a change in ADAP or Medicaid eligibility status.

For information on Medicaid:

<http://www.kff.org/medicaid/upload/7334-03.pdf>

Tracking all of these factors requires a carefully tailored and systematic approach. In some States, the ADAP is administered through the State Health Department, and the Medicaid program is administered by a different State agency (e.g., Department of Public Welfare). In other States however, the ADAP and Medicaid programs are administered by the same State agency, resulting in a high level of cooperation between the two programs. In practice, there are general areas of cooperation between ADAP and Medicaid, which typically happens within the broader context of RWHAP Part B and Medicaid collaboration:

- Eligibility coordination.
- Coordination of benefits.
- Participation in the development of State Medicaid waivers.

Within each area, several levels of cooperation are possible. Simple cooperative strategies require a minimal level of interaction between the ADAP and the Medicaid Office; more complex strategies require a greater, sustained level of interaction.

The National Academy for State Health Policy outlined a number of strategies for coordination between Medicaid and RWHAP in a November 2013 briefing

(http://www.nashp.org/?s=Ryan+White+Medicaid+&category_name=), including:

- Establish regular coordination between the Medicaid Directors and State AIDS Directors to assist in designing a Medicaid program that meets the needs of PLWA.
- Include state Medicaid representation on RWHAP Health Services planning groups.
- Establish or amend existing data sharing or data coordination capacity between Medicaid and RWHAPs.
- Share contracting, credentialing, and billing/reimbursement resources to ensure that RWHAP providers are prepared for coverage expansions.
- Assess and ensure provider and pharmacy network adequacy, particularly within Medicaid managed care plans.

- Analyze covered services under Medicaid and the RWHAP to identify gaps and opportunities for coverage completion by the RWHAP.
- Use ADAP formularies as a comparison point for HIV-related medications included on Medicaid formularies.
- Medicaid and Medicaid MCOs should consider allowing providers to choose the prescription refill period that most effectively meets a patient's needs.

Medicaid is complex and coverage and eligibility aspects vary from State to State. Understanding the particulars of a State Medicaid program—including the eligibility determination process, eligibility categories and available benefits, and Medicaid waivers in that state—will better prepare an ADAP for making contact with the program.

Informational resource on understanding Medicaid: <http://www.kff.org/medicaid/index.cfm>

B. Medicare Part D

Medicare is the second largest Federal payer of HIV care costs in the U.S. and a significant payer of HIV prescription costs under the Medicare Part D drug benefit. Similar to Medicaid/ADAP coordination, ADAP and Medicare coordination is essential for coordinating benefits and controlling costs under the RWHAP mandate to serve as the payer of last resort.

All Medicare beneficiaries are required to have prescription drug coverage—either through Medicare Part D or a private plan (e.g., retirement benefit from an employer) that provides coverage at least equal to Medicare Part D (called creditable coverage). Medicare Part D coverage is provided by private prescription drug plans (PDPs) and Medicare Advantage plans (MAPDs), which are overseen by HHS's Centers for Medicare & Medicaid Services (CMS), which administers Medicare and Medicaid.

ADAP Coverage of Medicare Part D Costs: TrOOP

Medicare Part D costs include premiums for coverage and additional out-of-pocket costs that are incurred during the year. Out-of-pocket costs vary according to when different levels of spending on prescription drugs are reached. These out-of-pocket costs under Medicare Part D are called "true out-of-pocket" (TrOOP) expenditures, which is what a beneficiary must spend in a calendar year on Medicare Part D covered drugs in order to move through different levels of spending in order to reach the Medicare Part D catastrophic coverage threshold. The gap (or self-pay component) in Medicare Part D coverage, called the 'donut hole', starts when total drugs costs reach a designated level and ends when expenditures for medications (TrOOP) reach the 'catastrophic coverage' threshold. A key benefit of the Affordable Care Act (ACA) for ADAP clients on Medicare Part D is that ADAP expenditures began counting towards TrOOP expenditures, helping clients meet the 'catastrophic coverage' threshold. Also, under the ACA the 'donut hole' is gradually decreasing and will close completely by 2020. Once an individual reaches the catastrophic coverage level, Medicare Part D drugs are available at a 5% percent share of cost for most antiretrovirals and at a nominal co-payment for generic medications.

Learn more about ADAP and Medicare Part D:

<https://hab.hrsa.gov/publications/library/associations-between-medicare-part-d-and-out-pocket-spending-hiv-viral-load-adherence-and-adap-use-dual-eligibles-hiv>

See **Appendix 3** for more information on Medicare electronic claims processing and steps for ensuring proper TrOOP calculation for ADAP clients with Medicare Part D.

C. Other Sources of Medications

In addition to Medicaid and Medicare Part D, PLWH may also be eligible for medications through one of the following sources:

- Veterans Affairs
- Department of Defense
- Indian Health Service
- Correctional facilities (Federal, State, and local)
- Non-Federal public funds (city, county or State/Territory funds)

CI. RWHAP Programs

As was covered in Section I, the RWHAP is comprised of multiple components, called Parts. While all RWHAP Parts focus on bringing PLWH into HIV care and providing them with quality services, some RWHAP-funded programs provide medication assistance. Some of these programs may provide assistance for medications not covered by ADAP, to those who cannot access ADAP (e.g., eligibility issues), and to those on ADAP waiting lists. When these other programs provide medication assistance similar to ADAP, coordination is essential in order to avoid duplication of services provided.

CII. Alternate Medication Assistance Resources Trials

In addition to the payers and programs listed above, pharmaceutical companies and others offer medication assistance in certain circumstances. NASTAD has compiled alternate medication assistance resources into one document, which is available on their website at https://www.nastad.org/sites/default/files/HIV-and-PAPs-CAPs-Resource-Documen_3.pdf.

Following is a summary of these resources.

- **Manufacturer Patient Assistance Programs**

A patient assistance program is a program run through pharmaceutical companies to provide free or low-cost medications to people with low-incomes who do not qualify for any other insurance or assistance programs, such as Medicaid, Medicare, or AIDS Drug Assistance Programs (ADAPs). Each individual company has different eligibility criteria for application and enrollment in their patient assistance program.

Common Patient Assistance Program Application Form

In 2012, the Department of Health and Human Services (DHHS), along with seven pharmaceutical companies, NASTAD, and community stakeholders developed a common patient assistance program application form that can be used by both providers and patients. This form combines common information to allow individuals to fill out one form. Once the form is completed, case managers or individuals submit the

single form to each individual company, reducing the overall amount of paperwork necessary to apply for patient assistance programs.

See the Common PAP Application: <http://hab.hrsa.gov/patientassistance/cpapaform.pdf>

The non-profit organization HarborPath operates a special patient assistance program for individuals on ADAP waiting lists. HarborPath creates a single place for application and medication fulfillment. This "one stop shop" portal provides a streamlined, online process to qualify individuals and deliver the donated medications of the participating pharmaceutical companies through a mail-order pharmacy.

- **Cost Sharing Assistance Programs**

A cost-sharing assistance program (CAP) is a program operated by pharmaceutical companies to offer cost-sharing assistance (including deductibles, co-payments and co-insurance) to people with private health insurance to obtain HIV drugs. CAPs are also always free of charge to eligible individuals.

- **Clinical Trials**

In addition, pharmaceutical companies often provide access to new investigational drugs under "compassionate use" programs. In a similar manner, clinical trials offer individuals with HIV access to other potential life-saving therapies. Clinical trials are controlled experiments of investigational agents or treatments and are approved by the U.S. Food and Drug Administration (FDA). Pharmaceutical manufacturers and the government typically pay for these trials.

Learn about clinical trials: <http://aidsinfo.nih.gov>

III.3.E. Exceptions to the Payer of Last Resort Requirement

RWHAP recipients may not deny services, including prescription drugs, to an individual receiving benefits through Veterans Affairs (VA) who is otherwise eligible for RWHAP services, even if they could obtain services and medications through the VA (PCN 16-01). Native Americans can also access RWHAP services, including prescription drugs, even if those services are available through Indian Health Service, tribal or urban Indian health programs (PCN 07-01).

III. Ch 4. Overview of Cost Containment Strategies

ADAPs are responsible for managing scarce resources in the most efficient and effective manner possible. ADAPs are experiencing greater demand for services due to: increased HIV testing, resulting in more people learning their HIV status; PHS 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-cutting and cost-saving strategies. HRSA HAB defines them as follows.

- **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 insurance eligibility criteria.

Caps on Medications and Supplies, Prior Authorization

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 payer); 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.
- **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 Program structural or operational changes such as expanding insurance assistance; improved systems and procedures for back-billing other payer sources; improved client recertification processes; strategies to increase enrollment in insurance through State or Federally funded Insurance Marketplaces; collection of rebates from drug manufacturer; and Medicare Part D Prescription Drug Plan data-sharing agreements with CMS.

These measures impact multiple facets of ADAP operations. For example, purchasing ADAP medications at a lower price can allow an ADAP to expand its formulary and also reduce or eliminate a waiting list. Improved client recertification processes might result in enhanced coordination with other payers and programs, cutting ADAP costs and allowing the ADAP to enroll new clients or expand the formulary.

In formulating strategies, ADAPs must often balance conflicting concerns: cutting costs versus maximizing coverage; developing quick fixes versus long-term saving strategies; and innovating while complying with legislative and program requirements.

III.5.A. Introduction and Definition

Despite appropriation increases, steady growth in the number of eligible clients combined with rising costs of complex HIV treatments sometimes results in States/Territories experiencing greater demand for ADAP services than available resources can cover. 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 defines a waiting list as a register of individuals who have applied for and been deemed eligible for a State'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 reviews the ADAP's budget forecasting to ensure that a waiting list is an appropriate response. The ADAP is required to actively monitor 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 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 DSHAP Project Officer.

If a RWHAP Part B recipient has a waiting list, it is not eligible to request a waiver from the requirement to allocate 75 percent of funds on core medical services. The HRSA HAB Fiscal Monitoring Standards state:

Section A: Limitation on Uses of Part B Funding. 8. Grantee Responsibility. "If a waiver is desired, certify and provide evidence to HRSA HAB that all core medical services funded under Part B are available to all eligible individuals in the area through other funding sources and that ADAP does not have a waiting list."

III.5.B. Requirements Regarding Waiting Lists

HRSA has the following requirements regarding ADAP waiting lists:

- **Rationale for Establishing a Waiting List**
ADAPs must be able to clearly demonstrate to HRSA the need for a waiting list prior to establishing one.
- **Policies and Procedures**
ADAPs 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 it is followed consistently across the State/Territory.
 - A revisions and appeals process.
- **Eligibility Determination**

ADAPs must assess each applicant for ADAP eligibility prior to placing the individual on an ADAP waiting list.
- **Monitoring Process**

ADAPs must, according to a schedule outlined in a waiting list policy and procedure, reassess eligibility on a pre-established basis. ADAPs 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 their waiting list to HRSA, as determined by HRSA.
- **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, with recommendations or requirements for clients to work with a case manager, PAPs, or other options on a continuous basis (e.g., apply and re-apply as necessary for other programs).

Section IV. ADAP Medication Assistance

IV. Ch 1. Overview

The purchase of FDA-approved medications for low-income individuals with HIV disease who have limited or no coverage from private insurance, Medicaid, or Medicare is the core historical component of ADAPs. ADAPs have developed a variety of drug purchasing and dispensing systems to respond to the needs of their 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 insurance 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:

- 1) **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 their program. Many ADAPs use Pharmacy Benefits Managers 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 ADAPs is to secure medications at the best price available to them in order to maximize 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 (see the next chapter for more information on the 340B Program).
- **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 Office of Pharmacy Affairs. 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 Prime Vendor Program may result in additional discounts of 20 to 50 percent of drug market prices. More information about the Prime Vendor Program: <http://www.340Bpvp.com>.
 - The ADAP Crisis Task Force negotiates reduced drug prices or price freezes with all eight manufacturers of antiretrovirals for all ADAPs. Task Force negotiated prices for antiretrovirals average a discount of more than 50% from Wholesaler

Acquisition Cost (WAC). More information about the ADAP Crisis Task Force can be found on the NASTAD website: <https://www.nastad.org/>

- ADAPs may receive additional wholesaler discounts due to prompt payment of other offers negotiated directly with wholesalers.

IV. Ch 2. 340B Drug Pricing Program

IV.2.A. Introduction

As a federally funded program, ADAPs are required 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’s Office of Pharmacy Affairs (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 resources, allowing them to reach more eligible patients and provide more comprehensive services. Manufacturers that 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).

On August 28, 2015, HRSA posted in the Federal Register proposed “340B Drug Pricing Program Omnibus Guidelines” for public comment. The proposed omnibus guidelines provide revised guidance on a number of issues relevant to ADAP, including the generation of ADAP rebates. The public comment period ended on October 27, 2015. HRSA received over 1,200 comments and is, as of this writing, analyzing the comments in an effort to determine next steps.

Definition of Covered Outpatient Drugs

Covered outpatient drugs, as defined in section 1927(k) of the Social Security Act, may be purchased under the 340B Program. Covered outpatient drugs generally include:

- A drug that can only be dispensed upon prescription.
- A prescribed biological product other than a vaccine.
- Insulin.
- 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.

See a list of drug manufacturers participating in 340B: <http://opanel.hrsa.gov/opa/default.aspx>

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 Act (PHSA) “Limitation on Prices of Drugs Purchased by Covered Entities,” codified at 42 U.S.C. 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 <http://www.hrsa.gov/opa/updates/2018/december.html>.

Who Has Access to 340B Prices: Covered Entities

Eligible covered entity types are defined in section 340B(a)(4) of the PHSA, as amended. 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 ADAPs are available at <http://www.hrsa.gov/opa/eligibilityandregistration/ryanwhite/index.html>

ADAPs are unique in that they are the only entities that may 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 provide its Medicaid billing status during registration and ensure the 340B Medicaid Exclusion File correctly reflects the ADAP’s Medicaid billing status at all times. See <http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html> for more information.

Related to the prohibition on duplicate discounts, a drug purchased under the 340B Program by a covered entity cannot also be claimed for a 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.

See Patient Definition Guidelines: 61 Fed. Reg. 55156 (October 24, 1996).

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

- **Maintenance of auditable records.** Covered entities (i.e., participating ADAPs) must retain records of 340B Program drug purchases for a period of not less than 3 years. This is critical documentation in the event of a manufacturer or HHS audit.
- **Audits.** The covered entity must permit the Secretary of HHS 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.

See the OPA Audit Process: <http://www.hrsa.gov/opa/programintegrity/index.html>

- **Violations of Statutory Requirements.** The covered entity must offer repayment to the manufacturer for any violations of the prohibitions on duplicate discounts/rebates or diversion.

IV. Ch 3. Accessing 340B Prices

IV.3.A. Introduction

340B covered entities can secure 340B pricing through a point of purchase discount (direct purchase), through a pharmacy network/rebate model, or both. The majority of 340B covered entities use a direct purchase model to access 340B prices. An ADAP may 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.B. Direct Purchase Model

Under the direct purchase model, a covered entity pays a discounted (i.e. 340B plus any additional discounts) price 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 Pharmacy Benefits Manager). 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 direct purchase options, 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. The ADAP has the discretion of working with a purchasing agent of their choice to access the most cost efficient options for purchasing medications. The 340B Program Prime Vendor Program (PVP) is available to covered entities to assist with drug distribution and to have access to sub-ceiling 340B prices (<https://www.apexus.com/>).

A 340B covered entity is prohibited from obtaining 340B pricing (either through a rebate or through a direct purchase) on a drug purchased by another covered entity at or below the 340B ceiling price. All covered entities, including ADAPs, must ensure that drugs that have been purchased at or below the ceiling price for a patient of a covered entity are not also subject to any additional 340B discounts.

IV.3.C. 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 copayments, 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. An ADAP must not submit a claim for a 340B rebate if the drug is also subject to a Medicaid rebate. ADAPs must submit claims to drug manufacturers to receive rebates on 340B drugs. ADAPs may not submit a rebate for a drug acquired by another 340B covered entity at or below the 340B price.

ADAPs are unique in that they are the only covered entities that may receive a 340B rebate from a drug manufacturer. 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 (or some combination of the two), a pharmacy benefits manager, or a State Medicaid 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

ADAP 340B rebate invoices are recommended to be submitted to the drug manufacturer within 90 days of the end of the quarter. Drug manufacturers normally remit rebates back to the ADAP within the next 90 days. ADAPs can determine how many or which drugs to submit for a rebate (e.g. drugs with highest utilization and/or cost, specifically ARV's) . An ADAP may submit rebate claims to all manufacturers with drugs on the ADAP formulary. ADAPs can also set a rebate billing limit based on the cost of billing for the rebate and the potential recovery amount. ADAPs should engage in a thorough cash flow analysis to determine the timing of rebate recoveries and availability of grant funds and other resources to assure 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 must provide the information required by the manufacturer, which includes, for each drug purchased: the National Drug Code (NDC), the drug name, the drug form, the quantity of the drug prescriptions dispensed, quantity of units reimbursed and amount reimbursed. ADAPs need to keep supporting records for all submitted claims and make them available to manufacturers, if necessary to resolve disputes.

IV.3.D. Contract Pharmacy Services Mechanism

ADAPs can choose to participate in the 340B Program by establishing a contract pharmacy services agreement with one or more pharmacies. The 340B Program guidelines create a system in which an ADAP (or other covered entity) may contract with one or more pharmacy(ies) to dispense 340B drugs. 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). For more information about 340B contract pharmacy implementation, see <http://www.hrsa.gov/opa/implementation/contract/index.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 the following link:

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

Track and Trace

The “track and trace” component of the DSCSA requires manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, and for manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market. ADAPs that meet the Act's definition of one of these components of the drug supply chain will need to comply with the “track and trace” requirements of the Act. The Act allows a dispenser to “enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser” (section 582 (d)(1)(B)). While this provision may provide a workable solution for an ADAP to be compliant with “track and trace”, especially when contract pharmacies are utilized, it may require an ADAP to make changes to its contracts or operations.

IV.3.F. Dispute Resolution

Due to the complexity of the rebate submissions and claims process, manufacturers may raise questions about certain rebates being requested. ADAPs are urged 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 a serious, protracted dispute occurs, it may be necessary to use the OPA informal dispute resolution process, as defined in a separate Federal Register notice (61 FR 65406). In this situation, the 340B program permits a participating drug manufacturer to audit (at its own expense) an ADAP's records that pertain to 340B rebates, covered drugs that may have generated a Medicaid rebate or may have been diverted to an individual who was not a client of the ADAP. These audits may only be performed within the guidelines developed by HRSA (e.g., manufacturer documentation demonstrating reasonable cause to believe that the ADAP has

violated these prohibitions). Any ADAP requiring more information about the dispute resolution process should contact OPA.

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 bills. OPA assistance with dispute resolution is available at any time during a rebate dispute with a manufacturer.

A manufacturer may withhold rebate payments beyond 90 days for the specific disputed amounts under either one of these conditions:

- If an ADAP has failed to respond to a manufacturer's request for additional information within 30 days.
- If a request has been filed with the HRSA Office of Pharmacy Affairs for a dispute resolution review or audit.

If a major problem of nonpayment or late payment develops, an ADAP should request assistance from OPA to resolve the problem.

IV. Ch 4. Pharmacy Benefits Managers (PBMs)

IV.4.A. Introduction

ADAPs can choose to utilize a pharmacy benefits manager (PBM) to provide administrative and pharmacy claim adjudication services. PBM services can include: contracting with a network of pharmacies; establishing payment levels for provider pharmacies; negotiating discount arrangements with wholesalers; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization review; and operating disease management programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies.

IV.4.B. PBM Administrative Functions

In addition to a PBM's combined purchasing power, it can provide a wide-range of administrative and drug utilization services that can benefit an ADAP. Administrative functions typically include:

- Establishing and maintaining a network of providers (recruit and manage a network of pharmacies that fill prescriptions for RWHAP ADAP clients; negotiate prices and payment terms and contract with pharmacies, monitor/audit 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; track data required to receive rebates; performing electronic split billing at pharmacy point of service, pay pharmacy invoices, and bill ADAP; manage rebates and discounts with pharmaceutical companies; serve as

electronic data transfer agent to meet all requirements related to Medicare TrOOP payments [serve as TrOOP coordinator and prepare reports]; paying health insurance co-payments and deductibles).

- Assist with benefit design and business rules (covered drugs, exclusions, limits cost-sharing provisions [differential co-payments for generic or preferred drugs], mail-order dispensing).
- Information management (risk assessment, profiling).
- Continuous electronic insurance eligibility checking.
- Pharmacoeconomic studies.

IV.4.C. 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 towards 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 (retrospective-drug utilization review (DUR), prospective-DUR [some PBMs use the term "concurrent-DUR"], DUR interventions, "academic detailing," provider education).
- Disease management (therapeutic outcomes management).
- Patient compliance (patient education, e.g., newsletters; phone reminders).

IV.4.D. PBM Administrative Fees

PBMs may charge a per transaction administrative fee, depending on the number and extent of services that they are contracted to perform. The fees charges, if any, are dependent on the contract terms negotiated between the ADAP and PBM. ADAPs that contract with a PBM pay for the cost of the drug, the pharmacy dispensing fee, and an additional per claim administrative fee. In some cases, the administrative fee is rolled into the dispensing fee charged per prescription. The costs of a PBM are considered a "direct service" and do not count against a RWHAP Part B recipient's 10% administrative cost cap. HRSA Policy Clarification Notice 15-01, *Treatment of Costs under the 10% Administrative Cap for Ryan White HIV/AIDS Program Parts A, B, C, and D*, provides updated guidance on what costs count towards the administrative cap.

Section V. ADAP Health Insurance Assistance

V. Ch 1. Introduction

The RWHAP legislation allows ADAPs the option of purchasing health insurance for ADAP clients instead of paying solely for HIV medications. Many RWHAP Part B recipients have health insurance purchasing programs—either through their RWHAP Part B grant and/or through their RWHAP Part B ADAP. Participation of ADAPs in health insurance assistance is increasing under the Affordable Care Act as options for purchasing insurance have expanded under State and Federal health insurance exchanges. In addition to the payment of premiums, ADAP health insurance assistance includes the payment of medication cost-sharing (deductibles, co-payments and/or co-insurance).

Policy Clarification Notice (PCN) 13-05 states, “If resources are available, RWHAP grantees and subgrantees are strongly encouraged to use RWHAP funds for premium and cost-sharing assistance for these individuals when it is cost-effective, as appropriate.”

Health Insurance Assistance funded through ADAP funding is considered a component of an ADAP, not a separate program. PCN 07-05 states that health insurance assistance “funds must continue to be managed as part of the established ADAP Program”. PCN 07-05 also stipulates that the health insurance assistance program must follow the same eligibility requirements as ADAP.

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

The RWHAP legislation defines ADAP health insurance 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).

HAB Policy Notice 13-05, Clarifications Regarding Use of Ryan White HIV/AIDS Program Funds for Premium and Cost-Sharing Assistance for Private Health Insurance, states, in part:

“If resources are available, Part A planning bodies and Ryan White Part B, C and D grantees may choose to prioritize and allocate funding to health insurance premium and cost-sharing assistance for low-income individuals in accordance with Section 2615 of the Public Health Service Act. The grantee must determine how to operationalize the health insurance premium and cost-sharing assistance program, including the methodology used by the grantee to: (1) assure they are buying health insurance that at a minimum, includes at least one drug in each class of core antiretroviral therapeutics from the HHS Clinical Guidelines for the Treatment of HIV/AIDS as well as appropriate primary care services; and (2) assess and compare the aggregate cost of paying for the health insurance option versus paying for the full cost for medications and other appropriate primary care services. The grantee may consider providing the resource allocation to the Part B/AIDS Drug Assistance Program (ADAP) which currently operates the health insurance continuation programs in some States and, therefore, has the infrastructure to verify coverage status and process payments to health plans for premiums, co-payments and deductibles, and to pharmacies for medication co-payments and deductibles. ”

See HAB’s policies and program letters:

<http://hab.hrsa.gov/manageyourgrant/policiesletters.html>

V. Ch 3. Requirements for Purchase of Health Insurance

In order to use RWHAP Part B ADAP funds to purchase insurance, ADAPs must indicate in the RWHAP Part B Base/ADAP Base (X07) application that the program intends to utilize RWHAP Part B/ADAP funds for a health insurance assistance program. The ADAP must have conducted a cost effective analysis to: (1) assure that they are buying health insurance that meet a minimum formulary requirement; and (2) assess and compare the cost of providing medications through the health insurance option versus the existing ADAP which may be made available to HRSA upon request.

V.3.A. Minimum Coverage Standard

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

1) Primary care services

The legislation states that the primary care services must be “appropriate”. HRSA PCN 07-05 states that the primary care services must be “comprehensive”.

2) HIV treatments

The RWHAP legislation states that the health insurance must include “a full range of such therapeutics”. HRSA’s guidance in PCN 13-05 clarifies that the health coverage purchased must include “at least one drug in each class of core antiretroviral

therapeutics from the HHS Clinical Guidelines for the Treatment of HIV/AIDS” (i.e. the minimum formulary requirement for ADAPs).

ADAPs cannot pay for health insurance premium that does not include a pharmacy benefit. For example, an ADAP cannot pay for a stand-alone dental or vision insurance policy.

HRSA allows ADAPs to pay for Medicare Part D premiums, since they provide the medication assistance component of the Medicare program.

V.3.B. Cost-Effectiveness Assessment

The RWHAP legislation states that an ADAP can purchase insurance 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 13-05 clarifies that the ADAP must “assess and compare the aggregate cost of paying for the health insurance option versus paying for the full cost for medications”. The required cost comparison is in the aggregate.

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 is:

[cost of the monthly premium x 12 months] = [annual premium cost for an insurance policy + (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 cost [$\$300 \times 12$] = [$\$3600 + (\$2,000 \text{ out-of-pocket maximum})$], then the annual cost is \$5,600. The ADAP would then compare the \$5,600 insurance 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
Total:	\$30,000	\$27,500

Since cost neutrality is required for the aggregate cost of the health insurance program, not for each participating individual, although the cost of health insurance 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. Ch 4. Health Insurance Assistance and ACA Premium Tax Credits

ADAPs assisting clients with health insurance assistance for plans through the Affordable Care Act (ACA) Marketplace need to address premium tax credits. Many RWHAP clients with incomes between 100-400% of the federal poverty level (FPL) who do not have minimum essential coverage⁶ may be eligible for a premium tax credit to offset the cost of purchasing a qualified health plan through the Marketplace (see PCN 13-05 for more information). 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 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 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 insurance in the Marketplace must establish appropriate mechanisms to vigorously pursue any excess premium tax credit a client receives from the IRS. Recipients and sub-recipients 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. As such, recipients and sub-recipients must use recovered excess premium tax credits in the grant year when the refund is received by the recipient or sub-recipient.
- **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.
- **Prohibition from Paying Client ‘Penalty’**
Under no circumstances can RWHAP funds be used to pay the fee (i.e., shared responsibility payment) for a client's failure to enroll in minimum essential coverage or any other tax liability owed by the client that is not directly attributed to the reconciliation of the premium tax credits.

⁶ Minimum Essential Coverage (MEC) is the type of health coverage an individual needs to meet the individual responsibility requirement under the Affordable Care Act. Information about what plans count as MEC can be found at: <https://www.healthcare.gov/fees/plans-that-count-as-coverage/>

HRSA HAB's Policy Notices can be found at:

<http://hab.hrsa.gov/manageyourgrant/policiesletters.html>

V. Ch 5. Health Insurance Assistance: Medication Cost-Sharing

ADAPs can choose to use their resources to pay for medication cost-sharing (deductibles, co-payments and/or co-insurance costs) for ADAP enrolled clients who have another payer. ADAPs can only provide cost-sharing for drugs that are on the ADAP formulary. **ADAP funds cannot be used for non-medication-related cost-sharing (e.g. medical visit deductibles, co-payments and/or co-insurance).**

Medication cost-sharing is considered by HRSA HAB to be health insurance 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.

Section VI. Technical Assistance for ADAP

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

- Within HAB’s Division of State HIV/AIDS Programs, the Project Officer and the ADAP Advisor work closely to provide technical assistance directly as well as facilitate access to HRSA-funded training and technical assistance resources. The ADAP Advisor can also provide clarity on ADAP requirements and ADAP-related policies.

Contact your HRSA Project Officer: 301-443-6745 or

<https://directory.psc.gov/employee.htm>

Contact the ADAP Advisor, Glenn Clark, at 301-443-3692 or GLClark@hrsa.gov.

- HRSA HAB has a cooperative agreement with the National Alliance of State and Territorial AIDS Directors (NASTAD) to provide to technical assistance to RWHAP Part B/ADAPs in the following areas:
 - Implementing an effective ADAP financial forecasting model.
 - Conducting analysis and evaluation of health plans and identifying barriers to access.
 - Leveraging data to improve health outcomes across the HIV Care Continuum (i.e., data to care), including building and enhancing comprehensive systems of care.
 - Implementing and participating in integrated planning processes.
 - Strengthening capacity to implement and administer insurance purchasing programs.
 - Implementing effective cost-containment strategies and preventing the use of waiting lists, including participating in the 340B program, CMS data sharing, and other data sharing.
 - “Getting the best price” for drugs and exploring opportunities to negotiate or gain access to discounts on high utilization, non-HIV-specific drugs.
 - Providing on-going mentorship and peer-to-peer training and educational opportunities.

More information on NASTAD’s services is found at: <http://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.

Learn more about TA and training for ADAPs: <https://targethiv.org>

Section VII. Appendices

Appendix 1: ADAP Requirements Table

Topic	Requirement	Requirement	Best Practice	Source Document
Formulary	• Minimum formulary requirement	X		PHSA 2616 (c)(1) PCN 11-06
	• FDA-approved medication requirement	X		PCN 11-06
	• PHS/DHHS Treatment Guidelines requirement	X		PCN 11-06
	• Advisory body input on formulary.		X	AM pg. 23
Eligibility Determination and Recertification	• Devise, implement, and rigorously monitor the use of consistent eligibility standards across all entities involved in certifying and recertifying ADAP eligibility	X		PCN 11-06 PCN 13-02
	• Minimum ADAP Eligibility Requirements	X		PHSA 2616.300ff-26 (b)
	• Requirement that eligibility criteria and services must be consistently applied across any State.	X		PCN 11-06 DGL 10/17/96
	• Required Documentation for Initial Eligibility Determination and Once a year Recertification	X		PCN 13-02
	• 6 month Recertification Requirement	X		PCN 11-06 PCN 13-02
	• Required Documentation for 6-month Recertification	X		PCN 13-02
	• Ban on presumptive eligibility	X		PHSA 2616.300ff-26(b) AM p. 30
	• Timeliness of eligibility determination	X		PHSA 2616.300ff-26(c)(4) AM p. 29
Best Pricing	• Requirement to use every means at disposal to secure the best price available for all products on the ADAP formulary	X		PCN 11-06
	• Compliance with 340B program rules (i.e. prohibitions on diversion, duplicate discounts and “double dipping”)	X		NOA
Payer of Last Resort	• Assure that service providers make reasonable efforts to secure non-RWHAP funds whenever possible for services to individual clients	X		PHSA 2617(b)(7)(F) PCN 13-03 PCN 13-06
	• Vigorously pursue expeditious enrollment into health care coverage for which clients may be eligible (recipients and subrecipients)	X		PCNs 13-01 to 13-06
	Regarding Vigorously Pursue: <ul style="list-style-type: none"> • 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 	X X		PCN 13-01, 13-04

Topic	Requirement	Requirement	Best Practice	Source Document
	documented efforts on the part of the recipient to enroll client.			
	<ul style="list-style-type: none"> Requirement to back-bill other payers and reimburse the ADAP when clients are determined to be eligible for other programs that provide prescription drugs. 	X		PCN 11-06 PCN 13-01
Rebates (if applicable)	<ul style="list-style-type: none"> Rebates must be applied to Part B activities, with priority given to ADAP 	X		PHSA 2616.300ff-26 (g)
	<ul style="list-style-type: none"> Rebates must be spent in the grant year in which they are received and prior to drawing down grant funds. 	X		PCN 15-04
	<ul style="list-style-type: none"> 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
	<ul style="list-style-type: none"> Prohibition on sharing ADAP rebates with any other entities 	X		PCN 11-06 PCN 15-04
Drug Distribution	<ul style="list-style-type: none"> Requirement that all ADAP-funded services must be equally and consistently available to all eligible enrolled individuals throughout the State/Territory 	X		PCN 11-06
Health Insurance Assistance (if applicable)	<ul style="list-style-type: none"> RWHAP recipients are strongly encouraged to use RWHAP funds to help clients purchase and maintain health insurance coverage, if cost-effective and in accordance with RWHAP policy 		X	PCN 13-04, 13-05
	<ul style="list-style-type: none"> Insurance purchased by ADAP must include a full range of “such therapeutics” and appropriate primary care services Clarification that health insurance includes at least one drug in each class of core ARV as well as appropriate primary care services 	X		PHSA 2616.300ff-26 (f)(1) PCN 13-05, 13-06
	<ul style="list-style-type: none"> Health Insurance Assistance funds must continue to be managed as part of the established ADAP Program. 	X		PCN 07-05
	<ul style="list-style-type: none"> Health Insurance Assistance must follow same eligibility requirements as ADAP 	X		PCN 07-05
	<ul style="list-style-type: none"> ADAP program must be able to account for and report on funds used to purchase and maintain insurance policies for eligible clients including covering any costs associated with these policies 	X		PCN 07-05
	<p>Cost-Effectiveness</p> <ul style="list-style-type: none"> The cost of purchasing health insurance cannot exceed the cost of otherwise providing drugs States must be able to document for HAB the methodology used by the State to determine cost neutrality 	X		PHSA 2616.300ff-26 (f)(2) PCN 13-05, 13-06
	<ul style="list-style-type: none"> Part B funds cannot be used to support the administration of a health insurance program 	X		DCL 3/15/11
	<ul style="list-style-type: none"> Must establish appropriate mechanisms to vigorously pursue an excess premium tax credit, including: 	X		PCN 14-01

Topic	Requirement	Requirement	Best Practice	Source Document
	<ul style="list-style-type: none"> ○ 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 			
ADAP Flex (if applicable)	<ul style="list-style-type: none"> • 5% cap (10% 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 ADAP Flex submitted annually through grant application or Prior Authorization 	X		PHSA 2616.300ff-25 (c)(6) PCN 07-03 NMS
ADR	Submit recipient and client level data in required format annually	X		NoA AM p. 20
CQM	Part B: As a component of the Part B grant, Part B CQM requirements apply to ADAP. Part B QM program must: <ul style="list-style-type: none"> • Have a statewide QM plan with annual updates. • Established processes for ensuring that services are provided in accordance with PHS treatment guidelines & standards of care • Incorporate quality-related expectations into RFPs and contracts 	X		PHSA 2618(b)(3)(E) PCN 15-02 PCN 11-06
	<ul style="list-style-type: none"> • ADAP-specific: Document progress in making drugs available 	X		PHSA 2616(c)(5)
	<ul style="list-style-type: none"> • “In relation to ADAP, the Part B CQM Program should monitor ADAP enrollment and recertification processes, formulary drug classes, inappropriate ARV regimens and client adherence to prescribed medication regimens” 	X		PCN 11-06
	<ul style="list-style-type: none"> • Use of HAB ADAP Performance Measures, or their equivalent 		X	HPM
Waiting List (if applicable)	Establishment of Waiting List Policies and Procedures, including waiting list criteria and methods for monitoring the list.	X		AM pg. 40
One Program/ One Set of Rules	One program/one set of rules/expectation: All funds allocated to ADAP are subject to HRSA HAB ADAP program expectations.	X		AM p. 12

PHSA = Public Health Service Act (the Ryan White HIV/AIDS Program legislation)

PCN = HAB Policy Clarification Notice

DGL = Dear Grantee Letter

AM = 2015 ADAP Manual

NMS = National Monitoring Standards

NOA = Notice of Award

HPM = HAB Performance Measures

Appendix 2: Key Resources Table

Key Resources	Web Links and Phone Contacts
HRSA and RWHAP	
HRSA HIV/AIDS Bureau	http://hab.hrsa.gov 301-443-6745 or http://hab.hrsa.gov/manageyourgrant/contacts.html
HRSA Project Officers	301-443-6745 or https://directory.psc.gov/employee.htm
RWHAP legislation	http://hab.hrsa.gov/abouthab/legislation.html
HRSA HAB Policies	http://hab.hrsa.gov/manageyourgrant/policiesletters.html
Reporting/Monitoring	
ADR Data Reporting	http://hab.hrsa.gov/manageyourgrant/reportingrequirements.html
Monitoring Standards	http://hab.hrsa.gov/manageyourgrant/granteebasics.html
Performance Measures	http://hab.hrsa.gov/deliverhivaidscare/habperformmeasures.html
Grants Management	
HRSA Electronic Handbooks	https://grants3.hrsa.gov/2010/WebEPSEExternal/Interface/common/accesscontrol/login.aspx?
HHS Grants Policies and Information	http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html
Technical Assistance and Training	
HRSA Office of Pharmacy Affairs	http://www.hrsa.gov/opa or 301-594-4353 or 800-628-6297
Prime Vendor Program	http://www.340bpvp.com or 888-340-2787
Technical Assistance and Training for RWHAP	http://careacttarget.org
HRSA Patient Safety and Clinical Pharmacy Services Collaborative	http://www.hrsa.gov/communitiesofpractice/ata glance/patientsafety.pdf
Key Resources	
HHS HIV/AIDS Treatment Guidelines	http://aidsinfo.nih.gov
HRSA HAB Clinical Protocols	http://hab.hrsa.gov/deliverhivaidscare/clinicalguidelines.html
Affordable Care Act	http://healthcare.gov
National HIV/AIDS Strategy	https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update

Appendix 3: Medicare Electronic Claims Processing

Medicare Electronic Claims Processing

Any payments made by an ADAP on behalf of a Medicare Part D-enrolled beneficiary are considered incurred costs, which means they are treated the same as if the patient paid the out-of-pocket cost. As such, ADAP payments count toward the beneficiary's Medicare Part D TrOOP. This provision was established in the Patient Protection and Affordable Care Act of 2010. The Medicare Part D Plan is responsible for tracking Plan member TrOOP spending. As a result, up-to-date, validated claim level information about benefits provided for a Medicare Part D enrollee must be communicated to the Medicare Part D Plan.

ADAPs must participate in electronic claims processing and sign a data sharing agreement with CMS to ensure that ADAP costs are accurately accounted for in the TrOOP calculation. Electronic processing helps ADAP automatically receive refunds due to retroactive adjustments to claims (e.g., as the result of changes in a member's low-income subsidy status under Medicare Part D that provides for Medicaid and or Medicare coverage of costs). As such, CMS encourages ADAPs to participate in real-time electronic claim processing at the point of sale, and submit electronic enrollment files to CMS's coordination of benefit contractor with specific information that will be provided to the TrOOP facilitation contractor.

Each ADAP enrollment file must include a unique prescription bank identification number (RxBIN) and Processor Control Number (PCN) for claim submission for Medicare Part D enrollees, codes used by network pharmacy payers to identify supplemental benefit coverage, such as ADAP. RxBIN and RXPCN codes can be obtained by contacting the American National Standards Institute at www.ansi.org or the National Council for Prescription Drug Programs at www.ncpdp.org.

ADAPs that do not have electronic claims processing capabilities may submit a batch file of supplemental claims information or make arrangements to submit information in another format to the TrOOP facilitator. If the ADAP uses the batch process, it must still establish a unique RxBIN/PCN and participate in the data sharing exchange with CMS' COB contractor. Further information on the batched claims process is available on the TrOOP facilitator's Web site.

NASTAD has instructional webinars about the TrOOP process on its website:

<http://www.nastad.org/>

Steps for Ensuring Proper TrOOP Calculation for ADAP Clients with Medicare Part D

Below are steps that should be taken by ADAPs to fully participate in the COB and TrOOP facilitation process:

1. Consider obtaining the services of an on-line claims processor to process claims electronically at the point-of-sale (not required for batch TrOOP facilitation process).

Obtaining the services of a processor or Pharmacy Benefit Manager (PBM) for real-time claims adjudication is not required to ensure TrOOP is calculated correctly. CMS understands that for some ADAPs, particularly smaller ones, the cost of doing this may be prohibitive. However, PBMs and processors are knowledgeable about the point-of-sale, real-time claims adjudication process, and can help ensure accuracy and effectiveness of TrOOP facilitation and claims reconciliation. If the ADAP would like to pursue real-time claims adjudication, HRSA suggests you contact the State Medicaid agency or SPAP to find out if you can contract with the same processor. The ADAP may also consult the Pharmaceutical Care Management Association (PCMA) or Pharmacy Benefit Management Institute (PBMI) for a list of member PBMs/processors.

2. Sign a data sharing agreement (DSA) and participate in the COB enrollment file exchange with CMS's COB contractor. (Required for TrOOP facilitation).

ADAPs are required to sign a data sharing agreement (DSA) when participating in the COB enrollment data file exchange. The information the ADAP provides via its enrollment file to the COB contractor, in particular, the unique RxBIN and PCN, is sent to both the TrOOP facilitator and the Part D sponsors.

3. Establish a unique RxBIN and PCN combination for their Part D members and submit this information as part of the COB contractor enrollment file exchange (Required for TrOOP facilitation).

The unique RxBIN/PCN allows the claim to be routed to the TrOOP' facilitator, who will provide the Part D sponsor with the supplemental payer information that is necessary to calculate TrOOP.

4. Ensure that the ADAP or its processor, when processing secondary claims, accepts and processes only those claims that use the same 4Rx information submitted on the ADAP's input file (4Rx -BIN/PCN/Group ID/Member ID) to the COB contractor. (Required for TrOOP facilitation)