

HIV/AIDS Bureau

Division of State HIV/AIDS Programs



AIDS DRUG ASSISTANCE PROGRAM (ADAP) MANUAL

2012

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



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Preface

The AIDS Drug Assistance Program (ADAP) Manual is for directors and staff of ADAPs, Ryan White Part B Program Directors, and others interested ADAP.

The ADAP is a program within Ryan White Part B, which awards grants to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality, community-based care for low-income individuals and families living with HIV/AIDS. Each State and Territory operates an ADAP, and each is unique. ADAPs vary significantly in their administrative structures and the mechanisms they use to make HIV/AIDS medications available to eligible individuals living with HIV.

With this in mind, the Manual—an update from the 2003 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 level, and the key issues and strategies used by ADAPs to broaden access to HIV/AIDS 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 ADAP is an ongoing endeavor of refining and reassessing operations in order to expand access to HIV/AIDS medications and pursue cost-saving and cost-cutting strategies within the complex and evolving U.S. and state specific health care systems.

The Health Resources and Administration's (HRSA) HIV/AIDS Bureau (HAB) prepared this version of the ADAP Manual with input from ADAP directors. HRSA is an Operating Division within the U.S. Department of Health and Human Services (HHS) and administers the Ryan White HIV/AIDS Program 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 the general and move to the specific. 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 Ryan White 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 Part B grant is presented in the Part B Manual and is not repeated in the ADAP Manual. Thus, the ADAP Manual and Part B Manual should be used as companion documents. The Part B Manual is scheduled for release in early 2013.

Routine Updates to the ADAP Manual

The ADAP Manual will be reviewed regularly and will be updated online as needed to reflect changes in ADAP requirements and conditions. ADAP directors will continue to inform HRSA to make the ADAP Manual a living document. HRSA Project Officers will keep grantees 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

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 is codified by Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009). It is the largest Federal program focused exclusively on HIV/AIDS care. The program focus is to award grants for the provision of primary care, and support services to individuals living with HIV/AIDS 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 Ryan White HIV/AIDS Program provides access to care and fills gaps in care not covered by other funding sources.

The Ryan White HIV/AIDS Program awards grants to cities, States, and local community-based organizations to provide HIV-related services to more than half a million people each year. The majority of Ryan White funds support core medical services including outpatient and ambulatory medical services and essential support services. A smaller but equally critical portion is used for technical assistance, clinical training, and research on innovative models of care.

The Ryan White legislation has Parts, which are focused on meeting the needs of communities and populations affected by HIV/AIDS. **Part A** provides emergency assistance to Eligible Metropolitan Areas and Transitional Grant Areas that are most severely affected by the HIV/AIDS epidemic; **Part B** provides grants to States and Territories; **Part C** provides comprehensive primary health care in an outpatient setting for people living with HIV disease; **Part D** provides family-centered care involving outpatient or ambulatory care for women, infants, children, and youth with HIV/AIDS; and **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 program.

The AIDS Drug Assistance Program (ADAP) is a program within Part B, which provides grants to all 50 States, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and five U.S. Pacific Territories or Associated Jurisdictions to provide access to HIV related medications. As such, ADAPs are administered by States and Territories under their Part B grant awards. The AIDS Drug Assistance Program ADAP focuses on providing HIV/AIDS medications to persons in need by either providing the medications directly, providing access through pharmacies, or providing health insurance continuation support for policies that include coverage for HIV/AIDS drugs. With the appropriate approval from HAB, ADAPs can also provide services that enhance access to, adherence to, and monitoring of drug treatments.

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 Ryan White grantees. Project Officers provide guidance on legislative requirements, relevant HRSA policies, and grant requirements. Project Officers also provide technical assistance and can facilitate grantees' access to additional technical assistance and training services.

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. Ryan White Legislation, HRSA Requirements, and Expectations

I.2.A. Introduction

All Ryan White grantees must comply with the Ryan White legislation. Grantees must also comply with Federal requirements and guidance 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. Ryan White Legislation and ADAP

The latest Ryan White legislation is Title XXVI of the Public Health Services (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009). The legislation was first enacted in 1990 as the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act. It has been amended and reauthorized four times: in 1996, 2000, 2006, and 2009 and is due for reauthorization in 2013. The Ryan White 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 Ryan White Program is comprised of multiple components called Parts, which were formerly called Titles under prior versions of the Ryan White legislation. Each Part is designed to address varied HIV/AIDS care needs across local and State jurisdictions and populations. Part

B awards grants to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality care for eligible individuals living with HIV/AIDS. Part B has seven grant programs including ADAP (the “ADAP earmark”). These include the Part B Base Award, the ADAP Earmark, ADAP Supplemental, Minority AIDS Initiative, Part B Supplemental, Emerging Communities, and TGA Transfer grants.

Below is the legislative language for ADAP:

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 Ryan White legislation: <http://hab.hrsa.gov/abouthab/legislation.html>

I.2.C. HRSA/HAB Policies

HRSA develops policies that implement the Ryan White legislation, providing guidance to grantees in understanding and implementing legislative requirements. These policies are available online, along with program letters that provide additional guidance for grantees.

Unless otherwise noted, ADAP policies are issued as Part B grantee policies. Policies with particular relevance to ADAPs include:

Health Insurance Continuation Policy.

Diagnostics and Laboratory Tests Policy.

Funds for Access, Adherence, and Monitoring Services (Flexibility Policy).

Rebate Policy (in progress as of Fall 2012).

See all the HRSA/HAB Policies for Ryan White:

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

I.2.D. HRSA Program Requirements and Expectations

For each Fiscal Year, HRSA releases a Funding Opportunity Announcement (FOA) (previously called program guidance) to provide instructions to applicants in preparing their Fiscal Year grant application. Upon award, all HHS discretionary and cooperative agreement grantees are notified of requirements in a Notice of Award. The Notice of Award provides the total amount of Part B funds awarded for that fiscal year, as well as a breakdown of funding, including the ADAP earmark and the ADAP Supplemental funding (as relevant).

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

Access HHS Grantee Information: <http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html>

The FOA also outlines the following requirements:

- **HRSA/HAB National Monitoring Standards.** HRSA/HAB has issued Monitoring Standards for Part A and Part B grantees. The Standards apply to Part B ADAPs and have particular relevance to ADAPs in terms of such topics as: eligibility criteria, six-month ADAP recertification, and clinical quality management. Grantees are required to implement the Part A and B National Monitoring Standards at both the grantee and provider/sub-recipient levels. To help grantees meet this requirement, HRSA has developed guidelines outlining the responsibilities of HRSA, grantees, and provider staff.

See the National Monitoring Standards:

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

- **Data Reporting.** Part B grantees are required to submit quarterly reports on ADAP activities on the ADAP Quarterly Report (AQR), including aggregate data on the number of clients, total funds expended for ADAP, substantive programmatic changes, and prices paid for specific HIV pharmaceuticals. In October 2012, data collection began for the ADAP Data Report (ADR) a client level data report. The ADR addresses limitations of the aggregate data reporting under the AQR and will enable HRSA/HAB to evaluate the impact of the ADAP on a national level, by describing who is using the program, what ADAP-funded services are being used and the associated costs of these services. The

AQR will be phased out as ADAPs become accustomed to the ADR and the quality of the information provided through the ADR accurately represents the program.

Learn more about ADAP Reporting:

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

- **Quality Management and HRSA/HAB Performance Measures.** HAB has created performance measures that Ryan White HIV/AIDS Program grantees can use to monitor the quality of care they provide. The measures can be used at the provider or system level—in their current format or further modified to meet agency needs.

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

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

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

ADAP Requirements		
Topic	Ryan White Legislation	HRSA/HAB Policy and Program Requirements
Ryan White Legislation/Policy		
Part B Provisions (e.g., Use of Funds)	See Part B Manual	Various National Monitoring Standards
Administrative Costs	Section 2616(c)	Policy 07-03 National Monitoring Standards
Monitoring Standards	Section 2616(c)(5)	National Monitoring Standards
Data Reporting	Section 2616(c)(5)	National Monitoring Standards
Quality/Performance Measures	Section 2616(c)(5)	HRSA/HAB Performance Measures National Monitoring Standards
HIV/AIDS Treatment Guidelines	Section 2616(e)	
Payer of Last Resort	Section 2617(b)(7)(F)	Policy 07-03

Formulary	Section 2616(c)(1) Section 2616(e)	
Eligibility	Section 2616(b)	Policy Notice 10-02 National Monitoring Standards
Six-Month Recertification		National Monitoring Standards: Universal Standards
Health Insurance	Section 2616(f)(1)(2)	Policy 07-05
Diagnostics and Laboratory Testing	Section 2616(c)(2)	Policy 07-02
Outreach, Access, Adherence, and Monitoring	Section 2616(c)(3-5) and Section 2616(c)(6)	Policy 07-03
Use of Drug Rebate Funds	Section 2616(g)	
Other Payers and Programs		
Pre-Existing Condition Insurance Program PCIP		Program Letter, 12/28/10
Portability of Coverage, Enrollee Notices, and Third Party Payments under PCIP		HHS/CMS, Policy Letter #3, 12/28/10
ADAP/TrOOP		Program Letter, 12/10/10
340B		See 340B Chapter

I. Ch 3. Key Resources

I.3.A. Glossary/Definitions and Acronyms

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

- **Ryan White Glossary.** Included here are definitions of Ryan White Parts, Federal agencies, and other program terms. Prepared by HRSA's HIV/AIDS Bureau.

See the definitions: <http://hab.hrsa.gov/abouthab/glossaryterms.html>

- **Ryan White Eligibility and Service Categories.** Eligible Individuals & Allowable Uses of Funds for Discretely Defined Categories of Services (Policy Notice 10-02) lists eligible individuals and allowable uses of Ryan White program funds.

See: <http://hab.hrsa.gov/manageyourgrant/pinspals/eligible1002.html>

- **Pharmacy Related Terms.** These definitions are from HRSA's Office of Pharmacy Affairs, which administers the Section 340B Drug Discount Program:

See the Glossary of Pharmacy-Related Terms:

<http://www.hrsa.gov/opa/faqs/dictionary/index.html>

- **HIV/AIDS 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 Ryan White programs, including ADAP. Of particular note are:

- **Patient Protection and Affordable Care Act of 2010 (ACA).** Measures within ACA that have a particular impact on ADAPs include: prohibitions on pre-existing conditions; expansion of Medicaid to persons up to 133 percent of the Federal Poverty Level; and the Health Insurance Exchanges. Collectively, these changes represent new opportunities for ADAPs to focus on providing access to HIV/AIDS medications through health insurance mechanisms.

Learn more: <http://healthcare.gov>

- **The National HIV/AIDS Strategy (NHAS).** Released in 2010, the Strategy is the Federal plan for addressing HIV/AIDS 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. The 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/AIDS.

States and Territories have used Part B grant funds to develop and/or expand systems of care to meet the needs of Persons Living with HIV/AIDS (PLWHA) in their jurisdictions. This includes HAB and grantee efforts to estimate and assess Unmet Need and the number of individuals who are unaware of their HIV/AIDS 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 PLWHA 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 1.1 million adults and adolescents at the end of 2006 living with HIV, 21 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

US through enhanced prevention efforts. The Part B Early Identification of Individuals with HIV/AIDS (EIIHA) legislative requirement calls for grantees to identify HIV positive individuals who are unaware of their HIV status and bring them into care.

Learn more: <http://aids.gov/federal-resources/national-hiv-aids-strategy>

I.3.C. Clinical Information

HHS HIV/AIDS Treatment Guidelines

HHS develops federal guidelines on the appropriate administration of HIV/AIDS treatments, including antiretroviral therapies and prevention and treatment of opportunistic infections. The Guidelines are regularly updated using the latest scientific research findings by expert panels. ADAPs and other Ryan White grantees that deliver 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>*

I.3.D. Technical Assistance for the Ryan White Community

Ryan White grantees can access many resources to guide them in managing their programs.

- The first point-of-contact for help is the Federal HRSA 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 <http://directory.psc.gov/employee.htm>

- The TARGET (Technical Assistance Resources, Guidance, Education & Training) Center website, funded by HRSA, collects tools and best practices from HRSA and Ryan White grantees 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 Ryan White.

Learn more about TA and training for Ryan White programs: <http://careacttarget.org>

Key Resources	Web Links and Phone Contacts
HRSA and Ryan White	
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 http://directory.psc.gov/employee.htm
Ryan White Legislation	http://hab.hrsa.gov/abouthab/legislation.html
HRSA/HAB Policies	http://hab.hrsa.gov/manageyourgrant/policiesletters.html
Reporting/Monitoring	
ADR/AQR Data Reporting	http://hab.hrsa.gov/manageyourgrant/reportingrequirements.html
Monitoring Standards	http://hab.hrsa.gov/manageyourgrant/granteebasics.html
Performance Measures	http://hab.hrsa.gov/deliverhivaidscares/habperformmeasures.html
Grants Management	
HRSA Electronic Handbooks	https://grants3.hrsa.gov/2010/WebEPSExternal/Interface/common/accesscontrol/login.aspx?
HHS Grantee Information	http://dhhs.gov/asfr/ogapa/aboutog/grantsnet.html
Technical Assistance and Training	
HRSA Office of Pharmacy Affairs	http://www.hrsa.gov/opa 301-594-4353 or 800-628-6297
Prime Vendor Program	http://www.340bpvp.com 888-340-2787
Technical Assistance and Training for Ryan White	http://careacttarget.org
HRSA Patient Safety and Clinical Pharmacy Services Collaborative	http://www.hrsa.gov/publichealth/clinical/patientsafety/index.html
Key Resources	
HHS HIV/AIDS Treatment Guidelines	http://aidsinfo.nih.gov
HRSA/HAB Clinical Protocols	http://hab.hrsa.gov/deliverhivaidscares/clinicalguidelines.html
Affordable Care Act	http://healthcare.gov
National HIV/AIDS Strategy	http://aids.gov/federal-resources/national-hiv-aids-strategy

Section II. AIDS Drug Assistance Program Overview

II. Ch 1. Introduction to ADAP

II.1.A. Purpose of ADAP

The ADAP provides medications to uninsured or underinsured individuals living with HIV disease. Medications can be provided by ADAPs through the purchase of medications or by purchasing health insurance that includes coverage for HIV/AIDS medications. With appropriate approval by HAB, ADAPs may also provide services that enhance access to, adherence to, and monitoring of drug treatments.

HIV/AIDS drugs are costly, and many Persons Living with HIV/AIDS (PLWHA) 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 for early treatment of infected individuals; people living longer with HIV/AIDS; more intensive use of HIV/AIDS drugs from long-term survivors; economic conditions and loss of insurance; increased cost of medications and insurance; and reductions in State funding for other programs.

II.1.B. ADAP within the Ryan White HIV/AIDS Program

The Ryan White HIV/AIDS Program is the largest source of Federal funding specifically directed to provide primary care and support services for PLWHA. The Ryan White legislation was enacted in 1990 and has since been reauthorized four times: in 1996, 2000, 2006, and 2009. ADAP is funded through Part B of the Ryan White legislation. 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/AIDS. This continuum includes a range of core medical services and support services.

ADAP is a core medical service within the Ryan White legislation. Among the categories of core medical services related to ADAP are: ADAP treatments, AIDS pharmaceutical assistance (local), health insurance premium and cost sharing assistance, and medical case management (inclusive of treatment adherence services). (Section 2612 (b)(3)(B), Section 2616, HAB Policy Notice 00-02, HAB Policy Notice 07-03.)

ADAPs provide one important link in an overall continuum of primary care and treatment for PLWHA. Other Ryan White programs work in conjunction with State ADAPs to bring people into a system of care and provide them with quality treatment and services. Some of these programs also operate drug purchasing and distribution systems. In these instances, coordination between the ADAP and the other Ryan White programs is crucial to ensure that the most cost-effective method of reaching the maximum number of eligible clients is being utilized by that State.

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

II.1.C. History of ADAPs

ADAP started as a HRSA demonstration project to provide low-income individuals with access to zidovudine / azidothymidine (AZT, Retrovir), the first drug approved by the Food and Drug Administration (FDA) to treat HIV disease. The annual cost of this drug—about \$10,000 per year per person—placed it out of the reach of most PLWHA. 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/AIDS treatment advances occurred and as resources permitted, States expanded their programs to cover multiple categories of antiretroviral drugs. States 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 had the option to cover any FDA-approved drugs that treat HIV disease or prevent the serious deterioration of health due to HIV/AIDS.

ADAPs have expanded considerably since 1991 (when Congress first appropriated funds for Ryan White programs), both in terms of numbers of enrolled clients and in program resources.

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

II.1.D. ADAP Funding

The ADAP earmark funding is a component within the Ryan White Part B and is authorized by the Ryan White legislation. Part B funding is available through several forms:

- **Formula Grants.** The Part B formula/base award, the ADAP and Emerging Communities awards are formula awards in that they are 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. Similarly, Minority AIDS Initiative (MAI) formula awards are based on the number of reported and confirmed living minority cases of HIV/AIDS for the most recent calendar year and code-based HIV data submitted to HRSA.
- **ADAP Supplemental Grants.** These funds are awarded to States demonstrating severe need for medications. Section 2618(a)(2)(F)(ii) of the Ryan White legislation 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. This funding is made available to States and Territories based on one of the following criteria: financial requirement of less than or equal to (\leq)200 percent of the Federal Poverty Level (FPL); limited formulary compositions for all core classes of antiretroviral medications; waiting list, capped enrollment or expenditures; an unanticipated increase of eligible individuals with HIV/AIDS.
- **Part B Supplemental Grant.** These funds are awarded to States demonstrating the severity of the HIV/AIDS epidemic using quantifiable data on HIV epidemiology, co-

morbidities, cost of care, the service needs of emerging populations, unmet need for core medical services, and unique service delivery challenges. The funds are intended to supplement the services otherwise provided by the State. The funding is made available to States and Territories base on an Objective Review Committee.

- **Minority AIDS Initiative (MAI).** MAI funds that are awarded to Part B Grantees are to be specifically used to conduct outreach and education activities designed to increase minority enrollment and participation in ADAP and medication access programs. This can be done through a number of different core and support service categories, but all must enable the grantee to track and report client enrollment into ADAP.

All funds allocated to ADAP, including grant funds and other state, local and federal resources are subject to the ADAP program expectations. Please review the section on ADAP related rebates to learn about the provisions and requirements for handling rebates.

II.1.E. Program Criteria Overview

The Ryan White legislation outlines various requirements to guide ADAP decisions on program operations, including eligibility, the classes of medications to provide, ADAPs focus on addressing these legislative and program requirements as they seek to maximize access to HIV/AIDS medications in the context of limited resources, ever-changing conditions related to medication costs, and increasing demand for medications as the number of PLWHA continues to increase. Below is a summary of the criteria and techniques ADAPs use to manage their programs. Subsequent chapters go into greater detail, outlining legislative and program expectations as well as approaches for each area.

Eligibility

Ryan White legislation and National Monitoring Standards state that an individual must meet multiple requirements in order to be deemed eligible for ADAP enrollment. Eligible individuals must demonstrate the following:

- HIV/AIDS diagnosis
- Low income (**Note:** for ADAP supplemental, low income is defined as $\leq 200\%$ of the Federal Poverty Level)
- Uninsured or underinsured status
- Determination of eligibility and enrollment in other third party insurance programs including Medicaid and Medicare

More specific eligibility for ADAP enrollment is determined at the State level and often also includes residency in the jurisdiction. Regardless of the specific criteria used by the State ADAP, the HHS Office of the General Counsel has determined that eligibility criteria and covered

treatments for anyone enrolled in the State ADAP must be consistently applied across the State.

It is unallowable for an ADAP to provide services before a client has been determined to meet that 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 Medicaid is back-billed if Medicaid is awarded retroactively.

Formularies

All ADAPs are required to include at least one drug from each class of HIV antiretroviral medications on their formulary, but are otherwise given the authority to determine the specific FDA-approved drugs to cover (Section 2616 (c) of the PHS act). Most States focus on medications specifically for HIV/AIDS treatment, including antiretroviral medications and medications to prevent and to treat opportunistic infections. Some ADAPs also cover medications for co-morbid conditions that frequently occur in PLWHA (e.g., Hepatitis C).

HHS HIV/AIDS Treatment Guidelines

ADAPs must follow HHS HIV/AIDS treatment guidelines on the management of HIV/AIDS disease. Guidelines cover multiple aspects of treatment, including the use of antiretroviral therapies and medications for prophylaxis and treatment and opportunistic conditions. ADAPs and their advisory bodies use the Guidelines to guide their decisions about formulary coverage.

Access HHS HIV/AIDS Treatment Guidelines: <http://aidsinfo.nih.gov>

ADAP Management and Cost Containment Strategies

ADAPs use many strategies and methods to realize efficiencies in terms of costs, management, and maximizing access to medications. HRSA has defined cost containment in two broad areas: cost-cutting measures, which are any measures taken that restrict/reduce enrollment or that reduce benefits; and cost-saving measures, which are any measures taken to improve the cost-effectiveness of ADAP operations. Both cost containment strategies, are discussed in greater detail in subsequent sections of this manual, and include:

- **Formulary Management.** ADAPs consider a variety of factors in determining which medications to include on their formularies, including Ryan White legislative requirements, standards of care, maximizing access to those in need, costs, and availability of medications from other payers and programs.
- **Purchasing and Dispensing.** ADAPs must make every effort to secure the best possible price for HIV/AIDS drugs. HRSA has continued to reiterate its expectation that grantees will maximize use of cost-saving strategies so that ADAPs are purchasing pharmaceuticals at the lowest possible price. Failure by ADAPs to participate in cost-saving programs may result in negative audit findings and cost disallowance.

The cost saving strategy used by almost all ADAPs is participation in the Section 340B Drug Discount Program, which provides drug discounts to certain Federal grantees, including Ryan White grantees, allowing them to save a significant amount of funds by lowering the price of medications. ADAPs can access the program, which is administered by HRSA's Office of Pharmacy Affairs (OPA) directly. The ADAP is required to apply with OPA for enrollment. Once enrolled the ADAP has three options for accessing medications: a direct purchase system; the 340B Rebate Option; or a combination of both options. OPA administers the Prime Vendor Program which, on behalf of ADAPs, negotiates additional discounts on 340B eligible medications and other non-340B services (i.e., medical supplies or equipment).

- **Enrollment and Utilization.** Some State ADAPs place limitations and restrictions on enrollment and utilization, including: eligibility provisions, capping client enrollment, restricting formulary size, instituting waiting lists, and limiting per patient expenditures. For some States, these restrictions can be reduced or eliminated as funding levels increase; other ADAPs operate under a continual shortage of resources.

Management of utilization can also happen through clinician education. While patient clinical needs must guide treatment decisions, cost considerations merit attention when less expensive and clinically appropriate regimens are available. ADAPs are in a position to provide information to clinicians about comparable costs for recommended treatments (e.g., cost guides for the most-frequently prescribed regimens).

- **Purchasing Health Insurance.** While most ADAPs focus their resources on the purchase of HIV/AIDS medications, programs can also purchase health insurance as a cost effective measure that includes coverage for the full range of HIV/AIDS medications and comprehensive primary care services. Funds can be used to pay for any costs associated with the health insurance policy, including premiums, co-payments, and deductibles. Ryan White funds may not be used to pay co-pays or deductibles for inpatient care.
- **Coordination with Other Payers and Programs.** Ryan White is the payer of last resort and is intended to fill gaps in care. ADAPs must ensure that funds are not used to provide items or services for which payment already has been made, or reasonably can be expected to be made, by a third party payer, including State or local entitlement programs, prepaid health plans, or private insurance. ADAPs seek to fulfill this mandate and provide enhanced access to medications and other services by coordinating with public health programs (e.g. Medicaid, Medicare, high-risk pools). Of particular focus is coordination with changes mandated under the Affordable Care Act that include expanded Medicaid eligibility and Pre-existing Condition Insurance Plans (PCIP).

II. Ch 2. ADAP Administrative Structures and Responsibilities

II.2.A. ADAP Administrative Structures

ADAPs are a component of the Ryan White Part B and are administered by 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 vary. The size of the program's budget and the number of people living with HIV and AIDS and other state medication distribution systems (i.e. Medicaid) are often the most significant factors in the design of the ADAP administrative and service delivery systems. In theory, a larger budget allows the ADAP more flexibility for staff positions, technical resources, and the ability to serve a greater number of eligible clients. ADAPs with smaller budgets are often faced with the difficult task of balancing limited staff and resources with the demands of clients and necessary program oversight and reporting activities. Because ADAPs are grant funded health care service delivery systems, the programs are faced with the unique challenge of providing access to medications and health care within a limited budget.

Below is a summary of factors that influence ADAP administrative structures:

- **Administrative Responsibility.** Almost all ADAPs have centrally administered eligibility determination and enrollment, usually by the State health department. A handful of ADAPs are located within their State's Medicaid program. A smaller number of ADAPs are decentralized and are administered through local consortia and/or county health departments. The State plays a key role in program oversight to assure eligibility and formulary parity across the State.
- **Staffing.** All ADAPs have an ADAP coordinator. ADAPs with smaller caseloads may operate as one-person staff (with responsibility for administering the overall Part B program and perhaps other health programs). States with more ADAP clients typically have multiple staff to handle different operations in addition to the ADAP coordinator.
- **ADAP Management Structure.** Larger and more complex staffing and administrative structures are necessary for ADAPs that use multiple strategies to manage their ADAP operations. For example, an ADAP that engages in direct purchasing of medications as well as collecting rebates may need more staff to oversee each of these activities. Multiple States contract with or operate their own pharmacy benefits manager (PBM) to administer the pharmacy and billing transactions for the program. In States that use a PBM, the State ADAP coordinator typically provides contract oversight and monitoring of the PBM. Otherwise, the ADAP coordinator and/or ADAP staff direct the day-to-day participant and pharmacy operations of the ADAP and provide the oversight and monitoring needed to ensure the fiscal soundness and overall quality of the ADAP.

II.2.B. ADAP Administrative Responsibilities

The following administrative functions are essential to ADAP operations:

- **Client Services.** These activities center around the ADAP client and typically include determining client eligibility for enrollment and six-month re-certification for ADAP services; coordinating with providers, pharmacies, manufacturers' patient assistance programs, clinical trials, and other sources of medication; and providing information on ADAP services to clients.
- **Purchasing and Dispensing.** Managing pharmaceutical purchasing and dispensing includes establishing and monitoring a drug purchasing and dispensing system; monitoring drug delivery to clients; processing reimbursement claims and submitting drug rebate claims; and providing quality assurance for these processes.
- **Oversight, Monitoring, Reporting.** The following activities fall under this broad category:
 - **Financial management:** While most States have accounting and auditing departments to handle overall health spending, some ADAPs benefit from having designated staff that focus their attention specifically on ADAP dollars. Their role typically involves use of an accounting system that documents grantee and sub-grantee 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.
 - **Grants and contract management:** This includes complying with HRSA grants management requirements (which are largely handled under the Part B grant) and establishing and managing contracts and grants within the State (according to State contracting provisions).
 - **Planning and development:** This includes securing input and guidance from the ADAP advisory body, consumers, and/or service providers. In particular, this area includes attention to changing conditions due to factors such as costs and other payers and programs (particularly in terms of health care reform).
 - **Data and reporting:** Assists program management in program planning and resource allocation activities. Data Analysis and reporting also fulfills HRSA reporting and grants management requirements. Programs with limited technical resources may contract out data-related activities. Identifying other State programs, such as the State Medicaid agency, that process similar types of data may assist the ADAP with its information management needs.
 - **Quality management:** This is tied to data reporting, monitoring quality indicators for ADAP, and complying with HHS HIV/AIDS treatment guidelines.

II. Ch 3. Planning/Advisory Bodies

II.3.A. Introduction

Part B programs are responsible for conducting planning in order to guide decisions about use of Part B funds, including the AIDS Drug Assistance Program (ADAP) earmark. Many Part B programs have advisory bodies to provide advice to the Part B Grantee on the use of Ryan White 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.3.B. Legislation, HRSA Program Requirements, and Expectations

Legislative and program requirements for planning for Part B are covered in the Part B Manual.

II.3.C. Planning

ADAP planning typically focuses on what medications to cover, purchasing and distribution, and cost-saving/cost-cutting strategies. ADAPs also carry out planning to assess use of ADAP funds to purchase health insurance as an option for securing HIV/AIDS medications and coordination of ADAP with other payers and programs. ADAP planning occurs under Part B planning structures as well as through ADAP Advisory Committees.

A current key focus of planning is determining the role of ADAP under the Affordable Care Act, particularly in relation to the expansion of Medicaid to all persons with incomes under the Federal Poverty Level and new options to purchase insurance under State or Federal Health Insurance Exchanges.

II.3.D. ADAP Advisory Committees

The Ryan White Program legislation does not mandate an ADAP Advisory Committee; however, most states convene one as a best practice. Below are common characteristics of ADAP Advisory Committees. Their operating rules are influenced by Ryan White planning as carried out under other Parts as well as State regulations on functioning of advisory bodies.

Composition

State ADAP Advisory Committees are typically comprised of clinicians, pharmacists, service providers, consumers, representatives from other Ryan White Parts, the health department, and the State Medicaid program. As a result, 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. Some meet once a month while others meet twice a year.

Advisory Committee Roles

Advisory committees can be responsible for the review of ADAP policies or regulations, functions, quality management issues, and budgets. Committees can use data derived from their reviews to make recommendations on formulary management, utilization management, or program eligibility to help guide the ADAP in implementing process or program changes. Reviews often occur on an annual basis, but may vary in frequency (monthly, quarterly).

The ability to make recommendations is an important function of an advisory committee. Members often discuss advances in HIV/AIDS treatment and assist ADAP staff in determining the cost effectiveness of program functions and recommended changes. ADAPs and their advisory bodies use HIV/AIDS treatment guidelines to guide deliberations program changes and development.

Advisory bodies can also play an important role within the ADAP development and sustainment process.

II. Ch 4. Eligibility

II.4.A. Introduction

In order to comply with the legislative requirement for Ryan White to serve as the payer of last resort, Ryan White grantees (including ADAPs) must conduct initial and a six-month recertification to verify whether individuals remain eligible for ADAP or are eligible for other programs that cover HIV/AIDS medications. While ADAPs focus on determining eligibility for ADAP coverage, State eligibility assessment processes are increasingly going online and assessing eligibility for a broad array of programs. Health Insurance Exchanges under the Affordable Care Act will further enhance cross-program eligibility determinations for individuals searching for coverage options.

II.4.B. Legislation, HRSA Program Requirements, and Expectations

The Ryan White legislation states that an individual must have a diagnosis of HIV/AIDS and “be a low-income individual as defined by the State.” More specific eligibility for ADAP enrollment is determined at the State level and includes residency in the jurisdiction. Regardless of the specific criteria used by the State ADAP, the HHS has determined that eligibility criteria and covered treatments for anyone enrolled in the State ADAP must be consistently applied across the State. The legislative provisions are detailed below.

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.

The HHS Office of the General Counsel has determined the following regarding ADAP eligibility criteria:

HHS/HRSA Office of the General Counsel has determined, with regard to a State ADAP, the Ryan White legislation means that both eligibility criteria and covered treatments for anyone enrolled in the program must be consistently applied across any State. As long as they comply with this essential requirement about equity and consistency, States have significant flexibility in how they administer their ADAPs.

HRSA/HAB Monitoring Standards include a standard for Part B ADAPs to have an eligibility determination and screening process. The standard, with corresponding performance measures/methods, grantee responsibilities, and provider/sub-grantee responsibilities, is as follows:

- *Universal Monitoring Standards: Section B: Eligibility Determination/Screening. Standard.1. Screening and reassessment of clients to determine eligibility as specified by the EMA, TGA, state, or ADAP:*
- *Screening of clients to determine eligibility for Ryan White services within a predetermined timeframe.*
- *Reassessment of clients every 6 months to determine continued eligibility.*

II.4.C. ADAPs and Eligibility

Criteria Used by ADAPs

Eligibility for ADAP enrollment is determined at the State level. Criteria typically used by ADAPs include the following:

- **Medical eligibility**, including HIV status. HIV status is most often a diagnosis of HIV infection based upon diagnostic testing. All States require proof of HIV positive status for ADAP enrollment. Some States implementing cost containment measures also require a determination of medical necessity, as evidenced by disease progression, including CD4 counts and viral load testing.
- **Financial eligibility**, which is usually determined as a percentage of the Federal Poverty Level (FPL).
- **Residency** in the jurisdiction.
- **Lack of other sources** to pay for prescribed HIV medications, or documented gaps in third party payment for the medications. (See sections on Insurance Continuation)

For a list of ADAP eligibility criteria by state, please refer to the most recent version of the National ADAP Monitoring Report at:
http://www.nastad.org/Docs/021503_National%20ADAP%20Monitoring%20Project%20Annual%20Report%20-%20August%202012.pdf

It is unallowable for an ADAP to provide services before a client has been determined to meet that 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 Medicaid is back-billed if Medicaid is awarded retroactively.

What Is The Federal Poverty Level?

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.

See the most recent Federal Poverty Guidelines: <http://aspe.hhs.gov/poverty>

Eligibility and Enrollment Process

Below are key elements of eligibility assessment processes:

- Inform clients about ADAP services and assist with completing the ADAP application process.
 - A. Determine if the client meets the ADAP eligibility criteria based on income, health status, and/or age and disability status (e.g., age, mental health status, co-morbidity and the ability to perform activities of daily living).
 - B. Assess sources of income in relation to eligibility for public health insurance (e.g., SSDI income and current or future Medicare eligibility).
 - C. Follow-up to ensure that clients apply for other programs, as eligible.
 - D. Assess eligibility for ADAP assistance with co-payments and deductibles for clients at varying eligible income levels.
 - E. Ensure that the ADAP application and required supporting documents are provided to the ADAP.
 - F. Assess whether the cost of using co-existing health care coverage poses a financial barrier to care or if there are limits on coverage such that individuals cannot reasonably be expected to use that coverage for their HIV related care and medications, i.e. a maximum medication coverage cap of \$2,000. State ADAPs do not cover all of the medications a PLWHA needs, allowing this \$2,000

to be used for other medications needs will prevent further deterioration of health and maximize the value of services purchased by ADAP.

- **Submission of ADAP Application and Required Documentation.** An ADAP application form is completed and submitted with required documentation to determine eligibility. A growing number of programs are allowing ADAP applications to be filled out online, which improves processing time and cross-program review. However, most ADAPs still allow applications to be submitted by mail and fax.
- **Reviews and Decisions.** The eligibility assessment process entails review of applications, verification of information, approval/disapproval, and 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. Decentralized systems must keep service providers up-to-date about HRSA requirements to ensure there is parity across the State.
- **Accessing Medications.** ADAPs typically provide enrollees with access to their prescription drugs through the provision of an ADAP card, code or other means for accessing medications.
- **Recertification.** ADAPs are required to recertify client eligibility every 6 months. ADAPs often use a process similar to their application process to determine clients' continuing eligibility. Recertification processes are determined at the state level and should follow state requirements. Self-attestation may be considered as a recertification process if it fulfills the state's requirements for verifying an individual's income status, residency status, and insurance status.

Grantees 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.). If a client does not recertify by the date specified by the grantee, the client is ineligible for the program as of that date; there is no grace period or "cushion". Grantees may choose to not recollect HIV diagnosis information if the original verification can be found in the client file. Grantees should design recertification processes that meet the requirements but do not create additional barriers to care.

II. Ch 5. Access, Adherence, and Monitoring Services

II.5.A. Introduction

AIDS Drug Assistance Programs (ADAP) and other Ryan White grantees that deliver HIV/AIDS medications must ensure that clients receive medication therapies consistent with current HHS HIV/AIDS treatment guidelines. Taking treatment regimens correctly is essential to successful

treatment. While ADAP funds are largely devoted to paying for HIV/AIDS medications, with appropriate approval from HAB, a limited amount of funds can be used to support clients in understanding their options for accessing medications and overall HIV/AIDS care, enrolling in ADAP, and monitoring their usage over time.

II.5.B. Legislation, HRSA Program Requirements, and Expectations

The Ryan White 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 on Access, Adherence, and Monitoring reads as follows:

HAB Policy Notice 07-03, The Use of Ryan White HIV/AIDS Program, Part B ADAP Funds for Access, Adherence, & Monitoring Services, established guidelines for allowable ADAP-related expenditures under the Ryan White HIV/AIDS Program for services that improve access to medications, increase adherence to medication regimens, and help clients monitor their progress in taking HIV-related medications. The policy provides grantees with greater flexibility in the use of ADAP funds. States may request to redirect up to 5 percent under this policy, and up to 10 percent in extraordinary circumstances. The amount that a grantee can request to be redirected is in addition to the aggregate of 15 percent of ADAP funds allowed for administrative, planning and evaluation costs. This does not include funds under other Parts that may be used to purchase medications. An example of an extraordinary circumstance would be identifying a targeted population with low adherence rates (e.g. substance abusers, homeless persons)(2012 FOA Part B.)

HRSA's Fiscal Monitoring Standards include a standard for limiting use of funds for adherence. The standard, with corresponding performance measures/methods, grantee responsibilities, and provider/sub-grantee responsibilities, is as follows:

Standard. Adherence to the 5 percent limit (or 10% in extraordinary circumstances approved by the HAB project officer) on the use of ADAP funds for access, adherence, and monitoring services.

II.5.C. Helping Clients Access Medications

Outreach and Education

Minority AIDS Initiative (MAI) funds that are awarded to Part B specifically Grantees are to be specifically used to conduct outreach and education activities designed to increase minority enrollment and participation in ADAP and medication access programs. This can be done through a number of different core and support service categories, but all must enable the grantee to track and report client enrollment into ADAP.

Maximizing Options for Accessing Medications

ADAPs consider client convenience when designing their medication distribution systems and clients can usually access medications through varied venues, including local pharmacies, health department dispensaries, and mail order. Mechanisms are generally in place to ensure that mail order prescriptions are safely and confidentially mailed to a client's home or other address in a timely manner.

Obtaining Client Input

ADAP Advisory Committees are a key forum for obtaining input on mechanisms for maximizing access, adherence, and monitoring. In addition, client satisfaction surveys and input from quality management activities can provide relevant input to ADAPs in the design of their client support activities.

II. Ch 6. Data and Reporting

II.6.A. Purpose of ADAP Reporting

Due to the size of its Congressional appropriation, the number of clients and the importance of the ADAP to the Nation's HIV prevention and care efforts, ADAP and HRSA receive a great deal of attention that includes oversight, and inquiry regarding the use of funds, the client mix and cost saving strategies. ADAP data reports are tools used by HRSA to help answer these questions for other entities included HHS, Congressional lawmakers and others. ADAP data reports serve a number of purposes, including:

- **Documentation on Use of Funds.** ADAP data reporting helps ADAPs report on how they are adhering to legislative and program requirements related to administrative caps and use of funds.
- **Budgeting and Forecasting.** Data is crucial for ADAPs to determine their ability to absorb additional clients and budget accordingly.

- **Service Delivery.** Data from ADAP reports can be used to monitor and manage utilization of ADAP services and guide programmatic decisions.
- **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 general counsel to determine the appropriate language to be included in the application to ensure communication with clinical providers, insurance companies, and pharmacies.

II.6.B. ADAP Reporting Responsibilities

As a condition of their grant awards, Ryan White HIV/AIDS Program grantees are required to report data on clients, services provided, and expenditures. Below are the types of required data reports for ADAPs.

- **ADAP Quarterly Report (AQR).** Part B grantees are required to submit quarterly reports on ADAP activities on the ADAP Quarterly Report (AQR), including aggregate data on the number of clients, total funds expended for ADAP, substantive programmatic changes, and prices paid for specific HIV pharmaceuticals. The AQR also includes information on the number of clients served, client insurance sources, client demographics, client regimen types, cost-saving measures, and other data.
- **ADAP Data Report (ADR).** In October 2012, data collection began for the ADAP Data Report (ADR) which is a client level data report. The ADR addresses limitations of the aggregate data reporting under the AQR and will enable HRSA/HAB to evaluate the impact of the ADAP on a national level, inclusive of describing who is using the program, what ADAP-funded services are being used and the associated costs with these services.

The AQR will be phased out as ADAPs become accustomed to the ADR and the quality of the information provided through the ADR accurately represents the program.

Learn more about ADAP Reporting:

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

II. Ch 7. Quality Management

II.7.A. Introduction

The Department of Health and Human Services (HHS) released the National Quality Strategy in March 2011 and put forth three broad aims to “guide and assess local, State and national efforts to improve the quality of health care.” The aims are (1) Better Care, (2) Healthy People / Healthy Communities, and (3) Affordable Care. The National Quality Strategy provides a roadmap requiring continuous advancement of measurement and initiatives with a

collaborative stakeholder process. As part of HHS, HRSA/HAB defines quality as “the degree to which a health or social service meets or exceeds established professional standards and user expectations.” To continuously improve systems of care, evaluations of the quality of care should consider the service delivery process, quality of personnel and resources available, and the outcomes. The overall purpose of an HIV quality management program is to ensure that:

- Services adhere to HIV/AIDS treatment guidelines and established clinical practice;
- Develop strategies for improvement of services provided, including clinical services and supportive services;
- Demographic, clinical and utilization data are used to evaluate and address characteristics of the local epidemic and quality of care;
- Appropriate leaders and stakeholders are included throughout the quality improvement process;
- Continuous processes to improve quality of care are in motion.

All Ryan White programs, including ADAPs, are responsible for ensuring their programs meet quality expectations.

Quality management is a systematic, structured, and continuous approach to meet or exceed established professional standards and user expectations. Quality management is implemented by using tools and techniques to measure performance and improve processes through three main components: quality infrastructure, performance measurement and quality improvement.

Quality infrastructure is the structure and supports that allow the organization to measure performance and improve processes. Quality infrastructure components include leadership, quality improvement teams, quality related training/capacity building, and a written quality management plan. It is often difficult to sustain a success quality management program if the infrastructure components are missing or weak.

When most people think about quality management, performance measurement and quality improvement come to mind. Performance measurement is the routine collection and analysis of data. The analysis is completed by defining the data elements used to calculate the numerator and denominator. Performance measures must be based on established professional standards and/or evidenced based research, when possible. An example of a performance measure is viral load suppression. The HIV/AIDS Bureau has developed, released, and refined performance measures for use by Ryan White Program grantees. The HIV/AIDS Bureau performance measures were developed using professional standards such as the Department of Health and Human Services HIV Clinical Guidelines including *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*, *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection*, among other federal and national guidelines for the care and treatment of people living with HIV.

These performance measures can be found on the HIV/AIDS Bureau website:

<http://hab.hrsa.gov/deliverhivaids/ab/habperformmeasures.html>

Quality improvement is a method that uses the tools of quality in an effective, logical and systematic process to solve problems, improve efficiency and eliminate non-value adding steps in the workflow. The most common quality improvement method is the Plan-Do-Study-Act or PSDA.

It is important to conduct performance measurement and quality improvement activities in balance. That is to say that you do not want to do one without the other and you want to implement equally amounts of each. You would not want to develop and implement a quality improvement project without regularly measuring performance to see if the project is having an impact

II.7.B. Legislation, HRSA Program Requirements, and Expectations

The Ryan White legislation addresses quality in several areas. For Part B grantees:

Section 2618(b)(3)(E) CLINICAL QUALITY MANAGEMENT. —

(i) REQUIREMENT. — 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.

The Ryan White legislation addresses quality specific to ADAP as follows:

Section 2616(c)(5) STATE DUTIES.—In carrying out this section the State shall—(5) document the progress made in making therapeutics described in subsection (a) available to individuals eligible for assistance under this section.

It is important to remember that the ADAP is a component of the Part B grant. Therefore, the Ryan White legislative requirements for clinical quality management apply to the clinical and support services funded by the grantee as well as the ADAP service.

HAB has established the following minimum expectations of Ryan White HIV/AIDS Program grantees regarding quality management. At a minimum, Part B grantee quality management must have:

- Established and implemented a statewide quality management plan with annual updates.

- Established processes for ensuring that services are provided in accordance with the Department of Health and Human Services (HHS) treatment guidelines and standards of care.
- Incorporated quality-related expectations into Requests for Proposals (RFPs) and State/Territory contracts, including contractors/subcontractors at the consortia and sub-recipient level.

In 2011, HAB released the *Ryan White HIV/AIDS Program Part A and B Monitoring Standards*. In the *Part B Program Monitoring Standards*, Section D is entitled *Quality Management* the Ryan White legislative requirement for clinical quality management (as mentioned above). The legislative requirements are referred to as the “standard” in the Monitoring Standards. The “performance measure” identifies what one would look for in order to understand if the grantee was meeting the “standard.” The “responsibility” states what the grantee and provider/sub-grantee need to complete in order to meet the “standard.”

HRSA/HAB Monitoring standards:

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

II.7.C. Quality Management and ADAPs

What sort of quality management activities can an ADAP implement?

ADAPs across the United States have established quality management programs either within or in addition to their larger Part B quality management program. The ADAP engages in all of the quality management activities that other grantees do. The only difference is the activities are focused on ADAP related services (e.g. efficiency of the application process, recertification, completeness of formulary, etc.) compared to medical care services offered in a health center (e.g. retention, syphilis screenings, cervical cancer screenings, etc.). A few examples include:

- Develop a written quality management plan. This plan is the written record of the program’s goals and objectives with a map of its infrastructure, routine performance measurement and implementation of quality improvement projects.
- Report ADAP performance measure data to stakeholders every other month and discuss the result.
- Review the performance measure data and conduct a quality improvement project based on one of the measures.
- Train staff and stakeholders on implementing a quality management committee and/or conducting quality improvement projects.
- Convene a quality management committee and meet regularly to provide program guidance and facilitate innovation and change.

HIV/AIDS Bureau HIV Performance Measures for ADAP

HIV/AIDS Bureau has created performance measures that Ryan White HIV/AIDS Program grantees can use to monitor the quality of care and services they provide. The performance measures can be used at the provider or system level—in their current format or further modified to meet grantee needs. Performance measures specifically designed to determine the

level of quality for ADAPs are listed in the table below (as of September 2012). The HIV/AIDS Bureau also created a general Frequently Asked Questions (FAQ) and ADAP specific FAQ to assist in the use of these performance measures.

The FAQs are also available on the HIV/AIDS Bureau website:
<http://hab.hrsa.gov/deliverhivaidscore/habperformmeasures.html>

HIV/AIDS Bureau HIV Performance Measures for ADAP		
http://hab.hrsa.gov/deliverhivaidscore/habperformmeasures.html		
Performance measure	Numerator	Denominator
Application Determination	Number of applications that were approved or denied for new ADAP enrollment within 14 days of ADAP receiving a complete application in the measurement year	Total number of complete ADAP applications for new ADAP enrollment received in the measurement year
Eligibility Recertification	Number of ADAP enrollees who are reviewed for continued ADAP eligibility at least 2 or more times which are at least 150 days apart in the measurement year	Number of client enrolled in ADAP in the measurement year
Formulary	Number of new antiretroviral classes included into the ADAP formulary within 90 days of the publication of updated HHS <i>Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents</i> that include new antiretroviral drug class during the measurement year.	Total number of new antiretroviral classes published in updated HHS Guidelines during the measurement year
Inappropriate antiretroviral regimen components resolved by ADAP	Number of antiretroviral (ARV) regimen components prescriptions included in the HHS Guidelines, “Antiretroviral Regimens or Components That Should Not Be Offered At Any Time” ¹ and “Antiretroviral Regimens or Components That Should Not Be Offered for Treatment of	Number of inappropriate antiretroviral (ARV) regimen components prescriptions included in the HHS Guidelines, “Antiretroviral Regimens or Components That Should Not Be Offered At Any Time” and “Antiretroviral Regimens or Components That Should Not Be Offered

	Human Immunodeficiency Virus (HIV) Infection in Children”2 that are resolved by the ADAP program during the measurement year.	for Treatment of Human Immunodeficiency Virus (HIV) Infection in Children” that are identified by ADAP.
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A brief story of ADAP Quality Management

During a routine monitoring call, the Part B project officer asked the ADAP director what quality management activities were currently being undertaken. The ADAP director told the project officer the quality management plan for this year included implementing the HIV/AIDS Bureau performance measures; a program assistant was working on preparing the data to be reviewed at the quality management committee meeting next month. The project officer suggested they discuss the content of the quality management committee meeting during the next monitoring call.

Prior to the quality management committee meeting, the program assistant who prepared the performance measure data met with the ADAP director. He presented the following data to ADAP director.

State ADAP performance measure data			
January – December 20xx			
Performance measure	Numerator	Denominator	Percent
Application Determination	67	85	79%
Eligibility Recertification	412	782	53%
Formulary	0	0	N/A
Inappropriate antiretroviral regimen components resolved by ADAP	Unknown	Unknown	Unknown

The program assistant and ADAP director discussed the data – the process to collect the data, complexity of the analysis, and next steps. The project assistant said he needed more time to examine the “inappropriate antiretroviral regimen components resolved by ADAP” measure. He also said that no new HIV antiretroviral classes were approved in 2011.

The ADAP director asked the program assistant to distribute the data at the next quality management committee meeting and facilitate a discussion about which performance measure to use for the quality improvement project. The program assistant did so at the next meeting. The committee members discussed the reasons to select the “application determination” measure over the “eligibility recertification” measure and vice versa. In the end, the committee decided to develop a quality improvement project for “eligibility recertification.” The committee decided to improve from 53% to 70%. Five people from the committee volunteered to work on the quality improvement project and report back at the next quality management committee meeting. Two other committee members said they would help the project assistant

with developing a strategy for collecting data for the “inappropriate antiretroviral regimen component resolved by ADAP” measure. The ADAP director reviewed the action steps and said the committee would meet again in two months because there were two important activities commenced.

In the meantime, the ADAP director shared the progress with the project officer at the next monitoring call and the two teams got to work. The team working on the quality improvement project decided to use the Plan-Do-Study-Act model. One of the team members had completed the National Quality Center Training-of-Trainers and the Training of Coaching Basics. She was able to walk the team through conducting a quality improvement project. The team met once a week to discuss progress, determine the next action steps, and decide what to share with the other ADAP committee members about the project. The team was able to test three system changes in the upcoming recertification process. The team decided that they be able to collect data in about three months to see if the changes caused an improvement in eligibility recertification.

The project assistant met with the other two committee members to work on the data collection for the “inappropriate antiretroviral regimen component resolved by ADAP” measure. One of the members works closely with billing vendor and would arrange a meeting to talk about receiving the needed data.

Two months passed very quickly. The quality management committee held the next meeting. The ADAP director asked for updates on the two projects. The teams shared their progress and future plans. The committee as a whole discussed the progress, provided the teams with feedback, and determined the next steps. The team that worked on the quality improvement project found that they did improve performance to 65%. They did not meet the target of 70% so they implemented two more changes for the next eligibility recertification process and measured performance again. The other team working on collecting data for the inappropriate regimens has a few setbacks. There was staff turnover. It took them two months longer than anticipated, but they eventually were able to collect and report the data every quarter. The teams continued to meet until they finished their work and the quality management committee was satisfied.

The quality management committee continued to receive data for each of the performance measures at each meeting. They discussed the data, decided on the next quality improvement projects, and updated the quality management plan to reflect the activities completed. The project officer checked in during monitoring calls with the ADAP director to hear the progress, challenges, and plans of the quality management committee. At times, the project officer was able to share experiences from other grantees.

II. 7. D Resources

HIV/AIDS Bureau Performance Measures – List of performance measures and FAQ (PDF)
<http://hab.hrsa.gov/deliverhivaidscore/habperformmeasures.html>

National Quality Center– HIV/AIDS Bureau cooperative agreement that provides free-of-charge training and technical assistance to Ryan White Grantee regarding quality management
<http://nationalqualitycenter.org/>

National Quality Center 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 providers, and methods for applying this information in HIV programs.
<http://nationalqualitycenter.org/index.cfm/17263>

National Association of State and Territorial Directors – HIV/AIDS Bureau cooperative agreement that NASTAD in coordination with the National Quality Center developed tutorials for ADAPs on quality management.

Tutorial 25: Introduction to Ryan White Quality Improvement for ADAPs

Tutorial 26: How to Write an ADAP-Specific Quality Management Plan

Tutorial 27: How to Develop ADAP Quality Indicators

Tutorial 28: How to Collect, Analyze, and Link Data to Quality Improvement Activities

Tutorial 29: How to Conduct a Quality Improvement Project

Tutorial 30: Building Sustainability for Quality Management in your ADAP

Link to NASTAD tutorials Quality Management Plan Checklist:
<http://nationalqualitycenter.org/index.cfm/5659>

Section III. ADAP Contract and Subcontract Management

III. Ch 1. Request for Proposal (RFP) and Contract Monitoring Process

III.1.A. Introduction

This chapter provides guidance on the Request for Proposal (RFP) process by which ADAPs request bids from organizations to provide pharmacy services for their programs. States must follow their own procurement processes; this section provides HRSA expectations and best practices for ADAP grant administration. When developing an RFP or contract, the ADAP may consider utilizing another state's RFP and contract language to ensure consideration of all the program's needs.

III.1.B. ADAP Contracts

Most AIDS Drug Assistance Programs (ADAPs) contract with other organizations to provide pharmacy services for their clients. These contracts can encompass a wide range of services, including drug dispensing and/or distribution, drug utilization reviews, shipping, and pharmacy services. In order to obtain quality, low cost services, ADAPs publish Request for Proposals (RFPs) as an invitation for organizations to compete for a contract with the State ADAP.

III.1.C. Request for Proposal

The purpose of the RFP is to convey information that prospective contract organizations need in order to prepare a proposal. It describes all the information that the organization must furnish to permit a meaningful and equitable evaluation of their offer for services. The RFP includes a Statement of Work (SOW), and the terms, conditions, and provisions that will form the basis for the final definitive contract. The RFP must be clear, complete, accurate, and consistent with the requirements of the acquisition so that it provides all who receive it with the same understanding of the requirements.

RFP Preparation

In most states, the ADAP staff is responsible for preparing the RFP and developing supporting documentation during the pre-solicitation phase that will fully satisfy program needs and objectives when included in the RFP.

Clear distinctions must be made between the contents and purpose of the SOW, the instructions to organizations, and the evaluation factors. The RFP should meet the following objectives:

- The statement of work must clearly specify the work to be done by the contractor, including reports routinely needed to fulfill the ADAP reporting requirements.
- The general, technical, and business instructions must delineate all the essential information prospective organizations need to prepare their proposals.

- Evaluation factors must clearly indicate the technical, management, personnel, and cost or pricing factors that will be the major considerations in selecting the successful organization.

Proposal Sections

The RFP should require that proposals be submitted in two parts: a "technical proposal" and a "business proposal." The technical and business proposal instructions in the RFP must describe all the information deemed essential for proper evaluation of the proposals. This will ensure that all prospective organizations are aware of all requirements, so that differences in proposals will reflect each organization's individual approach to the requirements, not different interpretations of the requirements. The instructions should request that the technical and business proposals be submitted as separate and complete sections so that the ADAP can independently evaluate each part. The technical proposal may include information on labor hours and categories, materials, and subcontractors.

Evaluation Factors

The RFP must inform prospective organizations of all evaluation factors and of the relative importance or weight attached to each factor. Evaluation factors must be described in sufficient detail to inform prospective organizations of the significant matters that should be addressed in the proposals. Only the evaluation factors set forth in the RFP can be used in evaluating proposals; these factors can only be modified by a formal amendment to the RFP.

Procurement Procedures

According to OMB Circular A-102 (or 45 CFR Part 92), local government grantees may use their own procurement procedures that reflect applicable State and local laws and regulations, provided that the procurement procedures conform to applicable Federal law and the standards identified in the Circular (Part 92.36). Identified standards concern the following areas:

- Written code of standards of conduct for employees involved in the award and administration of contracts.
- Procedures to avoid the purchase of unnecessary and duplicative items.
- Making awards to responsible contractors.
- Maintaining records to detail the history of procurement.
- Settlement of all contractual and administrative issues.
- Protest procedures to handle and resolve disputes.
- Providing for full and open competition.
- Written selection procedures for procurement transactions.

A contract must contain the clauses necessary to ensure that all requirements under the grant will be satisfied, since neither 45 CFR Parts 74 and 92 nor other documents are directly binding on a contractor.

III.1.D. Contract Monitoring

Introduction

Under Part B/ADAP, contract monitoring is the responsibility of the State grantee. Contract monitoring includes both program and fiscal monitoring activities. Part B grantees need to ensure that their ADAP and any contracts (e.g. PBM) follow HRSA fiscal guidelines as outlined in the National Monitoring Standards.

In cases where an ADAP is administered by another organization or State agency, such as the State Medicaid office, the ADAP may delegate some of its authority to monitor contracts to this agency. Such arrangements require a Memorandum of Understanding or Memorandum of Agreement (MOU/MOA) or a specific contract requirement that specifies methods, sets deadlines, and assigns responsibility for the monitoring activities. 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 providers. Contracted providers have an inherent conflict of interest when they are involved in monitoring their own contracts.

ADAPs vary in many ways and contract with a wide range of entities. Some contractors are large and well established, while others are new and inexperienced. While there is no one right way to monitor ADAP contracts, a strong monitoring program includes a core of basic strategies, activities, and standards that can be tailored to specific situations. This chapter outlines "good practice" in designing, developing, and implementing a contract-monitoring program.

Legislation, HRSA Program Requirements, and Expectations

Following are legislative requirements for Part B grantees that relate to contract monitoring:

- HIV/AIDS disease status, Section 2616(b).
- Priority for women, infants, children, and youth, Section 2611(b).
- Imposition of charges for services. Section 2617(c).
- Provision of outreach to low-income individuals, Section 2617(b)(7)(B)(iii).
- Payer of last resort, Section 2617(b)(7)(F).
- Administrative caps for first-line entities, Section 2618(b)(4).
- Maintaining appropriate relationships with points of access, Section 2617(b)(7)(G).

HRSA/HAB has developed Fiscal and Program Monitoring Standards to guide Part A and Part B grantees in managing their Federal grant funds and complying with legislative and program

requirements. These standards include standards and corresponding performance measures/methods along with grantee and sub-grantee/provider responsibilities that are tied to each standard and measure.

See HRSA/HAB Monitoring Standards:

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

Payer of Last Resort

The Payer of Last Resort issue is of particular importance during the contract-monitoring phase. This assures that funds are not used to provide items or services for which payment already has been made, or reasonably can be expected to be made by a third party payer including State or local entitlement programs, prepaid health plans, or private insurance. It is incumbent upon the ADAP to assure that eligible individuals are expeditiously enrolled in other programs (e.g., Medicaid, Medicare) and that Ryan White funds are not used to pay for any services covered by other programs.

In cases where the operations of the ADAP and/or its eligibility determinations are made through a sub-contractual relationship. The assurance that Ryan White program funds remain the payer of last resort should be maintained. Contractors with the authority to conduct ADAP eligibility should also perform insurance verification, and make every effort to identify primary payer verifications. Such actions will reinforce the integrity of the ADAP funds being spent on clients identified as eligible.

Contract Monitoring Versus Evaluation

Though many methods used in program and fiscal monitoring are the same as those used in program evaluation, these activities should be understood as distinct. Contract monitoring is concerned with oversight of the use of funds and accomplishment of activities as outlined in program contracts. Evaluation is similar in that it can also focus on documentation of program accomplishments. An important distinction, however, is that evaluation studies also assess the impact of programs on clients by examining delivery of services and outcomes attributable to service efforts. Contract monitoring cannot typically provide this type of information.

Program monitoring is the assessment of compliance, and the quality of the services being provided by sub-contractors according to federal regulations for the provision of direct RW services. For the ADAP staff involved in implementing a contract monitoring effort, program monitoring might include reviewing client enrollment, assessing eligibility criteria, interacting with participating pharmacies, reporting fiscal information, managing data, and monitoring a contracted PBM. Staff responsible for the monitoring contracts also need to evaluate possible barriers or problems associated with delivery of pharmaceuticals to clients.

Fiscal monitoring is a means of assessing whether a contractor is spending program funds in compliance with federal regulations for approved purposes, consistent with administrative caps and service allocation percentages (75% core medical /25% Supportive Services rule). Staff should monitor funding from various sources to the ADAP such as State funding, 340B rebates, income, and reimbursements from Medicaid. Fiscal monitoring should include regular reviews

and assessments of contractors' expenditure patterns and processes to ensure adherence to Federal, State, and local rules and guidelines on the use of Ryan White funds.

The following examples show how program monitoring and fiscal monitoring may be linked:

- Many States require program reports to accompany reimbursement invoices in order for payments to be processed.
- To reimburse providers on a unit cost basis, Part B/ADAP grantees require both fiscal and program information.
- Comprehensive monitoring site visits to funded contractors should include a program audit, a fiscal audit, and a universal monitoring review.

Establishing a Contract Monitoring System

Grantees should ensure, up front, that contractors understand how the grantee plans to monitor contracts. The grantee may want to outline the contract monitoring process before contracts are signed. In some cases, grantees may prefer to develop a process jointly with contractors after contracts are executed. For example, implementing a peer review process for contractor staff would require joint planning.

A complete contract monitoring system includes these key elements:

- Roles of funded agencies and contractors clearly specified.
- The written contract.
- A Memorandum of Understanding or Memorandum of Agreement (MOU/MOA).
- Approaches for effective contract monitoring.
- Plans for corrective actions and/or remedial steps.

Grantees should address each of the elements listed in full detail before a contract-monitoring program begins. The grantee and contractor should clearly understand the basis upon which contracts will be monitored.

III.1.E. Role of Funding Agencies and Contractors

Ryan White funding is based on a "partnering" model that links funding agencies and contractors in a collaborative effort to ensure the quality, quantity, effectiveness, and appropriateness of services for people living with HIV/AIDS (PLWHA). In this model, clear expectations and conditions help facilitate cooperative solutions to problems. Therefore, contract-monitoring roles for funding agencies and contractors should be clearly specified.

The Part B grantee retains ultimate accountability to the Health Resources and Services Administration (HRSA) for all contracts awarded through its Part B program. The grantee,

therefore, determines the personnel on the monitoring team and the nature and extent of each person's involvement.

III.1.F. The Written Contract

Scope of Work

The scope of work, or the activities to be performed by the contractor, must be outlined in the contract. The scope of work can be written in a number of ways, including sub-sections on goals, objectives, work plan, timelines, and deliverables.

The scope of work must include clear performance expectations and assessment criteria. Funding agencies must clearly describe what they will consider a successful or unsuccessful implementation of a program, to ensure that contractors document the program with the appropriate and necessary information.

Operating Budget

The written contract 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 provider draws funds down from a pool, based on fee-for-service or unit cost accounting systems.

If the provider is using multiple funding streams to support a particular service, the budget should clearly indicate the other funding sources and specify within the contract which line items are supported by each funding source. Because most ADAPs operate from a number of funding streams, the breakdown of funding source should be specified whenever possible. To the extent that contractors are providing services prohibited with ADAP earmark or other Federal dollars, the alternative funding source (e.g., State dollars) should be clearly stated.

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. In a written contract, fiscal assurances should be spelled out in a manner that ensures each party's ability to satisfy Federal, State, and local regulations.

Program Assurances

The funding agency may require contractors to follow policies on record maintenance, client confidentiality, standards of care, or client eligibility restrictions and protections. A written contract may include a commitment to follow HRSA and State program policies.

Administrative Provisions

Administrative provisions are processes and parameters tied to a contract. Such provisions may specify a budget modification process, procedures for modifying the scope of work mid-contract, method of payment, and duration of the contract.

Staffing Patterns

When a service provider is newly established, staffing patterns are key to a program's success. Particularly where funding agencies wish to build new capacity in a service category, a written contract may require that specific staff positions be filled by qualified individuals and by a stated deadline.

Reporting Requirements

Every ADAP contract must include expectations about providing data as needed by the grantee and HRSA-required data as follows.

- **ADAP Data Report (ADR).** The ADR is a client level data system. ADAPs will begin using the ADR in 2013 to report information on their program and the clients they serve to the HIV/AIDS Bureau.
- **ADAP Quarterly Report (AQR).** The AQR compiles aggregate data on the number of clients, total funds expended for ADAP, substantive programmatic changes, and prices paid for specific HIV pharmaceuticals.

The ADR will address limitation of the aggregate data reporting under the AQR and will enable HRSA/HAB to evaluate the impact of the ADAP on a national level, inclusive of describing who is using the program, what ADAP-funded services are being used and the associated costs with these services. The AQR will be phased out as ADAPs become accustomed to the ADR and the quality of the information provided through the ADR accurately represents the program.

Contracts should spell out how often and on what dates reports are due. In addition to the above reports, contracts should require monthly or quarterly expenditure and utilization reports. Local and State guidelines for HIV/AIDS surveillance may present additional reporting obligations for providers; these may be included in the written contract.

Corrective Actions

Funding agencies should describe a dispute resolution process, including a description of "worst case" corrective actions that may be taken if contractual obligations are not met.

Appeal

The contract should describe the administrative remedies available through the grantee office if a provider wishes to appeal any corrective action that has been taken.

III.1.G. Memoranda of Understanding (MOU) or Memoranda of Agreement (MOA)

The MOU/MOA clarifies local roles and responsibilities in all areas related to the contracts in question. The document spells out how the relationships between decision makers will be governed. Again, because of the enormous diversity across Part B/ADAPs, what works in one region may not work in another. The MOU/MOA should contain the following components:

Parties. The MOU/MOA should name the individuals or organizations entering into the agreement.

Contracts. The MOU/MOA should stipulate the number and type of contracts covered by the agreement.

Scope. The scope and purpose of each contract covered by the agreement should be described. If the agreement covers contracts and activities beyond Part B/ADAP, such as the Centers for Disease Control and Prevention (CDC), Housing Opportunities for People With AIDS (HOPWA), Medicaid, or other programs, the MOU/MOA should specify which provisions apply to Part B/ADAP and which do not.

Duration. The MOU/MOA should specify how long the agreement would be in place.

Roles. The MOU/MOA should identify those responsible for specific activities, and provide a time-line for delivery of services or obligations. The MOU/MOA should specify responsibilities for any activities that require extensive collaboration among a number of parties, such as a State-wide drug utilization review or other project.

Costs. If any costs are to be accrued, the MOU/MOA should describe how they are allocated and the means of paying them.

III.1.H. Approaches for Effective Contract Monitoring

Effective contract monitoring involves a constructive, interactive process of feedback by the grantee and the contractor on how the contract obligations are being met. A rigid, one-way process that looks only for flaws in provider performance runs the risk of undermining trust and communication between the funding agency and the contractor. Clarity and courtesy should guide the funding agency's approach to contract monitoring. For example, funding agencies should give advance notice before site visits are made, and supply the provider with a checklist of items to be reviewed during the visit; the items to be reviewed should follow directly from the obligations outlined in the provider's original contract.

Ongoing program expenditures and staffing requirements may be assessed without delay after a contract begins. However, monitoring of program performance should be delayed until programs have become established enough to provide sufficient data.

Grantees should use the monitoring process to reinforce and underscore mutual obligations between the funding agency and the contractor.

While grantees should use consistent contract monitoring methods for all funded providers, the methods should be flexible enough to address particular monitoring needs in different grantee/provider relationships. For example, while new programs may need more oversight of their fiscal accountability, program infrastructure, and staffing patterns, established programs may be monitored more for performance and output.

While a successful monitoring effort includes a number of these methods, funding agencies should also attempt to limit the time and resources required of contractors to meet their reporting obligations. Any single monitoring method is only as good as the accuracy of the information reported or collected. Mixing several types of monitoring activities into the process may help grantees verify the accuracy of information.

Disbursement of Funds and Budgeting

Grantees should closely monitor the rate of program expenditures to assure that adequate funding for pharmaceuticals is available through the fiscal year and into the future. Regular reports allow the grantee to review client utilization rates, expenditures, and client demographics.

Grantees should set up a system to track monthly expenditures, to quickly respond to program changes and utilization that indicate a possible funding shortage or other program related event requiring immediate intervention. Monthly monitoring allows the grantee to determine if any changes need to be made to the program, such as caps on expenditures per client, implementation of or changes to a client waiting list, or limitations on the formulary. Additionally, monthly monitoring allows the grantee time to seek additional funding sources to prevent possible program limitations.

Technical Assistance

Technical assistance (TA) programs provide contractors with resources to aid in the development or compliance of their programs. Peer and other professional consultants typically provide on-site TA with specific experience in assisting, training, or guiding contractors through Part B/ADAP requirements. ADAPs may also develop TA documents or products including manuals, reports, conference calls, meetings, training tools, and newsletters. HRSA provides ADAP grantees with a number of such documents, such as this manual, which can be used by grantees, consortia, lead agencies, and contractors.

At a minimum, TA should be deemed acceptable by the assigned federal project officer, to ensure that program development needs and deficiencies are appropriately addressed before any large-scale effort is undertaken. Significant time and money may be wasted if the intended recipient will not accept outside help.

Conditions of Award/Contract Remediation Plan

If a contractor does not accept TA even while obligations are not being met, the grantee or lead agency can issue "conditions of award." Issuing a condition of award is a way of repeating obligations set forth in the original contract. The conditions should include a clear statement of the obligations that are not being met and a timetable for making a correction. This approach may convince a contractor to accept TA that was resisted in the past. Conditions of award usually do not require acceptance of TA; the contractor may continue to work without assistance. The conditions are, however, a serious warning sign to the contractor that funding may be suspended or terminated if action is not taken.

The contract remediation plan combines the conditions of award with a TA plan. The plan can be mandated by the grantee or mutually agreed upon by the grantee and the contractor. In any case, it is a signed, dated document specifying the steps and timetable by which the contractor must come into compliance.

Suspension, Reallocation, or Termination of Funding

Any action with respect to funding must be preceded by extensive documentation of the contractor's compliance problems. Documentation should include the following:

- A full description of the problems.
- A summary of the informal and formal steps that were taken to address the problems.
- Relevant supporting documents such as memos, reports, and evaluations.

Funding can be suspended or reallocated without full termination of a contract. Efforts at building contractor compliance and accountability may extend over a number of years or contract periods.

All contractors should have the right to appeal decisions regarding suspension, reallocation, or termination of funding. If the contractor in question provides drug dispensing or distribution to ADAP clients, alternative sources of medications should be identified by the ADAP to ensure continual coverage.

Conclusion

Only the grantee is fully accountable to HRSA for contract monitoring in ADAPs. Contract monitoring processes should be based on obligations as outlined in a written contract and responsibilities as outlined in a Memorandum of Understanding or Memorandum of Agreement. Grantees may decide upon a range of contract monitoring methods. If contractors encounter repeated compliance problems, corrective action may be needed. It is best to offer a "graduated" corrective action plan so that a number of informal mechanisms are available before a contract gets into significant trouble and more formal approaches are necessary.

III. Ch 2. Part B/ADAP Grants Management

III.2.A. Introduction

The Federal rules governing grants management for Ryan White HIV/AIDS Program service providers are provided in Office of Management and Budget (OMB) circulars and the Code of Federal Regulations (CFR). Part B grantees are expected to be familiar with these documents and assure that all service providers follow the procedures outlined in these documents.

III.2.B. Legislation, HRSA Program Requirements, and Expectations

The Part B/ADAP grantee is responsible for the proper administration of all grant funds. The grantee needs to establish sound and effective programmatic and fiscal management systems to assure the proper provision of funds and activities. These systems must meet the requirements outlined by the Office of Management and Budget (OMB) for recipients of Federal funding.

Administration of Grants

Grantees can find relevant information regarding the administration of grants in the following OMB Circulars:

OMB Circular A-102 - *Grants and Cooperative Agreements with State and Local Governments* (codified by the U.S. Department of Health and Human Services [HHS] in 45 CFR Part 92), and

OMB Circular A-110 - *Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations* (codified by HHS in 45 CFR Part 74). A-110 applies to sub-awards and contracts made by State and local governments to organizations covered by this Circular.

Access to OMB Circulars:

<http://www.whitehouse.gov/omb/circulars>

<http://www.hhs.gov/grantsnet>

Costs Applicable to Grants and Contracts

The following OMB resources establish principles and standards for determining costs applicable to grants, contracts, and other agreements entered into by the types of organizations specified:

- OMB Circular A-122, Cost Principles for Nonprofit Organizations.
- OMB Circular A-87, Cost Principles for State and Local Governments.
- OMB Circular A-21, Cost Principles for Educational Institutions.

Audit Policies and Standards

The following OMB resource provides government-wide policies and standards for non-Federal organization-wide audits of recipients of Federal awards:

- OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations.

III.2.C. Additional Guidance

For additional guidance, ADAP grantees may also utilize the HHS Grants Policy Statement. This policy statement compiles policies and reviews policy issues that have been raised in the past regarding the administration of grant awards.

Access the HHS Grants Policy Statement: <http://www.hrsa.gov/grants/hhsgrantspolicy.pdf>

Unobligated Balances

The Ryan White Treatment Extension Act of 2009 includes provisions that impose penalties on Part B grantees that carry unobligated balances, or UOBs, of more than 5 percent of their formula award. All grantees requesting carryover of UOB, whether greater or less than 5 percent must submit a waiver application to HAB/DSHAP 60 days before the end of the grant year stating the purpose for which such funds will be expended during the carryover year. If a waiver for carryover is approved, and the grantee has UOB at the end of the grant year, those funds can be expended in accordance with the waiver requirements.

The exact amount of UOB will be reported on the Federal Financial Report (FFR) and submitted no later than 90 days after the closing of the grant year. **NO EXTENSIONS WILL BE GRANTED FOR LATE SUBMISSION OF THE FINAL FFR.** Grantees that have greater than 5 percent UOB will have their future year formula award offset by that amount. The grantee will also be ineligible for supplemental funding in the future year.

If the UOB funds are part of the supplemental award, the grantee will not become ineligible for supplemental funding in the future year.

The HAB Policy Notice 12-02 specifies that UOB provisions do not apply to funds from drug rebates under Part B. Rebate funds should never be recorded as an unobligated balance on any FFR. Rebate funds should be tracked and the total amount reported in the FFR under line 12 "Remarks", with attachments as necessary. If the state is indicating that the UOB is a result of the drug rebate funds and therefore the UOB penalty does not apply, that must be indicated in the "Remarks."

HAB Policy Notice 12-02:

<http://hab.hrsa.gov/manageyourgrant/pinspals/habpartauobpolicy.pdf>

III.2.D. Maintenance of Effort

The Ryan White legislation requires Part B grantees to contribute at least the same level of funding for HIV activities as they did in the previous fiscal year. For example, if a State contributed \$500,000 in a given Fiscal Year, then the State is expected to contribute at least the

same amount to HIV-related activities in the following Fiscal Year. To demonstrate compliance with this provision, States need to maintain adequate systems for consistently tracking and reporting HIV-related expenditure data from year to year.

Grantees must ensure that Federal funds do not supplant State spending but instead expand HIV-related activities. Funds that states may use to demonstrate compliance with MOE requirements are those that have, at a minimum, an identifiable line item in State budgets and expenditure reports from State agencies. These funds may include:

- State contributions to ADAP and/or other Ryan White services.
- Prescription drug rebates.
- State Pharmacy Assistance Programs (SPAP).
- State-funded salaries of Part B staff.
- State funds spent on health insurance.
- State-funded ADAP delivery fees.
- State Department of Corrections expenditures on care and treatment for HIV+ inmates.
- The state share of Medicaid expenditures for people living with HIV/AIDS.
- State contributions to HIV prevention and surveillance activities.
- State contributions to HIV research.

III. Ch 3. State Matching Funds Requirements

III.3.A. Introduction

The Ryan White legislation requires States that have reported to the Centers for Disease Control and Prevention (CDC) more than one percent of U.S. AIDS cases in the prior two years to provide a match for their Part B grant. The required matching rate is based on the number of years the State meets the one percent threshold. **The match ceiling is different for Part B ADAP Supplemental grants (\$1 for each \$4 of Federal funds) than the Part B formula award (\$1 for each \$2 of Federal funds), and the match requirement for ADAP Supplemental funds can be waived.** The ADAP Supplemental matching amount is based on the amount of the award, not the amount of grant funds actually expended.

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

The Ryan White legislation states the following regarding State matching requirements:

Section 2617(d)(1) In general. In the case of any State to which the criterion described in paragraph (3) applies, the Secretary may not make a grant under this part unless the State agrees that, with respect to the costs to be incurred by the State in carrying out the program

for which the grant was awarded, the State will, subject to subsection (b)(2), make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to—

(A) for the first fiscal year of payments under the grant, not less than 16 2/3 percent of such costs (\$1 for each \$5 of Federal funds provided in the grant);

(B) for any second fiscal year of such payments, not less than 20 percent of such costs (\$1 for each \$4 of Federal funds provided in the grant);

(C) for any third fiscal year of such payments, not less than 25 percent of such costs (\$1 for each \$3 of Federal funds provided in the grant);

(D) for any fourth fiscal year of such payments, not less than 33 1/3 percent of such costs (\$1 for each \$2 of Federal funds provided in the grant); and

(E) for any subsequent fiscal year of such payments, not less than 33 1/3 percent of such costs (\$1 for each \$2 of Federal funds provided in the grant).

(2) Determination of amount of non-federal contribution.—

(A) In general.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) Inclusion of certain amounts.—

(i) In making a determination of the amount of non-Federal contributions made by a State for purposes of paragraph (1), the Secretary shall, subject to clause (ii), include any non-Federal contributions provided by the State for HIV-related services, without regard to whether the contributions are made for programs established pursuant to this title;

(ii) In making a determination for purposes of clause (i), the Secretary may not include any non-Federal contributions provided by the State as a condition of receiving Federal funds under any program under this title (except for the program established [in this part]) or under other provisions of law.

(3) Applicability of requirement.—

(A) Number of cases.—A State referred to in paragraph (1) is any State for which the number of cases of HIV/AIDS reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the period described in subparagraph (B) constitutes in excess of 1 percent of the aggregate number of such cases reported to and confirmed by the Director for such period for the United States.

(B) Period of time.—The period referred to in subparagraph (A) is the 2-year period preceding the fiscal year for which the State involved is applying to receive a grant under subsection (a).

(C) Puerto Rico.—For purposes of paragraph (1), the number of cases of HIV/AIDS reported and confirmed for the Commonwealth of Puerto Rico for any fiscal year shall be deemed to be less than 1 percent.

(4) Diminished state contribution.—With respect to a State that does not make available the entire amount of the non-Federal contribution referred to in paragraph (1), the State shall continue to be eligible to receive Federal funds under a grant [under this part], except that the Secretary in providing Federal funds under the grant shall provide such funds (in accordance with the ratios prescribed in paragraph (1)) only with respect to the amount of funds contributed by such State.

Section 2618(a)(2)(F)(ii) outlines supplemental drug treatment grants as follows:

(III) State requirements.— The Secretary may not make a grant to a State under this clause unless the State agrees that the State will make available (directly or through donations of public or private entities) non-Federal contributions toward the activities to be carried out under the grant in an amount equal to \$1 for each \$4 of Federal funds provided in the grant, except that the Secretary may waive this subclause if the State has otherwise fully complied with section 2617(d) with respect to the grant year involved. The provisions of this subclause shall apply to States that are not required to comply with such section 2617(d).

III.3.C. State Match Principles and Definitions

Ryan White funds are intended to supplement resources provided by metropolitan areas and States in providing services to individuals with HIV/AIDS and their families. For States, Part B funding was never intended to be the sole source of support for community-based HIV care services, and the matching requirement, along with other legislative requirements such as maintenance of effort, assure a concomitant level of State support. This section focuses on issues relating to implementation of this legislative requirement. Such guidance is especially important given the recent concerns expressed by the Office of the Inspector General regarding compliance with, and oversight of, the matching requirement.

The following definitions may be helpful in reading and understanding this section:

- **In-Kind Contributions.** Non-cash contributions that a State may provide to support HIV-related services. These non-cash contributions must be fairly valued and may include plant equipment or services.
- **Required Rate of State Matching.** The minimum level of cash and/or in-kind contributions a State must provide according to a schedule established in 2617(d) of Ryan White.

- **State.** A State is defined to include each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico and the Territories of the Virgin Islands, Guam, American Samoa, Commonwealth of the Northern Mariana Islands, Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. However, Puerto Rico is specifically exempted from the State match requirement.
- **State Matching.** The non-Federal cash or in-kind contributions provided by the State to supplement the Federal funds received. State contributions claimed as match for other Federal programs (such as Medicaid) may not be used to meet the match requirement for the Part B grant. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in calculating the amount of the State matching contribution.

The HRSA/HAB National Monitoring Standards, Fiscal Monitoring Standards, address State matching requirements as follows:

Grantees are expected to ensure that non-Federal contributions (direct or through donations of private and public entities) are:

- Verifiable in grantee records.
- Not used as matching for another Federal program.
- Necessary for program objectives and outcomes.
- Allowable.
- Not part of another Federal award contribution (unless authorized).
- Part of the approved budget.
- Part of unrecovered indirect cost (if applicable).
- Apportioned in accordance with appropriate Federal cost principles.
- An integral and necessary part of the time allocated value similar to amounts paid for similar work in the grantee organization, if including volunteer services

Value services of contractors at the employees' regular rate of pay plus reasonable, allowable and allocable fringe benefits.

Assign value to donated supplies that are reasonable and do not exceed the fair market value.

Value donated equipment, buildings, and land differently according to the purpose of the award.

Value donated property in accordance with the usual accounting policies of the recipient (not to exceed fair market value). (From HAB fiscal monitoring standards)

III.3.D. Expectations

The Ryan White legislation stipulates that the HHS Secretary may not make grants to States with more than one percent of the reported AIDS cases for the two most recent Fiscal Years unless those States agree to make available non-Federal contributions to match the Part B funding they receive. The matching amount includes non-Federal contributions such as cash or in-kind contributions provided directly by the State or through donation from public or private entities. In making a determination of the amount of non-Federal contributions made by a State, the Secretary shall include any non-Federal contributions provided by the State for HIV-related services without regard to whether the contributions are made specifically for Ryan White programs. If a State provides matching funds/assets, but the rate of matching is not at the level prescribed in the legislation, the Part B grant will be reduced to achieve the required matching ratio.

Grantees **must ensure** that Federal funds **do not supplant State spending** but instead expand HIV-related activities. Funds that states may use to demonstrate compliance with match requirements are those that have, at a minimum, an identifiable line item in State budgets and expenditure reports from State agencies. These funds may include:

- State contributions to ADAP and/or other Ryan White services.
- Prescription drug rebates.
- State Pharmacy Assistance Programs (SPAP).
- State-funded salaries of Part B staff.
- State funds spent on health insurance.
- State-funded ADAP delivery fees.
- State Department of Corrections expenditures on care and treatment for HIV+ inmates.
- The state share of Medicaid expenditures for people living with HIV/AIDS.
- State contributions to HIV prevention and surveillance activities.
- State contributions to HIV research.

Determining the Rate of State Match

Program experience shows that a small number of States have been above, and have then fallen below the one percent threshold over different fiscal years. A State that meets the one percent threshold in a particular Fiscal Year and then falls below that threshold in a subsequent fiscal year is not required to meet the matching fund requirement for the year in which it is below the threshold. If, however, the State subsequently meets the threshold again, only the

years in which that State meets the one percent threshold are counted in determining the required rate of match.

Part B Match Documentation Requirements

Since the Secretary may not make a grant under Part B unless the State agrees to make available the required match, the State must provide documentation with its Part B application that such match requirements will be met. This documentation includes signed assurances, which include the agreement to meet the required State match and specific information submitted as per instructions found in the Part B Application Guidance for States. While the Part B grantee is not required to submit the specific calculations or sources for meeting the match requirements, the grantee must maintain that documentation for audit and site visit purposes.

Part B grantees are also required, 90 days after the end of each budget period, to submit a final Financial Status Report (FSR). Items 10b (Recipient Share of Outlays) and 10e (Recipient Share of Un-liquidated Obligations) of this report document that the required State match for the grant has been met (i.e., the requirement is met when the sum of 10b and 10e equals the required State match amount). In addition, starting with the Fiscal Year final progress report due 30 days after the end of the budget period, States must describe the activities, personnel, and other object class categories actually supported through use of matching funds.

Future awards will be unaffected for those States submitting an FFR and final progress report indicating the required State match has been met and how, as outlined in the previous section. If a State submits an FFR indicating a level of recipient outlays and un-liquidated obligations below the required State match, subsequent grant awards will be offset by the appropriate proportional amount. The amount by which the grant is offset will be reallocated to other Part B grantees.

III. Ch 4. Administrative Costs and Program Income

III.4.A. Introduction

The Ryan White legislation defines administrative activities in Part B programs to include routine quality management monitoring, and limits the percentage of the award that the grantee can spend on administrative activities. Ryan White includes several requirements regarding the use of Part B funds to carry out administrative activities. Some of these requirements apply to grantees, while others apply to lead agencies, consortia, and subcontractors. While the legislation does not require any single provider to meet administrative cost caps on their own, the State grantee must limit the aggregate administrative costs of its first-line entities to 10 percent of the total funds awarded to those entities.

III.4.B. Legislation, HRSA Program Requirements, and Expectations

Planning, Evaluation, Administration Costs, and Clinical Quality Management

The Ryan White legislation defines administrative activities for Part B grantees as follows: Section 2618 (b)(3)(A) of the limits Part B grantees to spending not more than 10 percent of their grant on planning and evaluation activities, not more than 10 percent of their grant on administration, and, when combined, not more than 15 percent of their grant on planning, evaluation, and administration. Administration activities may include clinical quality management.

Each State that receives a grant under section 2611 shall provide for the establishment of a clinical quality management program. The purpose of the program will be to assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent HHS guidelines for the treatment of HIV/AIDS and related opportunistic infections, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in access to and quality of HIV health services. From amounts received under a grant awarded under section 2611 for a fiscal year, a State may not use more than 5 percent of amounts received under the grant or \$3,000,000, whichever is less.

In the case of entities and subcontractors to which a State allocates amounts received by the State under a grant under section 2611, the State shall ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10 percent (without regard to whether particular entities expend more than 10 percent for such expenses).

HRSA/HAB Monitoring Standards on administrative costs state:

Part B Fiscal Monitoring Standards: Section A. Limitation on Uses of Part B Funding. 5. Appropriate sub-grantee assignment of Ryan White Part B administrative expenses, with administrative costs to include:

- a. Usual and recognized overhead activities, including rent, utilities and facilities costs; and*
- b. Costs of management oversight of specific programs funded under [Part B], including program coordination, clerical, financial, management staff not directly related to patient care, program evaluation, liability insurance, audits, computer hardware/software not directly related to patient care.*

III.4.C. Defining Administrative Costs

Part B Grantees

Administrative costs associated with the 10 percent administrative cap for Part B grantees include the following:

- Development of funding applications and receipt and disbursement of program funds.
- The receipt and disbursement of pharmaceutical funds.
- The development and establishment of reimbursement systems (340B rebate, Medicaid back billing), and accounting systems.
- The preparation of routine programmatic and financial reports, including the minimum requirements of completing Ryan White data reports.
- Compliance with grant conditions and audit requirements.
- All activities associated with the grantee's contract award procedures, including the development of requests for proposals, contract proposal review activities, negotiation and awarding of contracts, development and implementation of grievance procedures, monitoring of contracts through telephone consultation, written documentation or on-site visits, reporting on contracts, and funding reallocation activities.

First Line Entities/Lead Agencies with Management and Oversight Functions

While first line entities are subject to the aggregate cost cap associated with the administrative activities listed above, they may also be subject to the grantee administrative cap associated with the following activities:

- Development of funding applications and proposals.
- Receipt and disbursement of program funds.
- Development and establishment of reimbursement and accounting systems.

- Preparation of routine programmatic and financial reports, including the minimum requirements of completing Ryan White data reports.
- Compliance with contract conditions and audit requirements.
- Subcontract monitoring and reporting, through telephone consultation, written documentation or on-site visits, developing funding applications and proposals, and the receipt and disbursement of program funds.

Planning and Evaluation (Grantees)

Planning and evaluation includes grantee activities related to planning for the use of ADAP funds and evaluating the effectiveness of those funds in delivering needed services. Specific activities that planning and evaluation funds may support for ADAPs include the following:

- Capacity-building to increase the availability of services.
- Technical assistance to contractors.
- Program evaluation.
- Assessment of service delivery patterns.
- Assessment of need.
- Obtaining community input.
- Drug utilization reviews.

Program Support and Quality Control by First-Line Entities

Program support and quality control activities for first-line entities include the following:

- Client satisfaction surveys.
- Technical assistance to subcontractors.
- Staff training.

III.4.D. Administrative Cost Caps

Part B Grantees

In accordance with Section 2617(b)3(A) of the Ryan White legislation, grantees are allowed to use up to 10 percent of Part B funding for the payment of administrative costs in any given grant year, with a total of 15 percent of the Part B grant used for the combination of grantee administration, planning and evaluation.

Part B grantee administrative, planning and evaluation costs charged to the Part B grant must fall within the limits as calculated above. Part B grants include a Federal earmark for the ADAP.

The calculations for planning and evaluation, administrative costs, and quality management costs may be done separately on each portion of the grant. The selected percentages taken from each part of the grant do not have to be the same, but they each must fall within the caps as calculated above. Any funds taken out of the ADAP earmark must be spent on the grantee's administration, planning, evaluation, and quality management costs related to the ADAP.

Part B grantees are free to use as much of that non-earmarked amount for ADAP as they see fit. There is no requirement that funds taken out of that non-earmarked amount for administration costs be used in any set proportion between ADAP and other program components.

First-Line Entities The 10 percent administrative cost cap applies only to first line entities, which can include State-run ADAPs and Health Insurance Continuation programs, among others. A program's administrative costs may be separated from the grantee's administrative costs if the program is run by the grantee itself or by a closely related unit of State government. The basis for calculating the aggregate administrative cost cap for first line entities under Part B is the total amount remaining after the grantee takes its administrative, planning, and evaluation costs out of the award. The 10 percent factor is applied to this total amount. For example, if a grantee receives a grant award of \$3,000,000 and uses the maximum amount of 15 percent (\$450,000) for its own administrative, planning, and evaluation activities, \$2,550,000 remains for distribution. For first line entities that receive \$2,550,000, a maximum of 10 percent (\$255,000) can be charged to the Part B grant for administrative costs. That is, regardless of how much an individual first line entity spends on administrative costs, when added across all such entities, administrative costs that are paid for with Part B Ryan White funds cannot exceed \$255,000.

Second or Third-Line Entities Second and third line entities (sub-contractual providers) administrative costs are included as part of the aggregate administrative costs. Therefore their 10% cap would apply against the first line entity cap. The Grantee responsibility is to monitor all administrative costs to ensure they do not exceed the allowable rate.

Program Income and Client Charges

HRSA/HAB Monitoring Standards on program income state:

HRSA/HAB Fiscal Monitoring Standards. Section C: Income From Fees for Services Performed. 5. Ensure service provider retention of program income derived from Ryan White-funded services and use of such funds in one or more of the following ways: Funds added to resources committed to the project or program, and used to further eligible project or program objectives; Funds used to cover program costs. Note: Program income funds are not subject to the federal limitations on *administration (10%), quality management (5%), or core medical services (75% minimum)*. For example, all program income can be spent on administration of the Part B program, except in ADAP.

HRSA/HAB Fiscal Monitoring Standards. Section D: Imposition & Assessment of Client Charges. 1. Unless waived, Ensure grantee and sub-grantee policies and procedures that specifies charges to clients for services, which may include a documented decision to

impose only a nominal charge. **Note: This expectation applies to grantees that also serve as direct service providers and/or ADAP pharmacies.**

Standard. No charges imposed on clients with incomes below 100 percent of the Federal Poverty Level (FPL).

HRSA/HAB Fiscal Monitoring Standards. Section D: Imposition & Assessment of Client Charges
3. Charges to clients with incomes greater than 100 percent of poverty that are based on a discounted fee schedule and a sliding fee scale. Cap on total annual charges for Ryan White services (including ADAP) based on percent of patient's annual income, as follows: 5 percent for patients with incomes between 100 percent and 200 percent of FPL; 7 percent for patients with incomes between 200 percent and 300 percent of FPL; 10 percent for patients with incomes greater than 300 percent of FPL.

In accordance with Section 2617(c)1 of the Ryan White legislation, an ADAP must have a sliding fee scale if clients are billed for services.

III.4.E. Definitions

Subcontractors

The term "subcontractor" refers to entities that receive funding directly from the Part B grantee. In general, this interpretation means that other entities (commonly called subcontractors in grants management terminology) that receive funding from those direct recipients of funds are subject to the 10 percent aggregate administrative cost cap.

Lead Agency, Fiduciary Agent, or Fiscal Agent

Lead agency, fiduciary agent, or fiscal agent refers to the agency, organization, or other entity which functions within regional consortia to assist the grantee in carrying out administrative activities (e.g., disbursing program funds, developing reimbursement and accounting systems, developing RFPs, monitoring contracts). "Lead agency" is the term most commonly used by State grantees. The ADAP should work with the lead agency to assist in coordination with additional streams of funding for pharmaceuticals.

III.4.F. Documentation and Compliance

Grantees

Part B grantees are required to submit categorical budgets and narrative justifications to the HRSA for approval. These budgets must be submitted for administration, planning, evaluation, and services. Project officers and grants management staff review the grantee budgets and determine whether the grantee's administrative costs fall within the statutory limits.

First Line Entities

Governors (or their designees) are required to sign program assurances with their application to HRSA for funding (SF 424B, Program Assurances). Included among them is an assurance that the 10 percent aggregate administrative cost cap requirement will be met. Like all other program

assurances and legal requirements, compliance is subject to audit by such entities as the Office of the Inspector General at the U.S. Department of Health and Human Services and the Government Accountability Office. HRSA/HAB strongly recommends that grantees encourage lead agencies to use a budget format that clearly identifies the costs for administration (as defined in this chapter under "Definitions, Defining Administrative Costs, and Lead Agencies").

In their budget justifications, grantees will be required to identify the following information for "first-line" entities:

- The aggregate amount of funds available for the entities to spend on administrative costs.
- An estimate of the total amount of administrative costs those entities will incur over the budget year.

At the end of the budget year, as part of the final progress report submitted to HRSA, this information must be updated to reflect actual expenditures. Both the initial and final documentation of these figures will have to be signed by the financial officer in charge of the Ryan White grant.

Section IV. ADAP Management Strategies

IV. Ch 1. 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/AIDS; more intensive use of HIV/AIDS drugs by long-term survivors; economic conditions and loss of insurance; increased cost of medications and insurance; reductions in State funding for other programs, and reductions in state and federal funding for ADAP.

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

- **Cost-Cutting Measures:** Any measures taken that restrict or reduce enrollment (e.g. financial eligibility reductions and capped enrollment) or that reduce benefits (e.g. formulary reductions with respect to HIV antiretroviral and medications to treat opportunistic infections or complications of HIV disease). These measures are instituted out of necessity due to insufficient resources and/or to avoid starting a waiting list.
- **Cost-Saving Measures:** Any measures taken to improve the cost-effectiveness of ADAP operations. Cost-saving strategies are required to achieve, improve, and/or maximize available resources.
 - Examples of “cost-saving” measures: Improved systems and procedures for back billing Medicaid, improved client recertification processes, Part B Program structural or operational changes such as expanding insurance assistance, purchase of insurance, collection of 340B rebates for insurance co-payments, deductibles, co-insurance, TrOOP expenditures, and data-sharing agreements with other medication payment sources.
 - HRSA has prioritized the following cost containment strategies through its monitoring and technical assistance efforts: purchase of insurance, collection of 340B rebates for insurance co-payments, deductibles, co-insurance and True Out Of Pocket Expenditures (TrOOP) expenditures, back billing Medicaid for payments made during the retroactive eligibility period, Centers for Medicare and Medicaid Services (CMS) and state Medicaid data-sharing agreements, 6-month re-certification, and controlling ADAP administrative costs.

These measures impact multiple facets of ADAP operations. To illustrate, purchasing ADAP medications at a lower price (e.g., through use of 340B rebates) 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.

IV. Ch 2. Formulary Management

IV.2.A. Introduction

The Ryan White legislation requires all ADAPs to include at least one drug from each class of HIV antiretroviral medications on their formularies. ADAPs are also required to set guidelines on how clients can access medications in a timely manner. 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. Financial resources largely determine the resulting variations in ADAP formularies whereby some states are able to expand their formularies while other must limit options. Other factors influencing formulary design are cost containment strategies in use, standards of care, input from an ADAP Advisory Committee, availability of medications from other payers and programs, and medical prescriber preferences.

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

The Ryan White 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;

HHS/HRSA has determined to the following:

HRSA , October 17, 1996 letter from DSS to grantees re: Expectations and Recommendations about the Administration of State ADAPs supported with Ryan White CARE Act funds: “State ADAP,” in the, Ryan White legislation, to mean that both eligibility criteria and covered treatments for anyone enrolled in the program must be consistently applied across any State. As long as they comply with this essential requirement about equity and consistency, States have significant flexibility in how they administer their ADAPs.

IV.2.C. Formulary Management Strategies

ADAPs manage their formularies with primary attention to Ryan White 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

The most effective way for ADAPs to maximize what they offer under their formularies is to secure the best price available for all the products they offer.

Coverage By Other Sources

Ryan White is legislatively required to serve as the payer of last resort. Thus, an ADAP's formulary might include a range of medications offered by other programs and payers, but the ADAP must determine if a given client can access those medications through other programs before providing them under its formulary.

Advisory Body Input

ADAP advisory bodies typically make decisions or recommendations about formulary changes. Advisory bodies are normally comprised of clinicians, consumers, and others well positioned to provide expert guidance on changes to formularies. Members often discuss advances in HIV/AIDS treatment and assist ADAP staff in determining the cost effectiveness of adding new treatments to formularies. Although not statutorily required, advisory bodies can also play an important role when ADAPs face serious budgetary constraints and choose to restrict their formularies to decrease program costs.

Prioritizing Drugs Based on Clinical Indications

ADAPs often have a process to prioritize categories of drugs based on clinical indications, based on considerations like:

- Severity of the clinical condition and frequency in the HIV/AIDS population.
- Toxicity; cost; available alternatives; and potential for unintended use.
- Input from experts (e.g., advisory committees, pharmacists).

Prioritizing Based on Costs

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 used with ADAP clients. Prior authorization is typically used for high cost

drugs that have a narrow clinical indications. Over 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 disapprovals).
- Monitor utilization (e.g., to determine if additional patients can access the medication) and monitor the process (e.g., to determine if the approval/disapproval process is working).

IV. Ch 3. Managing Enrollment and Utilization: Waiting Lists

IV.3.A. Introduction

ADAPs use a number of techniques to manage enrollment and utilization in order to maximize funding and to ensure that ADAP funds are used appropriately. Strategies include waiting lists, caps (e.g., on enrollment, number of medications covered), and provisions to manage utilization (e.g., prior authorization for use of given medications, especially costly drugs). These techniques are often used when ADAPs are confronted with funding shortfalls. With the exception of waiting lists, these techniques are effective in managing ADAP resources on an ongoing basis.

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

Waiting Lists

In the Part B FOA, HRSA/HAB has defined an ADAP waiting list as follows:

A waiting list is a mechanism used to limit access to the ADAP when funding is not available to provide medications to all eligible persons requesting enrollment in that State.

A Part B grantee is not eligible to request a waiver from the requirement to allocate 75 percent of funds on core medical services if it has a waiting list. 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."

IV.3.C. Waiting Lists

What Is a Waiting List?

An ADAP waiting list is a mechanism used to limit access to the ADAP when funding is not available to provide medications to all eligible persons requesting enrollment in that State. The

ADAP verifies overall eligibility for the program and places eligible individuals on a waiting list, as necessary, prioritized by a pre-determined criterion. The ADAP manages the waiting list to bring clients into the program as funding becomes available.

Despite appropriation increases, steady growth in the number of eligible clients combined with rising costs of complex HIV/AIDS treatments sometimes results in states experiencing greater demand for ADAP services than available resources can cover. In these instances, ADAPs have implemented waiting lists for program services and medications. Once established the accurate reporting of individuals on the waitlist is key to assessing need and progress. Once enrolled waitlisted clients must be documented as a waitlisted until such time that the client is deemed ineligible and removed from the waitlist or is fully enrolled in to the ADAP. Below are considerations in establishing and managing a waiting list.

Gather Information and Input

A waiting list protocol can be developed by gathering input from:

- **Other ADAPs.** Review models and lessons learned by other programs by contacting the HRSA Project Officer or reaching out directly to other programs.
- **ADAP Advisory Committee.** Input from the State’s advisory group can provide insights that are specific to the State (e.g., physician prescribing practices that have an impact on utilization of certain ADAP medications that in turn impacts costs and the need for a waiting list, means for managing and minimizing the waiting list) and can confirm to the community that a mechanism is in place for public input on the process.

Establish Waiting List Policies and Procedures

Written policies and procedures for managing a waiting list provides information to clients and others that the process is fair and rational. Key factors to address include:

- Waiting list criteria (see below).
- A clearly stated rationale for the waiting list criteria.
- Compliance with State laws and regulations that impact establishment of a waiting list.
- A means for public input and communications to the public.
- Methods for monitoring the list to ensure that it is followed consistently across the State.
- A revisions and appeals process.

Waiting List Criteria

A fair and equitable waiting list protocol should consider the following factors:

- **Priority: First-Come, First-Served.** The basic rule for waiting list management is to add individuals to the list once they have completed their enrollment. Those on the list the

longest period of time should have priority when new slots open, although exceptions (as follows) should be considered.

- **Exceptions.** While first-come, first-served is good rule for fair and equitable management of a waiting list, the following medical considerations may be used in prioritizing certain individuals for more rapid enrollment:
 - Patients at specific points in their HIV disease, including: patients with acute HIV infection; treatment naïve individuals who meet HHS guidelines criteria for initiation of treatment; those with a CD4 count <200 cells/mm³; individuals already on antiretroviral treatment; and those experiencing treatment failure as complete antiretroviral cessation at this stage has resulted in rapid progression to AIDS and death.
 - Consideration to patients in specific circumstances (e.g., HIV-infected adolescents, injection drug users, women of child bearing potential and pregnant women, those with hepatitis B or C, or tuberculosis co-infections).

Monitor the Waiting List

Mechanisms for monitoring a waiting list must include: Clear ADAP eligibility standards, a confidential registry of individuals waiting for enrollment; current income and insurance data for clients, current health status of clients, recertification of client data to ensure eligibility (e.g., income, eligibility, and disease progression status), and identifying and facilitating options for clients to access medications while on the waiting list.

Manage Enrollment/Disenrollment

Patients on waiting lists should be provided with information about:

- An explanation of 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).

Enrollment processes might include:

- Regular communications with clients and assistance for those with special needs.
- Expectations of case managers to report regularly to ADAPs on the status of clients on the waiting list.
- Steps for moving an individual from the waiting list to active enrollment (e.g., reconfirmation of eligibility, notification of the client, case manager, pharmacy, and/or pharmacy benefits manager).

Disenrollment processes are important to allow new clients to utilize slots from persons who are no longer eligible for ADAP or who are not utilizing ADAP assistance. It is critically important that ADAP staff and case managers make every effort to address adherence issues prior to disenrollment of a client. Disenrollment might be prompted by:

- Failure to pick up medications within a designated time frame.
- Non-compliance with medication regimens.
- Failure to meet program requirements.
- Changes in circumstances such as becoming eligible for other coverage or moving out of State.

IV.3.D. 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. Caps may be used, for example, when there are significant fluctuations in drug costs each month, like for certain drugs.
- **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 repeatedly loses medications.
- **Prior Authorization.** For certain medications and regimens, ADAPs may cover the cost only after formal ADAP authorization. This is used in cases where drugs are costly and there are narrow clinical indications for the drug.

IV.3.E. Clinical Review of Prescribing Patterns

As part of clinical quality management, ADAPs can undertake a review of prescribing patterns of clinicians to determine consistency with treatment guidelines.

Cost considerations merit attention when less expensive clinically appropriate regimens are available. ADAPs are in a position to provide information to clinicians about costs for regimens that are recommended in HIV/AIDS treatment guidelines, such as development of cost guides for the most-frequently prescribed regimens.

IV. Ch 4. Coordination With Other Payers and Programs

IV.4.A. Introduction

AIDS Drug Assistance Programs (ADAPs) should work with other payers and programs to provide clients with access to HIV/AIDS medications and a continuum of care. As the level of expenditures and the number of individuals needing HIV/AIDS 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.

IV.4.B. Legislation, HRSA Program Requirements, and Expectations

Ryan White funds are intended to fill gaps in care and serve as the payer of last resort. This means that Ryan White resources should be used only when other public and private payers are not covering services needed by individual clients or that the costs with using other coverage is a barrier to care.

Section 2617(b)(7)(F) of the Ryan White 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);

HRSA/HAB Policy on coordination states:

Policy Notice 10-02, Eligible Individuals & Allowable Uses of Funds for Discretely Defined Categories of Services reads: As ADAPs seek to coordinate with other providers and payers, Ryan White grantees are reminded that “Pursuant to 42 U.S.C. § 300ff-27(b)(6)(F), grant funds may not be used to pay for items or services that are eligible for coverage by other Federal, State, or private health insurance”.

Policy Notice 07-05, The Use of Ryan White HIV/AIDS Program Part B ADAP Funds to Purchase Health Insurance reads: Funds “may be used to purchase health insurance whose coverage includes HIV treatments and access to comprehensive primary care services, subject to specific conditions.”

IV.4.C. How Coordination Can Happen

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

- **Understanding Other Payers and Programs.** ADAPs need to be knowledgeable about other payers and programs and their enrollment and utilization requirements. The next section summarizes key public and private programs.
- **Planning.** ADAPs can engage in planning and assessments (through ADAP advisory groups and 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 Expenditures for Medicare, and participation in State or Federal Health Insurance Exchanges.
- **Eligibility Screening.** ADAPs typically have their own eligibility processes. Increasingly, enrollment processes are being centralized and handled online, providing new opportunities for streamlined handling of clients, enrollment, and referrals.
- **Funding of Services.** Ryan White programs are required to coordinate their services and seek payment from other sources before Ryan White funds are used. This makes Ryan White 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), Pre-existing Condition Insurance Plans (PCIPs), private health insurance, and in 2014, State and/or Federal Health Insurance Exchanges.
- **Service Delivery.** The Ryan White legislation requires Part B grantees to coordinate specific services with other payers and programs (e.g., outreach, substance abuse prevention and treatment, HIV counseling and testing, and early intervention services). Coordinated service delivery is particularly important in conducting early intervention and engaging and retaining Persons Living with HIV/AIDS (PLWHA) in care. Many of these services are funded primarily by other Federal, State, and local sources. For example, HIV/AIDS prevention is funded through the CDC, while State substance abuse programs are supported partially through block grants from the Substance Abuse and Mental Health Services Administration (SAMHSA).

IV.4.D. Other Payers and Programs

Ryan White Programs

The Ryan White Program is comprised of multiple components, called Parts. All focus on bringing PLWHA into HIV/AIDS care and providing them with quality services. Some of these programs provide medication assistance. Some of these programs may provide assistance as follows: 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.

Medicaid

Medicaid is the largest payer of health care for PLWHA (counting both Federal and State funds), including prescription drug costs, and is thus a critical component of any ADAP management

strategy for coordinating benefits and controlling costs under the Ryan White mandate to serve as the payer of last resort. The level of cooperation between ADAPs and State Medicaid programs varies significantly across States, ranging from very high levels of collaboration on multiple issues to very limited or nonexistent dialogue between programs. ADAPs should increase the interface between the program and Medicaid due to the potential transition of ADAP clients to Medicaid. For example:

- Clients may transition from ADAP to Medicaid temporarily, and then transition back to ADAP during Medicaid spend-down waiting 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 should 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 as it pertains to HIV/AIDS care:

<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 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. Below are several strategies that can build high levels of cooperation between an ADAP and its State Medicaid program:

- **Identifying a Medicaid Contact Person.** The main prerequisite for establishing and maintaining a collaborative relationship between ADAP and Medicaid is the identification of, and ongoing communication with, a specific contact person within the Medicaid office. This person may sit on the ADAP advisory body or may simply be the point of contact within the Medicaid office. If several people staff an ADAP, it may be helpful to identify one staff person to be the Medicaid liaison.

- **Support of Departmental Leadership.** Communication and collaboration at the departmental level is another important factor in establishing and sustaining cooperation between ADAP and Medicaid, especially when working on Medicaid waiver/expansion issues. While cooperation at this high echelon in the State bureaucracy is helpful, some ADAPs and Medicaid offices cooperate fully on eligibility and benefits issues without the explicit participation of departmental leadership.
- **Understanding Medicaid.** 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>

- **Emphasize Cost Effectiveness and Efficiency.** Some Medicaid programs may feel that it is unnecessary to collaborate on eligibility and benefits issues because the financial stake for Medicaid is relatively low. However, ADAPs have found that the overall cost effectiveness and efficiency of collaboration tends to overcome such barriers. For example, individuals who have been receiving services through ADAP and later become Medicaid eligible may be healthier and represent less cost to the Medicaid program. ADAPs can also support Medicaid beneficiaries who are returning to the workforce.
- **Reduce Bureaucratic Barriers and Build Linkages.** Since the ADAP and Medicaid programs may be administered by two different State agencies that may historically have different missions, there may be bureaucratic structures (and a historical lack of cooperation) that act as barriers to communication and cooperation between the two agencies. Once initial contact is established, it is important to reduce these barriers by building linkages across programs. One way this may be accomplished is for the ADAP/HIV program to offer assistance to the Medicaid program in the form of sharing information or data, offering to convene meetings, and/or reviewing proposals of mutual interest.

Medicare Part D

Medicare is the second largest Federal payer of HIV/AIDS care costs in the U.S. and a significant payer of HIV/AIDS 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 Ryan White mandate to serve as the payer of last resort.

All Medicare beneficiaries must 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). Part D insurance coverage is provided by private prescription drug plans (PDPs) and Medicare Advantage plans (MAPDs), which are overseen by HHS's 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. These out-of-pocket costs vary according to when different levels of spending on prescription drugs are reached. (More generous Part D policies have lower out-of-pocket costs, but they cost more.) These out-of-pocket costs under Part D are called "true out-of-pocket" (TrOOP) expenditures, which is what a beneficiary must spend in a calendar year on Part D covered drugs in order to move through different levels of spending in order to reach the Part D catastrophic coverage threshold. The gap in Part D coverage, called the donut hole, starts when total drugs costs reach the designated level and ends when expenditures for medications (out of pocket costs) reach the catastrophic coverage threshold. Once an individual reaches the catastrophic coverage level, Part D drugs are available at a 5% percent share of cost for most antiretroviral and at a nominal co-payment for generic medications.

Any payments made by an ADAP on behalf of a 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 Part D TrOOP. This provision was established in the Patient Protection and Affordable Care Act of 2010. The 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 Part D enrollee must be communicated to the Part D Plan.

Learn more about ADAP and Medicare Part D:

<http://hab.hrsa.gov/manageyourgrant/pinspals/adaptr1011.pdf>

Medicare Electronic Claims Processing

ADAPs should 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 *RxBIN and Processor Control Number (PCN)* for claim submission for 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.ncdp.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.

To report patient TrOOP utilization on hardcopy HCFA 1500 forms and meet TrOOP requirements: <https://medifacd.relayhealth.com>

*Instructional webinars on the process outlined:
<http://www.nastad.org/webinars/2010-09-ADAP-TROOP/index.htm>*

Steps for Ensuring Proper TrOOP Calculation for Medicare Part D ADAP Members

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)

Instructional webinars on the process outlined:

<http://www.nastad.org/webinars/2010-09-ADAP-TROOP/index.htm>

Patient Assistance Programs and Clinical Trials

Patient Assistance Programs (PAPs) are sometimes available to clients who fail to qualify for ADAP or who are on ADAP waiting lists. Funded and operated by HIV pharmaceutical manufacturers, PAPs are short-term sources of treatment assistance, normally free of charge. These programs are available to eligible, financially disadvantaged patients in order to help them get necessary prescriptions or maintain an existing regimen until another option is available.

Eligibility requirements for PAPs vary. Clients usually require assistance from a doctor, patient advocate, case manager, or ADAP staff person to apply. In order to ease the task of applying for a PAP, a Common Patient Assistance Program (PAP) Application has been developed by HRSA, in collaboration with a number of pharmaceutical firms and NASTAD. The Common PAP Application can be used to apply for most any pharmaceutical-sponsored PAP.

See the Common PAP Application: <http://hab.hrsa.gov/patientassistance/index.html>

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/AIDS 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>

Other Sources of Medications

The following programs may also be potential sources of medications for individuals with HIV/AIDS:

- Veterans Affairs (see HAB Policy 07-07, Ryan White HIV/AIDS Program & Veterans).
- Department of Defense (active duty, retirees, and dependents (see HAB Policy 07-07, Ryan White HIV/AIDS Program & Veterans).
- Indian Health Service.
- Correctional facilities (Federal, State, and local).
- Non-Federal public funds (city, county or State funds).
- Private foundations, clinics, and other donors.

Because each State is unique, ADAPs need to conduct initial and ongoing eligibility assessments (including recertification of client eligibility every six months) to determine client eligibility under other payers and programs. As a reminder, ADAP funds, like all Ryan White dollars, should be used as the payer of last resort when other payer sources can be reasonably expected to make payments for any item or service.

IV.5.A. Introduction

Most Americans receive health insurance coverage through their employers under group policies, while a smaller proportion buys individual policies. Group and individual health insurance policies are offered through private health insurance companies or self-administered plans that employers fund. Complementing private coverage are public programs that offer health insurance coverage similar to private plans. It is within this health insurance marketplace that ADAPs have the option of purchasing health insurance for ADAP clients instead of paying solely for HIV/AIDS medications.

Many States have health insurance purchasing programs—under Part B and/or through their Part B ADAP. The programs are expected to increase under the Affordable Care Act as options for purchasing insurance expand under State Health Insurance Exchanges. Options include:

- **Coverage on the Individual Health Insurance Market.** State Health Insurance Exchanges will be fully operational in 2014, providing expanded options to purchase individual and small group health insurance coverage.
- **State High-risk Pools.** Risk pools are mechanisms to provide insurance for people in a variety of situations: when individuals have lost their coverage, are ineligible for Medicaid or Medicare, cannot purchase insurance due to eligibility criteria that exclude pre-existing conditions, and/or cannot otherwise afford insurance. Risk pools are likely to wane with full implementation of the Affordable Care Act, which—for example—prohibits pre-existing condition exclusions.
- **Pre-existing Condition Health Insurance Plans (PCIP).** This Affordable Care Act provision (scheduled to end December 31, 2013) is a Federal version of State high risk pools. Federal funds enabled states to establish state-administered PCIPs or default to the Federally-administered PCIP. Persons eligible for PCIPs must have a pre-existing condition, be a U.S. citizen, and be uninsured without creditable coverage for the prior six months. Nearly half of ADAPs were able to enroll ADAP clients in PCIPs, although some barriers were reported (e.g., establishing the infrastructure to coordinate with PCIPs, individual state PCIP prohibitions on third party payers). Ryan White funds may be used to pay the premiums, co-pays and deductibles for clients that are enrolled in a PCIP, just as they may for Medicare Part D or other health insurance. Ryan White funds may not be used to pay for administrative costs associated with PCIP.

IV.5.B. Legislation, HRSA Program Requirements, and Expectations

The Ryan White legislation defines core medical services, including:

2612 (b)(3)(F): Health insurance premium and cost sharing assistance for low-income individuals in accordance with section 2615.

The Ryan White legislation defines health insurance and plans 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 07-05, The Use of Ryan White HIV/AIDS Program Part B ADAP Funds to Purchase Health Insurance states, states, in part:

HAB Policy Notice 07-05. Part B funds, including ADAP funds, may be used to purchase health insurance that includes the full range of HIV treatments and access to comprehensive primary care services, subject to the conditions noted in the

ADAP earmark funds (and other ADAP designated funds) can be used to purchase health insurance for ADAP clients. These health insurance policies must include access to comprehensive primary care services and, at a minimum, include coverage for medications that are equivalent to the State’s ADAP formulary. ADAP dollars may be used to cover any costs associated with the health insurance policy, including co-payments, deductibles, or premiums to purchase or maintain insurance policies.

HAB’s Dear Colleague letter on insurance plans states, in part:

*HAB’s Pre-existing Condition Insurance Plan and the Use of Ryan White Funds “Dear Colleague” letter dated March 15, 2011: Ryan White funds may be used to pay the premiums, co-pays and deductibles for clients that are enrolled in a PCIP, just as they may for Medicare Part D or other health insurance. Ryan White funds may **not** be used to pay for administrative costs associated with PCIP.*

See HAB’s policies and program letters:

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

IV.5.C. Methodology Required to Determine Health Insurance Purchasing

In order to use Part B ADAP funds to purchase insurance, State ADAPs must provide HRSA/HAB with the methodology used by the State to: (1) assure that they are buying health insurance that, at a minimum, includes pharmaceutical benefits equivalent to the Part B ADAP formulary; and (2) assess and compare the cost of providing medications through the health insurance option versus the existing ADAP.

States that are considering using ADAP funds to purchase health insurance may want to use the following model for planning, implementation, and evaluation:

- Establish program philosophies and priorities in conjunction with the State HIV or ADAP community advisory group(s). For example, one State ADAP's priorities are:
 - The long-term fiscal stability of the program.
 - Protecting the doctor/patient relationship and treatment choices.
 - Expansion of the formulary.
 - Expansion of program financial eligibility criteria.
- Conduct an inventory of the coverage and costs of local health insurance plans and State laws governing the health insurance market. Questions to ask may include:
 - Does Part A or Part B fund an insurance continuation program? Is there a State high-risk insurance pool that individuals with HIV disease can access? Are there qualified HIV/AIDS providers on the preferred provider list for potential health insurance policies?
 - Assess the overall budgetary impact of moving clients onto insurance. The ADAP may want to perform a cost comparison using average client costs from the current ADAP compared to average premium and supplementary costs for the State's existing insurance purchase program under other sections of Part B, if such a program exists. The insurance cost estimate can also use information from the health insurance plans that the ADAP expects its patients to use.
 - Build relationships with the administrators of the State high-risk pool, case managers, key consumer groups, advocates, and other stakeholders. This will facilitate the creation of partnerships with individuals who are integral to the success of an ADAP's health insurance initiative.
 - Design the program. This may include modifying the original ADAP enrollment form to cover both traditional ADAP enrollment and the health insurance component. Expansion of the ADAP's data system may also be necessary to track information on both insurance and drug purchases.
 - Create or modify the drug purchase and dispensing system so that it can interact with health insurance payers. The dispensing pharmacy will be able to "split bill" for each prescription (e.g., bill 80 percent of the cost of the drug to an insurance plan and 20 percent to the ADAP).
 - Finally, evaluate and measure the cost effectiveness of the ADAP purchasing health insurance. A simple formula to begin with 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. It is important for the ADAP to remember that the assurance of cost neutrality is required for the aggregate cost of the health insurance program, not for each participating individual.

Individual vs. Aggregate Example

Client	Cost of Purchasing Drugs Through ADAP	Cost of Health Insurance
A	\$12,000	\$10,000
B	\$20,000	\$10,000
C	\$6,000	\$10,000
Total	\$38,000	\$30,000

Although the cost of health insurance for Client C 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.

Section V. Purchasing and Dispensing Medications

V. Ch 1. Overview

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. The design of an ADAP's purchasing and dispensing system is influenced by many factors, including:

- **Infrastructure.** ADAPs use variable staffing structures to manage purchasing and dispensing operations. Some states tap into existing pharmacy purchasing and dispensing models that provide cost-efficiencies (e.g., a centralized pharmacy, capacity to process rebates). Others are decentralized and are characterized by use of local and retail pharmacies. Some State ADAPs utilize a hybrid model where the ADAP is administered through both central and decentralized methods, which can expand access to medications. 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 rebates.
- **Purchasing Options.** Options for ADAPs to pay for medications include directly purchasing medications from the manufacturer or a wholesaler, reimbursing pharmacies for medications disbursed to ADAP clients, or some combination of these strategies. Regardless of approach, the primary concern for ADAPs is to secure medications at the best price in order to maximize availability of HIV/AIDS treatment to the most people. This is most effectively accomplished through participation in the Public Health Service Act's 340B Drug Pricing Program, which provides eligible entities (including ADAPs and other Ryan White grantees) with access to cost effective medication options through a calculated 340B ceiling price (see the next chapter for more information on the 340B program).
- **Additional Cost Savings.** ADAPs can seek deeper discounts beyond the 340B ceiling price on any drug purchased through the program. One example is the ADAP Crisis Task Force, through which ADAPs negotiated with certain manufacturers to secure agreements for voluntary rebates. ADAPs that purchase at 340B prices up front may negotiate on their own behalf, or through a purchasing agent, for additional manufacturer discounts on those medications. ADAPs that utilize a retail pharmacy network to purchase drugs and then reimburse the retailer can negotiate an across-the-board lower retail cost for all drugs on its formulary. For drug purchases through a retail pharmacy contract, the starting retail cost of a drug is the AWP price or "best price" (whichever is lower). The ADAP in negotiating this type of contract will typically specify that the retail pharmacy network may only charge AWP minus some percentage (e.g., AWP minus 10 percent). The discount off the AWP can range from around 5 percent to 13 percent off AWP for brand name drugs, and 25 percent to 30 percent for generic drugs.

Finally, ADAPs might be able to achieve lower costs by use of centralized pharmacies and regional/local networks (that have lower costs in terms of managing inventories and processing payments), contracting with PBM's, or securing reductions in dispensing fees. ADAPs also have the option to dispense medications through a replenishment model, where drugs dispensed from local, retail, or other contracted pharmacy services provider stock to eligible patients of the ADAP can be replenished using ADAP existing stock.

- **Pricing for Types of Drugs.** For single source drugs (meaning an outpatient drug that is produced or distributed under an original new drug application approved by the Food and Drug Administration) or innovator (brand name) multiple source drugs (outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent or pharmaceutically equivalent and bioequivalent), the 340B ceiling price is the AMP reduced by the Medicaid rebate percentage. Average Manufacturers Price (AMP) adjusts for inflation, and price increases over time.
- **340B Pricing.** For over-the-counter and generic drugs, the 340B ceiling price is set under Section 1927(c) of the Social Security Act.

V. Ch 2. 340B Drug Discount Program

V.2.A. Introduction

The 340B Drug Pricing Program is a Federal drug pricing program that provides various Federally-designated entities (including ADAPs and other Ryan White grantees) with access to cost-effective medications at lower costs. The 340B Program enables eligible entities to stretch scarce resources, allowing them to reach more eligible patients and providing more comprehensive services. The costs of drugs purchased through the 340B Program are established by a legislatively-mandated calculation similar to the Medicaid rebate calculation. The price calculated, using variables specific to the 340B program, establishes what is known as the "ceiling price." This ceiling price establishes the highest price at which a 340B drug can be sold. However, if the AWP or "best price" is lower than the calculated ceiling price, then the ceiling price is adjusted to mirror the best price available. This price is available to direct purchase model programs.

The 340B program, which is authorized by the Veterans Health Care Act of 1992, was initially focused on providing saving through a ceiling price for covered drugs since the vast majority of 340B entities use a direct purchase system for medication purchases. In 1998 the 340B program legislation was amended to provide access to a statutory rebate for ADAP's seeking additional methods to access savings on drug expenditures that are assessed via alternative mechanisms for purchase. Rebates under the 340B program may be claimed for medications purchased at the full market price up front. Medications purchased as part of a 340B rebate program are not eligible for the upfront 340B ceiling price. Nor can they be submitted for rebates under Medicaid. ADAP's must submit claims to manufacturers to receive rebates on 340B drugs.

ADAP's may not submit a rebate for a drug acquired by another 340B eligible entity at the 340B discount.

Manufacturers that want to participate in Medicaid are required to participate in 340B through a Pharmaceutical Pricing Agreement (PPA) and therefore must offer medications at or below the set ceiling price. The Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) administers the 340B Program.

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

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

The Section 340B program's authorizing legislation is Public Law 102-585, Title IV of the Veterans' Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act.

Section 340B is also guided by additional legislation (that amends or relates to 340B) and Federal guidelines to implement the legislation. Key provisions, which relate to basic concepts of drug pricing and procurement, are described below.

Who Has Access to 340B Prices: Covered Entities

Section 602 authorizes discounts on covered outpatient drugs for covered entities. Ryan White grantees are among the host of agencies defined under Section 602 as eligible for 340B pricing. Section 7101 of the Patient Protection and Affordable Care Act of 2010 added an additional number of eligible entities, as did the Social Security Act (SSA) as amended by the Deficit Reduction Act. Almost all categories of covered entities are HHS grantees under various programs. Section 602 also defines certain types of non-grantees as eligible covered entities.

Covered entities must go online with HRSA's OPA to register or modify their 340B status. ADAPs registered with the 340B program must also provide their Medicaid pharmaceutical billing status to OPA. This information is necessary to ensure that a drug purchased under the drug discount program is not subject to both a 340B discount or rebate and a Medicaid rebate under Section 1927 of the Social Security Act. This is only an issue for ADAPs that retroactively bill Medicaid. If this does not apply, the ADAP needs to notify OPA that the ADAP does not bill Medicaid.

See the HRSA OPA site for more information for covered entities (e.g., a list of 340B eligible entities, online registration, steps in completing required annual recertification, policy releases): <http://www.hrsa.gov/opa/introduction.htm>

Definition of Covered Outpatient Drugs

The drugs that may be purchased under the 340B program are referred to as "covered outpatient drugs," which generally includes:

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

Key Requirements for Covered Entities

A covered entity must comply with a number of statutory requirements to access 340B prices. Below are highlights:

- **Prohibition on Duplicate Discounts (Medicaid and 340B Drug Purchases).** A drug purchased under Section 340B cannot also receive a Medicaid rebate under Section 1927 of the Social Security Act.

See Final Notice, Duplicate Discounts and Rebates on Drug Purchases published at 58 Fed. Reg. 34058 (June 23, 1993)

- **ADAP Rebate Option.** ADAPs are the only program type eligible to receive rebates for drug purchases. Rebates must be collected through a claim process after purchase. Drugs purchased under the rebate option are not eligible for up-front 340B ceiling prices.
- **Drug Access Limited to Patients.** Drugs secured under the 340B Program can only be utilized by the individuals who are defined as the “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 Guideline: 61 Fed. Reg. 55156 (October 24, 1996).

- **Prohibition on Diversion of 340B Drugs.** Drugs purchased through the 340B program cannot be diverted to individuals who are not patients of the covered entity, to ineligible entities within the same facility, or to services outside of the grant funded scope of the entity. ADAPs can avoid drug diversion to non-eligible patients by implementing administrative controls that carefully track enrollees (in terms of eligibility requirements, initial enrollment, and recertification of eligibility) as well as drug purchases and inventory (including when and to whom drugs are dispensed).
- **Audits.** The covered entity must permit the Secretary of HHS and manufacturers to audit entity records, in accordance with procedures established by the Secretary, to assure compliance with prohibitions on duplicate discounts/rebates or diversions. Both HRSA and pharmaceutical manufacturers may audit participating ADAPs to ensure that drug diversion has not occurred. (Note: The A-133 compliance supplement includes 340B compliance questions.)

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

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

V. Ch 3. Accessing 340B Prices

V.3.A. Introduction

Entities that are eligible to participate in the 340B program (covered entities) can secure 340B discount prices up front, through direct purchase. ADAP additionally have the ability to access 340B savings through a rebate process.

ADAP only may pursue rebates from manufacturers for drug costs, when they have paid for all or any part of the cost of the prescription including cost sharing or co-payments. Payments of premiums only do not allow ADAP to access rebates on covered 340B drugs. Additionally those drugs, for which rebates are sought, must be purchased drugs that have been purchased at the full price up front.

ADAPs may participate under either direct purchase or rebate options separately or a combination of the two options (“hybrid model”) in order to meet the needs of their clients and maximize resources. 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.

V.3.B. Direct Purchase:

Under the point of purchase discount, covered entities pay a discounted price for each drug at the point of purchase. Participation in a direct purchase system is easiest for States that centrally purchase and dispense medications. HRSA/OPA guidelines require covered entities that purchase medications through direct purchase to 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 under different mechanisms (e.g., a State pharmacy may combine dispensing fees and be unable to apportion costs for ADAP medications). These factors need to 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 also administers the Prime Vendor Program (PVP), as an option for a purchasing agent for 340B participating eligible entities.

Direct Purchase Dispensing Options

State ADAPs that directly purchase drugs can have multiple mechanisms for dispensing drugs to clients. Mechanisms include a Central State pharmacy; another 340B covered entity such as a disproportionate share hospital or community clinic; or a contract pharmacy services mechanism. Many ADAPs have built on existing State pharmaceutical purchasing and dispensing infrastructures to achieve their current mode of operation. Examples include:

- **Central State Pharmacy.** For those ADAPs that use a central State pharmacy, the State health department generally maintains a centralized pharmacy and then either dispenses drugs by mail-order to individual clients or distributes drugs through a system that will ship the product in bulk to a pharmacy for dispensing on-site to clients (e.g., a community health center, a local public health jurisdiction, a county public health unit). This system allows the ADAP to retain centralized reporting and inventory control mechanisms. For States that dispense via mail order, system strengths include client confidentiality and client convenience. Through either mechanism, States should continually monitor the time that it takes the client to receive their medications.

V.3.C. ADAP 340B Rebate Option

Under the ADAP 340B rebate option, ADAPs submit claims to manufacturers for rebates on medications that were not purchased at the 340B prices. Rebates can be submitted either directly or through reimbursement mechanisms like PBM's. ADAPs using the rebate option achieve cost savings comparable to those received by ADAPs that directly purchase medications at the 340B price.

Benefits of participating in the ADAP 340B rebate include:

- Ability to access ADAP exclusive rebates for drug related expenditures
- Ability to negotiate rebate amounts to enhance cost savings.
- Standardized format to request drug rebates from manufacturers.
- Assuring lowest pricing for ADAP covered medications.

Only ADAP's are eligible for rebates. Rebates generated by ADAP (whether the source of the funding was HRSA, State funds, or other rebate dollars) can be used for the overall Part B program only with preference given to ADAP.

Distribution Systems Used Under the ADAP 340B Rebate Option

As stated above, ADAPs that make medications available under a rebate model typically 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.

State ADAPs that make medications available through a network of retail pharmacies often do so for a variety of reasons. Some of these include:

- The use of multiple, convenient pharmacies for improved client access.
- The ability of clients to have immediate access to pharmacy services.
- 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).
- 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 requests are normally submitted within 90 of the end of the quarter. The timeline for submission is set by the specific agreement in place between the ADAP, and specific manufacturer. ADAPs can determine how many or which drugs to submit for a rebate. 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.

Rebates received must be returned to the Part B and expended during the fiscal year they are received. ADAPs should also be aware that, once received, rebate dollars must be expended prior to the continued usage of Ryan White Part B/ADAP dollars. While this can affect the expenditure rate for Ryan White Part B/ADAP dollars, and potentially result in an unobligated balance (UOB), a UOB resulting from the expenditure of rebate dollars will not count against the 5 percent UOB penalty. As such, the total Rebate dollars received during the grant year must be reported in the remarks section of the final FFR submission.

Aggregate Data

To submit a rebate to a manufacturer, the ADAP must provide the information required by the manufacturer, which may include the following aggregate data elements: the National Drug Code (NDC), drug name, number of prescriptions, total reimbursement amount per NDC, total units to be reimbursed, and unit rebate amount (URA) (when available).

Supporting Records

ADAPs need to keep supporting records for all submitted claims and make them available to manufacturers, if necessary to resolve disputes. ADAPs should maintain the following data:

- Name and address of dispensing pharmacy.
- Prescription number.
- Units dispensed.
- Date dispensed or paid.
- Amount reimbursed.

The Pharmaceutical Pricing Agreement, which the manufacturer signs with the Secretary of HHS to initiate their participation in the Section 340B program, also requires covered entities (i.e., participating ADAPs) to retain records of covered outpatient drug purchases for a period of not less than 3 years. This is critical documentation in the event of a manufacturer or HHS audit.

Comparison: Direct Purchase and ADAP 340B Rebate Option

Below is a comparison of direct purchase (paying for medications up-front) versus rebates (paying for medications and then securing discounts afterwards).

- The 340B direct purchase allows ADAPs that operate a central drug purchasing and dispensing system to receive an up-front discount by purchasing a covered drug from a manufacturer at or below the Section 340B ceiling price. These ADAPs receive immediate cost-savings by directly purchasing drugs at the discounted price. Additional operating costs are incurred through dispensing fees paid to contracted pharmacies and/or overhead for ADAPs that operate/manage a distribution/dispensing system (e.g., personnel, storage, shipping costs).
- The 340B Rebate option allows ADAPs that reimburse pharmacies for any part of a client's medications and then claim a rebate to achieve cost savings. The cost of 340B drugs, after the rebate, is primarily the same as the savings achieved on brand medications through the direct purchase model.

340B Prime Vendor Program

The 340B Prime Vendor Program (PVP) is an optional program 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 eligible entities electing to join the program. Purchasing pharmaceuticals through

the 340B Prime Vendor Program may result in additional discounts of 20 to 50 percent of drug market prices.

Learn more about the Prime Vendor Program: <http://www.hrsa.gov/opa/primevendor.htm> or <http://www.340Bpvp.com>

V.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. This mechanism is designed to facilitate 340B program participation for eligible covered entities that do not have access to “in-house” pharmacy services. The 340B program guidelines create a system in which an ADAP (or other covered entity) may contract with multiple pharmacies to dispense drugs purchased at 340B discount prices. Guidelines state that the ADAP must purchase and retain ownership of drugs procured through the 340B program. A contract pharmacy may in fact 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 requirements for preventing drug diversion and double discounts/rebates are met by the contract pharmacy

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, proposed 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. Persistent nonpayment could be grounds for terminating the manufacturer's 340B and Medicaid agreement with the Secretary of HHS.

Alternative Methods Demonstration Project Initiative

The Alternative Methods Demonstration Project (AMDP) is a process to apply to HRSA in order to test alternative methods of participating in the 340B program. AMDP was in part a response to requests for increased flexibility among existing 340B program participants. ADMP allows organizations that participate in the 340B program to take actions to reduce administrative costs and make buying drugs for patients easier. More specifically, project administrators will be able to:

- Participate in single purchasing and dispensing systems that serve covered entity networks.
- Utilize economies of scale theory (formulation of networks [larger than individual entities] that would purchase drugs in bulk and/or at discounted rates).

Entities seeking to participate in an AMDP must submit a written proposal.

For more information on Alternative Methods Demonstration Projects, contact the HRSA Office of Pharmacy Affairs at (301) 594-4353.

V. Ch 4. Purchasing and Dispensing Strategy: PBMs

V.4.A. Introduction

A PBM is an organization or system that provides administrative and pharmacy claim adjudication services, and pharmacy benefit coverage programs. PBM services can include: contracting with a network of pharmacies; establishing payment levels for provider pharmacies; negotiating rebate arrangements; 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.

For ADAPs, distribution activities are coordinated through a pharmacy benefits management (PBM) company that has its own contracted network of retail pharmacies and often has a mail

order component. Because the ADAP is one of several customers of the PBM, the company can secure significant discounts for pharmacy services and drug prices.

V.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 Ryan White 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; handle 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 HIC 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.

V.4.C. 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 (provider incentives, patient incentives, 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).

V.4.D. 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.