

Ryan White HIV/AIDS Program

Part B Manual

U.S. Department of Health and Human Services

Health Resources and Services Administration

HIV/AIDS Bureau

Revised 2015

Preface

The Ryan White HIV/AIDS Program (RWHAP) Part B Manual is for RWHAP Part B Program Directors and staff and others interested in the RWHAP Part B Program. The Ryan White HIV/AIDS Program is administered in the Federal government by the Health Resources and Services Administration (HRSA), an Operating Division within the U.S. Department of Health and Human Services (HHS). The RWHAP Part B Program awards grants to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality HIV care and treatment for low-income people living with HIV (PLWH). Each State and Territory operates a RWHAP Part B program, including an AIDS Drug Assistance Program (ADAP). RWHAP Part B programs, as well as the ADAPs, vary significantly in their administrative structures and the mechanisms used to ensure access to HIV care and to make HIV/AIDS medications available to eligible individuals living with HIV.

This Manual is designed to serve as:

- An orientation guide for new RWHAP Part B staff, with sections explaining how the RWHAP Part B and ADAPs are structured at the Federal and State level, and the key issues and strategies used by the RWHAP Part B and ADAPs to broaden access to HIV/AIDS care and treatment to persons in need.
- A reference document for RWHAP Part B staff on legislative and program requirements.
- A tool to guide RWHAP Part B programs in managing their fiscal and program components.

How This Manual is organized

The RWHAP Part B Manual includes sections that include a series of chapters that cover related topics. The information is presented in clearly labeled subsections so that RWHAP Part B staff can quickly find the information they need.

- The first section is most helpful to those new to RWHAP Part B as it presents basic information about the Ryan White HIV/AIDS Program, including ADAP, and where to find information and assistance. Later sections cover more detailed RWHAP Part B management and technical issues.
- Legislative and program requirements are included in the front sections of most chapters, providing RWHAP Part B staff with essential information in one place. Many chapters then present highlights (e.g., best practices, resources) on ways to address these requirements.
- In-depth information on management of the ADAP Program is presented in HAB's ADAP Manual and is not repeated in this Manual. Thus, the ADAP Manual and RWHAP Part B Manual should be used as companion documents. The ADAP Manual is available online at <http://hab.hrsa.gov>.

Routine Updates to the RWHAP Part B Manual

The RWHAP Part B Manual will be reviewed regularly and will be updated online as needed to reflect changes in RWHAP Part B requirements and conditions. State Part B Directors will continue to inform HRSA to make the RWHAP Part B 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.

CONTENTS

SECTION I: OVERVIEW OF THE RYAN WHITE HIV/AIDS PROGRAM	5
I. CHAPTER 1. INTRODUCTION	5
I. CHAPTER 2. RYAN WHITE HIV/AIDS PROGRAM LEGISLATION.....	6
I. CHAPTER 3. RYAN WHITE HIV/AIDS PROGRAM MOVING FORWARD	7
I. CHAPTER 4. RWHAP STRUCTURE.....	7
I. CHAPTER 5. RYAN WHITE HIV/AIDS PROGRAM ADMINISTRATION	9
I. CHAPTER 6. OVERVIEW OF THE RWHAP PART B PROGRAM	10
I. CHAPTER 7. THE DIVISION OF STATE HIV/AIDS PROGRAMS	12
I. CHAPTER 8. TECHNICAL ASSISTANCE FOR THE RWHAP COMMUNITY.....	13
I. CHAPTER 9. REFERENCES, LINKS, AND RESOURCES.....	13
SECTION II: HIV SERVICE DELIVERY SYSTEM	14
II. CHAPTER 1. INTRODUCTION	14
II. CHAPTER 2. LEGISLATIVE BACKGROUND	14
II. CHAPTER 3. NATIONAL HIV/AIDS STRATEGY AND THE RWHAP	16
II. CHAPTER 4. COMPREHENSIVE SERVICE DELIVERY SYSTEM FOR PLWH.....	17
II. CHAPTER 5. RYAN WHITE HIV/AIDS PROGRAM CORE MEDICAL SERVICES.....	18
II. CHAPTER 6. RYAN WHITE HIV/AIDS PROGRAM SUPPORT SERVICES	19
II. CHAPTER 7. CONTINUUM OF HIV CARE.....	20
II. CHAPTER 8. COORDINATION OF SERVICES AND FUNDING STREAMS.....	21
II. CHAPTER 9. REFERENCES, LINKS, AND RESOURCES.....	23
SECTION III. AIDS DRUG ASSISTANCE PROGRAMS (ADAPS).....	24
III. CHAPTER 1. INTRODUCTION	24
III. CHAPTER 2. LEGISLATIVE BACKGROUND	25
III. CHAPTER 3. PURCHASING AND DISPENSING MEDICATIONS BY ADAPS	27
III. CHAPTER 4. HEALTH INSURANCE PROGRAMS	28
IX. CHAPTER 5. REFERENCES, LINKS, AND RESOURCES.....	32
SECTION IV: REPORTING REQUIREMENTS	33
IV. CHAPTER 1. INTRODUCTION	33
IV. CHAPTER 2. LEGISLATIVE BACKGROUND	33
IV. CHAPTER 3. THE ELECTRONIC HANDBOOK (EHB) AND THE SUBMISSION OF REPORTS.....	34
IV. CHAPTER 4. OVERVIEW OF RWHAP PART B REPORTING REQUIREMENTS	34
IV. CHAPTER 5. PROGRAM AND FISCAL REPORTS	36
IV. CHAPTER 6. BUDGET AND BUDGET NARRATIVE JUSTIFICATION GUIDELINES	40
IV. CHAPTER 7. CLIENT LEVEL DATA REPORTING	41
IV. CHAPTER 8. GRANTEE AND PROVIDER RESPONSIBILITIES FOR DATA REPORTING	42
IV. CHAPTER 9. TRAINING AND TECHNICAL ASSISTANCE FOR THE ADR AND RSR	43
IV. CHAPTER 10. REFERENCES, LINKS, AND RESOURCES.....	44
SECTION V: GRANTEE AND SUBRECIPIENT MONITORING.....	45
V. CHAPTER 1. INTRODUCTION.....	45
V. CHAPTER 2. LEGISLATIVE BACKGROUND	45
V. CHAPTER 3. RWHAP PART B NATIONAL MONITORING STANDARDS	45
V. CHAPTER 4. MONITORING OF RWHAP PART B GRANTEES BY HAB.....	46
V. CHAPTER 5. MONITORING OF RWHAP PART B SUBRECIPIENTS BY GRANTEE OR DESIGNEE	47
V. CHAPTER 6. REFERENCES, LINKS, AND RESOURCES	49
SECTION VI: CLINICAL QUALITY MANAGEMENT	50

VI. CHAPTER 1. INTRODUCTION	50
VI. CHAPTER 2. LEGISLATIVE BACKGROUND	50
VI. CHAPTER 3. HAB PROGRAM EXPECTATIONS	51
VI. CHAPTER 4. MEASURING CLINICAL QUALITY WITH PERFORMANCE MEASURES	52
VI. CHAPTER 5. REFERENCES, LINKS, AND RESOURCES	54
SECTION VII. GRANTS ADMINISTRATION	55
VII. CHAPTER 1. INTRODUCTION	55
VII. CHAPTER 2. GRANTS MANAGEMENT REGULATION AND POLICY DOCUMENTS	56
VII. CHAPTER 3. COSTS FOR ADMINISTRATION, PLANNING, EVALUATION, AND CLINICAL QUALITY MANAGEMENT	57
VII. CHAPTER 4. CLIENT CHARGES AND PROGRAM INCOME	61
VII. CHAPTER 5. TRACKING AND REPORTING UNOBLIGATED BALANCES	62
VII. CHAPTER 6. PAYER OF LAST RESORT	63
VII. CHAPTER 7. MAINTENANCE OF EFFORT (MOE)	64
VII. CHAPTER 8. STATE MATCH	65
VII. CHAPTER 9. GRANTEE AND PROVIDER CONTRACT REQUIREMENTS	67
VII. CHAPTER 10. REFERENCES, LINKS, AND RESOURCES	68
SECTION VIII. PLANNING REQUIREMENTS FOR RWHAP PART B	69
VIII. CHAPTER 1. INTRODUCTION	69
VIII. CHAPTER 2. LEGISLATIVE BACKGROUND	69
VIII. CHAPTER 3. NEEDS ASSESSMENT	71
VIII. CHAPTER 4. STATEWIDE COORDINATED STATEMENT OF NEED	74
VIII. CHAPTER 5. COMPREHENSIVE PLANNING	76
VIII. CHAPTER 6. PLWH/CONSUMER PARTICIPATION	77
VIII. CHAPTER 7. COORDINATION BETWEEN RWHAP PARTS AND PROGRAMS AND OTHER PAYERS	78
VIII. CHAPTER 8. REFERENCES, LINKS, AND RESOURCES	81
SECTION IX. THE ROLE OF CONSORTIA IN RWHAP PART B GRANTS	82
IX. CHAPTER 1. INTRODUCTION	82
IX. CHAPTER 2. LEGISLATIVE BACKGROUND	82
IX. CHAPTER 3. THE ROLE OF CONSORTIA	84
IX. CHAPTER 4. RWHAP PART B GRANTEE RESPONSIBILITIES WITH A CONSORTIA MODEL	84
IX. CHAPTER 5. REFERENCES, LINKS, AND RESOURCES	85
SECTION X. TECHNICAL ASSISTANCE	86
X. CHAPTER 1. OVERVIEW	86
X. CHAPTER 2. LEGISLATIVE BACKGROUND	86
X. CHAPTER 3. PURPOSE AND TA TOPICS	86
X. CHAPTER 4. HOW TA IS PROVIDED	87
X. CHAPTER 5. HOW TO OBTAIN TA	87
X. CHAPTER 6. REFERENCES, LINKS, AND RESOURCES	87
APPENDIX A: HIV/AIDS BUREAU ORGANIZATIONAL CHART	88

Section I: Overview of the Ryan White HIV/AIDS Program

I. Chapter 1. Introduction

The HIV epidemic has taken an enormous toll since its onset in the early 1980s. The Centers for Disease Control and Prevention (CDC) updates HIV epidemiologic data annually. The following information was current as of June 2014; current information can be found on the CDC website. HIV has been reported in all 50 states, the District of Columbia, and U.S. territories. Today, more than 1.1 million Americans are living with HIV disease.¹ An estimated 50,000 Americans become infected with HIV each year.² Approximately 636,000 people in the United States with an AIDS diagnosis have died, and many others are living with HIV-related illness and disability, or are caring for people with the disease.³ The epidemic has hit hardest among racial and ethnic minorities, and gay and bisexual men.

Congress first enacted the Ryan White HIV/AIDS Program legislation in 1990 to improve the quality and availability of care for low-income, uninsured, and underinsured individuals and families affected by HIV disease. The Ryan White HIV/AIDS Program currently provides services to an estimated 536,000 people each year.⁴ By statute, the grant awards made under the Ryan White HIV/AIDS legislation are the “payer of last resort,” meaning that the Ryan White HIV/AIDS Program grant funds may not be used for any item or service for which payment has been made, or can reasonably be expected to be made by any other payer. In 2012, more than 73 percent of Ryan White HIV/AIDS Program clients self-identified as members of racial or ethnic minority groups. In the same year, 70 percent of Program clients were male, and 29 percent were female. The FY 2014 appropriation for the Ryan White HIV/AIDS Program is \$2.31 billion.

The Ryan White HIV/AIDS Program is administered by the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB).

Continuum of HIV Care

Identifying people infected with HIV and linking them to HIV primary care with initiation and long-term maintenance of life-saving antiretroviral treatment (ART) are important public health steps toward the elimination of HIV in the United States. The continuum of interventions that begins with outreach and testing and concludes with HIV viral load suppression is generally referred to as the Continuum of HIV Care or Care Treatment Cascade. The Continuum of HIV Care includes the diagnosis of HIV, linkage to HIV medical care, lifelong retention in HIV

1 CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 U.S. dependent areas—2010. HIV Surveillance Supplemental Report 2012;17(No. 3, part A).

http://www.cdc.gov/hiv/surveillance/resources/reports/2010supp_vol17no3/index.htm. Published June 2012.

2 CDC. Estimated HIV incidence in the United States, 2007–2010. HIV Surveillance Supplemental Report 2012;17(No. 4). <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/#supplemental>. Published December 2012.

3 CDC. HIV Surveillance Report, 2011; vol. 23. <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/>; Published February 2013. CDC Fact Sheet: New Infections in the United States, November, 2013, http://www.cdc.gov/hiv/pdf/statistics_basics_factsheet.pdf.

4 Ryan White HIV/AIDS Program: Program Overview Fact Sheet, January, 2013 <http://hab.hrsa.gov/about/hab/files/programoverviewfacts2012.pdf>

medical care, appropriate prescription of ART, and ultimately HIV viral load suppression. More information on the Continuum of HIV Care can be found in Section II Chapter 7.

National HIV/AIDS Strategy (NHAS)

On July 13, 2010, the White House released the National HIV/AIDS Strategy (NHAS) for the United States, with an accompanying Federal Implementation Plan. The vision of the NHAS calls for the United States to “become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance will have unfettered access to high-quality, life extending care, free from stigma and discrimination.” The NHAS is the nation’s first-ever comprehensive coordinated HIV/AIDS roadmap with clear and measurable targets to be achieved by 2015.

The National HIV/AIDS Strategy (NHAS) has three primary goals: (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 NHAS states that more must be done to ensure that new prevention methods are identified and that prevention resources are more strategically deployed. Further, the NHAS recognizes the importance of early entrance into care for people living with HIV (PLWH) to protect their health and reduce their potential of transmitting the virus to others. HIV disproportionately affects people who have less access to prevention, care and treatment services and, as a result, often have poorer health outcomes. Therefore, the NHAS advocates adopting community-level approaches to identify people who are HIV-positive but do not know their serostatus and reduce stigma and discrimination against people living with HIV. More information on the NHAS can be found in Section II Chapter 3.

I. Chapter 2. Ryan White HIV/AIDS Program Legislation

The Ryan White HIV/AIDS Program (RWHAP) is authorized and funded under Title XXVI of the Public Health Service 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 Comprehensive AIDS Resources Emergency (CARE) Act. It has been amended and reauthorized four times: in 1996, 2000, 2006, and 2009.

The RWHAP legislation has been adjusted with each reauthorization to accommodate new and emerging needs, such as an increased emphasis on funding of core medical services and changes in funding formulas. The legislation provides a structure through which the RWHAP can address HIV/AIDS care and treatment needs of PLWH. Legislative provisions (called Sections) address, for example, planning and decision-making, type of grants that are available, usage of funds, requirements for entities submitting applications for funding, and available technical assistance to help programs run more effectively.

I. Chapter 3. Ryan White HIV/AIDS Program Moving Forward

In response to the NHAS and the evolving health care landscape, HAB has developed the ***Ryan White HIV/AIDS Program Moving Forward*** visual depiction of the essential role of the RWHAP in achieving an AIDS Free Generation. HAB's collaborative approach emphasizes the importance of working with grantees, stakeholders, PLWH, and federal partners to focus on the critical activities of Service Delivery, Policy, Assessment, Capacity Development, and Quality.



I. Chapter 4. RWHAP Structure

The RWHAP is divided into five “Parts,” outlined in the authorizing legislation.

RWHAP Part A Program – Eligible Metropolitan Areas (EMAs)

The RWHAP Part A Program provides grant funding for HIV core medical and support services to Eligible Metropolitan Areas (EMAs) and Transitional Grant Areas (TGAs). These are population centers most severely affected by the HIV/AIDS epidemic. EMA eligibility requires an area to report more than 2,000 AIDS cases in the most recent 5 years. TGA eligibility requires an area to report 1,000 to 1,999 AIDS cases in the most recent 5 years. Both EMAs and TGS must have a population of at least 50,000.

RWHAP Part B Program – States and Territories

The RWHAP Part B Program provides grants to States and Territories to improve the quality, availability, and organization of HIV/AIDS health care and support services. RWHAP Part B grants include a Base grant for core medical and support services; the AIDS Drug Assistance Program (ADAP) award; the ADAP Supplemental award for eligible entities that choose to apply; the Part B Supplemental award for grantees with demonstrated need; Minority AIDS Initiative funding for education and outreach to improve minority access to medication assistance

programs, including ADAP; and supplemental grants to States with “emerging communities,” defined as jurisdictions reporting between 500 and 999 cumulative AIDS cases over the most recent 5 years. Congress designates a portion of the RWHAP Part B Program appropriation for ADAP; the ADAP Base is now the largest portion of the RWHAP Part B Program appropriation. Five percent of the ADAP Base is set aside for the ADAP Supplemental award to assist eligible States in meeting the need for additional ADAP support. Since 2010, funds have also been available through the ADAP Emergency Relief Funds (ERF) to help states prevent, reduce or eliminate ADAP waitlists or implement cost-containment measures.

RWHAP Part C Program – Community-Based Programs

The RWHAP Part C Program provides comprehensive primary health care in an outpatient setting for PLWH. Part C grants are awarded directly to medical care providers, such as ambulatory medical clinics. Part C also funds capacity development grants to expand an organization’s capability/infrastructure to deliver HIV/AIDS care and support services.

RWHAP Part D Program – Women, Infants, Children, and Youth with HIV/AIDS and Their Families

The RWHAP Part D Program provides family-centered, outpatient, ambulatory comprehensive HIV care and support services to women, youth, children, and infants and their families. Part D also seeks to educate clients about clinical trials and research opportunities.

RWHAP Part F Program – Special Projects of National Significance (SPNS)—Research Models

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

The Special Projects of National Significance (SPNS) Program supports the demonstration and evaluation of innovative models of care delivery for hard-to-reach populations. SPNS also provides funds to help grantees develop standard electronic client information data systems.

The AIDS Education and Training Centers (AETC) Program supports education and training of health care providers through a network of 11 regional and 4 national centers.

The Minority AIDS Initiative (MAI) was established in FY 1999 through Congressional appropriations to improve access to HIV/AIDS care and health outcomes for disproportionately affected minority populations. MAI-funded services under Parts A, C, and D are consistent with their “Base” programs, whereas the RWHAP Part B MAI focuses on education and outreach to improve minority access to medication assistance programs, including ADAP.

Oral Health Services. All RWHAP Parts can support the provision of oral health services. However, two Part F programs focus on funding oral health care for PLWH:

The HIV/AIDS Dental Reimbursement Program (DRP) reimburses dental schools, hospitals with postdoctoral dental education programs, and community colleges with dental hygiene programs for a portion of uncompensated costs incurred in providing oral health treatment to patients with HIV disease.

The Community-Based Dental Partnership Program (CBDPP) supports increased access to oral health care services for PLWH while providing education and clinical training for dental care providers, especially those practicing in community-based settings.

More information on the Ryan White HIV/AIDS program can be found at <http://hab.hrsa.gov/abouthab/aboutprogram.html>.

I. Chapter 5. Ryan White HIV/AIDS Program Administration

As noted, the HRSA HIV/AIDS Bureau (HAB) administers the RWHAP. The Office of the Associate Administrator for HAB manages the Bureau, provides leadership and direction for HRSA's HIV/AIDS programs and activities, including the RWHAP, and oversees collaboration with other national health programs.

The mission of HAB is to “provide leadership and resources to assure access to and retention in high quality, integrated care and treatment services for vulnerable people living with HIV/AIDS and their families.” The vision of the HIV/AIDS Bureau is “Optimal HIV/AIDS care and treatment for all.”

The HIV/AIDS Bureau Organizational Chart

The HAB organizational chart can be found in Appendix A.

HAB Offices and Divisions

In addition to the Office of the Associate Administrator, HAB has six offices and divisions:

1. **The Division of State HIV/AIDS Programs (DSHAP)** administers the RWHAP Part B Program, which includes the following funds: Part B Base, the AIDS Drug Assistance Program (ADAP) Base, ADAP Supplemental, Emerging Communities, Part B Minority AIDS Initiative (MAI), Part B Supplemental and ADAP Emergency Relief.
2. **The Division of Metropolitan HIV/AIDS Programs (DMHAP)** administers the RWHAP Part A Program.
3. **The Division of Community HIV/AIDS Programs (DCHAP)** administers the RWHAP Part C Program, RWHAP Part C Capacity Development, RWHAP Part D, the Community Based Dental Partnership Program (CBDPP), and the HIV/AIDS Dental Reimbursement Program (DRP).

4. **The Division of HIV/AIDS Training and Capacity Development (DTCD)** administers the RWHAP Part F Program, including the planning, training, and technical assistance activities for RWHAP grantees and the AIDS Education and Training Centers (AETC) Program. The division also administers the Global Program as well as the Special Projects of National Significance (SPNS) Program.
5. **The Division of Policy and Data (DPD)** serves as HAB's focal point for program data collection and evaluation, coordination of program performance activities, development of policy guidance, coordination of technical assistance activities, and development of analyses and reports to support HIV/AIDS decision making.
6. **The Office of Operations and Management (OOM)** provides administrative and fiscal guidance and support for HAB and is responsible for all budget execution tasks, personnel actions, contracting services, and facility management.

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

I. Chapter 6. Overview of the RWHAP Part B Program

Eligibility

All 50 States, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and the six U.S. Pacific Territories/Associated Jurisdictions are eligible for RWHAP Part B Program funding. The grant awards are accepted by the Governor or Chief Elected Official of the jurisdiction and designated to the State Health Department or another State/Territory agency that implements and manages the RWHAP funds.

Services

Section 2612(b)(3) of the PHS Act lists the services that are allowable under the RWHAP Part B Program, and distinguishes between core medical and support services. Unless approved for a waiver, grantees are required to spend at least 75 percent of their RWHAP Part B grant funds on core medical services and no more than 25 percent on support services. Please see Chapters 3 and 4 for a list of allowable services under the RWHAP Part B.

Implementation

The State Health Department or State administering agency may either provide core medical or support services directly to eligible individuals in their jurisdiction or may establish contracts, fee for service, Memorandums of Understanding (MOU), Memorandums of Agreement (MOA) or Letters of Agreement (LOA) with service providers to deliver the core medical or support services. These providers may include public or nonprofit entities. For-profit entities are eligible only if they are the sole available providers of quality HIV care in the area. Some States may subcontract with HIV Care Consortia, which are associations of public and nonprofit health-care and support service providers, and community-based organizations that the State contracts with to provide planning, resource allocation and contracting, program and fiscal monitoring, and required reporting. All services provided through consortia are considered support services,

regardless of the service being provided. More information about consortia is available in Section IX.

Administrative and National Policy Requirements

Grantees must comply with all relevant federal policies and regulations. Currently, RWHAP Part B grantees must comply with the administrative requirements outlined in 45 CFR Part 92 Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments and must ensure that all funded subrecipients comply with administrative requirements relevant to their type of organization. In accordance with requirements imposed by the Office of Management and Budget, HHS adopted new grant regulations, codified at 45 CFR Part 75, with an effective date of December 26, 2014.

HRSA grant and cooperative agreement awards are subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable based on recipient type and purpose of award. This includes any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at <http://www.hrsa.gov/grants/hhsgrantspolicy.pdf>. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Grant Award). Please see Section VII for more information on grants management.

Federal regulations require grantees to oversee their service providers. HRSA has compiled existing requirements into a comprehensive document called the National Monitoring Standards (NMS). These standards were designed to help Ryan White Part A and Part B grantees meet Federal requirements for program and financial management, and to improve program efficiency. Please see Section V, Chapter 3 for more information on the National Monitoring Standards.

Learn more at <http://www.hab.hrsa.gov/manageyourgrant/granteebasics.html>.

RWHAP Part B Program Funding

There are three separate grant awards under the RWHAP Part B Program. Each award is applied for and awarded separately. Funding is determined through formula and through demonstrated need, depending on the RWHAP Part B Program grant. The primary RWHAP Part B Program formula award is the “X07” award, which includes the RWHAP Part B Base award, the ADAP Base award, the Minority AIDS Initiative (MAI) award (for those States that are eligible), the Emerging Communities (EC) award (for those States that are eligible) and the ADAP Supplemental award (for those states that HRSA deems eligible and that choose to apply). The “X08” award is the Part B Supplemental Grant, which is a competitive award for States that demonstrate the need for additional Part B funds. The “X09” competitive award is the ADAP Emergency Relief Funds (ERF) to help States prevent, reduce or eliminate ADAP waiting lists or implement ADAP –related cost-containment measures.

Formula and Supplemental Grants

RWHAP Part B Program Base, ADAP Base, and Emerging Communities funding are distributed using a funding formula process. The RWHAP Part B Base, ADAP Base, and Emerging Communities formula awards 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. The

RWHAP Part B Base formula is a weighted relative distribution that also takes into account RWHAP Part A funding. Similarly, for grantees applying for MAI formula funds, awards are based on the number of reported living minority HIV/AIDS cases for the most recent calendar year as confirmed by CDC. Supplemental ADAP grants are awarded by the same formula as ADAP Base to states which meet any of the criteria listed in that section of the FOA for the purpose of providing medications or insurance assistance for PLWH.

RWHAP Part B Program Supplemental Grants, including ADAP Supplemental, Part B Supplemental and ADAP ERF, are awarded to States demonstrating the severity of the HIV/AIDS epidemic and the need for additional federal assistance. The funds are intended to supplement the services otherwise provided by the State. The applications are reviewed through a federally approved technical review process. Supplemental funds applications must provide 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 provided by States/territories.

I. Chapter 7. The Division of State HIV/AIDS Programs

The **Division of State HIV/AIDS Programs** (DSHAP) within HRSA's HAB administers RWHAP Part B Program Base, ADAP, ADAP Supplemental, the RWHAP Part B MAI funds, Emerging Communities, Part B Supplemental, and the ADAP Emergency Relief (ERF) Grants.

DSHAP Project Officers (PO)

The Project Officer (PO) is the HRSA official responsible for working with grantees to ensure compliance with the legislative, programmatic and technical aspects of RWHAP Part B Program grants and to provide technical assistance resources to the State to ensure a comprehensive HIV service delivery system. POs are supervised by DSHAP branch chiefs, who are responsible for ensuring that POs are meeting their responsibilities. The PO works with the HRSA Office of Financial Assistance Management's (OFAM) grants management specialists (GMSs). GMSs are responsible for providing non-programmatic administrative assistance to grantees, including assistance in interpreting provisions of grants administration, law, regulation and policy. These provisions include how grantees can drawdown grant funds and how grantees are to administer and close out grants. GMSs are supervised by Grants Management Officers. Additionally, within the OFAM, staff in the Division of Financial Integrity (DFI) provides technical assistance to the POs and GMSs on audit issues.

Specifically, the DSHAP PO is responsible for:

- being the primary contact between grantees and DSHAP;
- working with grantees to ensure appropriate planning activities for the implementation and administration of the RWHAP Part B Program, including HIV care and prevention planning;
- monitoring and documenting programmatic performance to ensure compliance with legislative requirements through: monthly calls with the grantee; conducting site visits; reviewing grantee submissions such as grant applications, conditions of award, carry-

over requests, needs assessments, the Statewide Comprehensive Statement of Need, and comprehensive plans;

- understanding and tracking the healthcare service delivery systems for PLWH in the jurisdiction.
- identifying and responding to specific technical assistance needs of grantees and entities within the jurisdiction. The project officer is the point of contact to coordinate the technical assistance request;
- maintaining a summary of major grantee key program accomplishments and challenges; and
- representing the concerns/perspectives of grantees in HRSA/HAB initiatives.

I. Chapter 8. Technical Assistance for the RWHAP Community

The Ryan White HIV/AIDS Program legislation authorizes technical assistance (TA) to help programs comply with Ryan White HIV/AIDS Program legislative and programmatic requirements. Ryan White HIV/AIDS Program Part B Program grantees can obtain TA from HAB through their assigned Project Officer. Assistance focuses on implementing legislative and programmatic requirements in order to improve health care access, health care quality and health outcomes for PLWH. For more information on technical assistance, please see Section X.

I. Chapter 9. References, Links, and Resources

For More Information

HIV in the United States: at a Glance: <http://www.cdc.gov/hiv/resources/factsheets/us.htm>

About HAB: <http://hab.hrsa.gov/abouthab/index.html>

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

Section II: HIV Service Delivery System

II. Chapter 1. Introduction

The RWHAP is the single largest Federal program designed specifically for PLWH in the United States, and serves over half a million people with HIV each year. The RWHAP is also the third largest source of federal funding for HIV care in the U.S. after Medicare and Medicaid.⁵ The RWHAP requires States and territories to develop coordinated service delivery systems of care and treatment for PLWH. A comprehensive continuum of HIV/AIDS care requires grantees to develop collaborative, partnering and coordinating relationships between multiple sources of HIV testing, treatment, care and prevention service provider agencies on the State and local levels.

The Ryan White HIV/AIDS Part B Program grantees are expected to reflect these requirements in their HIV comprehensive plan and community-based needs assessment and planning processes. Ryan White HIV/AIDS Program grantees must integrate the NHAS goals and Early Identification of Individuals living with HIV/AIDS (EIIHA) strategies in addressing the service needs of newly affected and underserved populations. The goals of EIIHA are: 1) increase the number of individuals who are aware of their HIV status, 2) increase the number of PLWH who are in medical care, and 3) increase the number of HIV negative individuals referred to services that contribute to keeping them HIV negative.

II. Chapter 2. Legislative Background

The RWHAP under Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 2009) includes formula and supplemental grants to assist States and Territories in developing HIV/AIDS service delivery systems that reflect a comprehensive continuum of care that include essential core medical services and appropriate support services that assist PLWH in accessing treatment for HIV/AIDS infection.

Core Medical Services Requirement

Part B of the Ryan White HIV/AIDS Program legislation requires that, unless a waiver is requested and granted, 75 percent of grant funds are to be used for core medical services, after grantees reserve amounts for administrative services. Core medical services are identified under Section 2612(b) of the PHS Act.

In addition to core medical services, key support services needed to achieve medical outcomes may be funded by the RWHAP. These are described in Section 2612(c) as services, “that are needed for individuals with HIV/AIDS to achieve their medical outcomes (such as respite care for persons caring for individuals with HIV/AIDS, outreach services, medical transportation,

⁵ Ryan White Program Fact Sheet, March 2013, Kaiser Family Foundation,
<http://kaiserfamilyfoundation.files.wordpress.com/2013/30/7582-07.pdf>

linguistic services, and referrals for health care and support services).” In the absence of an approved waiver, no more than 25 percent of grant funds may be used for support services.

Comprehensive Plan and Statewide Coordinated Statement of Need (SCSN)

Section 2617(b)(5) of the PHS Act describes the requirement for grantees to develop a comprehensive plan that establishes priorities for funding allocation; includes a strategy that identifies individuals who know their HIV status and are not receiving HIV care services; coordinates the provision of such services; and describes the services and activities to be implemented to maximize quality and coordinated with available resources.

Sections 2617(b)(6) and (7) of the PHS Act address the importance of full participation by key entities in the HIV/AIDS care and treatment service delivery process, by way of the Statewide Coordinated Statement of Need (SCSN) and Comprehensive Plan, by requiring the convening of public meetings with all affected stakeholders, and assurances regarding public advisory planning processes:

(6) an assurance that the public health agency administering the grant for the State will periodically convene a meeting of individuals with HIV/AIDS, members of a federally recognized Indian tribe as represented in the State, representatives of grantees under each part under this title, providers, and public agency representatives for the purpose of developing a statewide coordinated statement of need;

(7) an assurance by the State that (A) the public health agency that is administering the grant for the State engages in a public advisory planning process, including public hearings, that includes the participants under paragraph (6), and the types of entities described in section 2602(b)(2), in developing the comprehensive plan under paragraph (5) and commenting on the implementation of such plan

Collaboration with Key Points of Access

In addition, section 2617(b)(7)(G) of the PHS Act outlines requirements for the State regarding collaboration with important points of access and components of a health care system for PLWH.

“(7) an assurance by the State that—

(G) entities within areas in which activities under the grant are carried out will maintain appropriate relationships with entities in the area served that constitute key points of access to the health care system for individuals with HIV/AIDS (including emergency rooms, substance abuse treatment programs, detoxification centers, adult and juvenile detention facilities, sexually transmitted disease clinics, HIV counseling and testing sites, mental health programs, and homeless shelters), and other entities under section 2612(c) and 2652(a), for the purpose of facilitating early intervention for individuals newly diagnosed with HIV/AIDS and individuals knowledgeable of their HIV status but not in care”

II. Chapter 3. National HIV/AIDS Strategy and the RWHAP

Introduction

On July 13, 2010, the White House released the NHAS for the United States, with an accompanying Federal Implementation Plan. The vision of the NHAS calls for the United States to “become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance will have unfettered access to high-quality, life extending care, free from stigma and discrimination.” The NHAS is the nation’s first-ever comprehensive coordinated HIV/AIDS roadmap with clear and measurable targets to be achieved by 2015.

Goals of the National HIV/AIDS Strategy

The National HIV/AIDS Strategy (NHAS) has three primary goals: 1) reducing the number of people who become infected with HIV, 2) increasing access to care and optimizing health outcomes for PLWH, and 3) reducing HIV-related health disparities. The NHAS states more must be done to ensure that new prevention methods are identified and resources are more strategically deployed. Further, the NHAS recognizes the importance of early entrance into care for PLWH to protect their health and reduce their potential of transmitting the virus to others. HIV disproportionately affects people who have less access to prevention, care and treatment services and, as a result, often have poorer health outcomes. Therefore, the NHAS advocates adopting community-level approaches to identify people who are HIV-positive but do not know their serostatus and reduce stigma and discrimination against PLWH. By 2015, the NHAS goals and outcomes will achieve the following:

1. Reduce new HIV infections.
 - Lower the annual number of new infections by 25%.
2. Reduce HIV transmission by 30%.
 - Increase the percentage of people living with HIV who know their serostatus from 79% to 90%.
 - Increase access to care and improve health outcomes for people living with HIV.
 - Increase the proportion of newly diagnosed patients linked to clinical care from 65% to 85%.
 - Increase the proportion of RWHAP clients who are in continuous care from 73% to 80%.
 - Increase the number of Ryan White HIV/AIDS Program clients with permanent housing from 82% to 86%.
3. Reduce HIV-related health disparities.
 - Improve access to prevention and care services for all Americans.
 - Increase the proportion of HIV-diagnosed gay and bisexual men with undetectable viral load by 20%.
 - Increase the proportion of HIV-diagnosed Blacks with undetectable viral load by 20%.
 - Increase the proportion of HIV-diagnosed Latinos with undetectable viral load by 20%.

The Impact of NHAS on the RWHAP Part B Program

Ryan White HIV/AIDS Program activities must strive to support the three primary goals of the NHAS. To ensure success, the NHAS requires the Federal Government and State, tribal and local governments to increase collaboration, efficiency, and innovation.

HAB recognizes that States/Territories have used RWHAP Part B grant funds to develop and/or expand systems of care to meet the needs of PLWH. 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 PLWH that will be seeking services. This requires ongoing assessment 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.

The NHAS also calls for improved Federal coordination of HIV/AIDS programs, as evidenced by streamlining and standardizing data collection and reducing reporting requirements for grantees. In 2012, the Office of HIV/AIDS and Infectious Disease Policy in HHS worked with a group of Federal agencies, national partners and grantees to identify indicators, data systems, and elements used across HHS programs to monitor HIV prevention, treatment, care services. As part of this effort a set of seven HIV common core indicators were developed and approved by the Secretary of Health and Human Services. These HHS common HIV indicators, which have been vetted and are consistent with treatment guidelines as well as with the Institute of Medicine's recommendations for monitoring HIV services and indicators developed by the National Quality Forum (NQF) and the National Committee for Quality Assurance (NCQA), are as follows:

- 1) HIV Positivity
- 2) Late HIV Diagnosis
- 3) Linkage to HIV Medical Care
- 4) Retention in HIV Medical Care
- 5) Antiretroviral Therapy (ART) Among Persons in HIV Medical Care
- 6) Viral Load Suppression Among Persons in HIV Medical Care
- 7) Housing Status

HRSA/HAB has also revised its performance measures, in part, to better align with HHS priorities, guidelines and initiatives. Please see Section VI, Chapter 4 for more information on HAB's performance measures.

II. Chapter 4. Comprehensive Service Delivery System for PLWH

A comprehensive service delivery system for PLWH is an integrated service network that guides and tracks HIV clients over time through a comprehensive array of clinical, mental, and social services in order to maximize access and effectiveness. The characteristics of a comprehensive service delivery system include:

- Patient centered coordination among provider treatment activities.
- Seamless transition across levels of care.
- Coordination of present and past treatment.

The following table illustrates the continuum of client and provider engagement in HIV medical care.

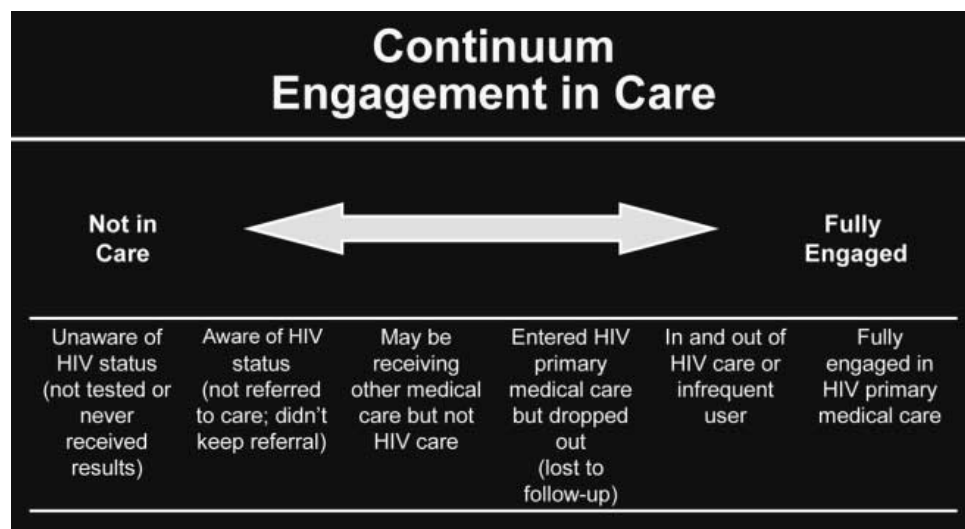


Figure 1: Continuum of Engagement in HIV Medical Care

A comprehensive service delivery system includes primary medical care and supportive services, which aim to promote health, enhance quality of life and enable PLWH to achieve and maintain HIV viral load suppression. The RWHAP requires States and Territories funded by RWHAP Part B to develop a comprehensive continuum of HIV/AIDS care accessible to eligible PLWH. The system of care should address the service needs of all PLWH, including newly affected and underserved populations, especially disproportionately impacted communities of color and emerging populations. The HIV/AIDS care should be consistent with HRSA's goals of increasing access to services and decreasing HIV/AIDS health disparities among affected subpopulations and historically underserved communities. A continuum of HIV prevention and care services should be designed to address the needs of PLWH across all life stages, from those unaware of his/her HIV status, through HIV counseling and testing, early intervention and linkage to care, to retention in care and treatment adherence.

The services that the RWHAP Part B grantee can fund as part of the comprehensive service delivery system for PLWH, core medical services and support services, are outlined in the RWHAP legislation and defined by the HRSA/HAB.

II. Chapter 5. Ryan White HIV/AIDS Program Core Medical Services

Introduction

The HIV care service delivery coordination efforts are dependent on the availability of core medical services through Ryan White HIV/AIDS Program funding and other payers. As of

2006, the Ryan White HIV/AIDS Program legislation requires that that not less than 75 percent of the funds be used to provide core medical services that are needed in the State for individuals with HIV/AIDS who are identified and eligible under the RWHAP. All services (whether on the list of core medical or support services) provided by or contracted through consortia are considered support services and must be counted as part of the maximum 25% of service dollars that may be expended for such services (see Section IX for more information on Consortia).

Defined Core Medical Services

The Ryan White HIV/AIDS Program legislation specifies that the following 13 core medical services are allowable. Grantees must ensure that RWHAP Part B services are provided within the scope of the service category definitions provided by HRSA/HAB.

1. Outpatient and ambulatory health services.
2. AIDS Drug Assistance Program treatments.
3. AIDS pharmaceutical assistance.
4. Oral health care.
5. Early intervention services.
6. Health insurance premium and cost sharing assistance for low-income individuals.
7. Home health care.
8. Medical nutrition therapy.
9. Hospice services.
10. Home and community-based health services .
11. Mental health services.
12. Substance abuse outpatient care.
13. Medical case management, including treatment adherence services.

The most recent service category definitions can be found in the Ryan White Services Report (RSR) Instructions available online at: <https://careacttarget.org/library/ryan-white-hiv-aids-program-services-report-rsr-instruction-manual>

Waiver of Core Medical Services Requirement

Applicants seeking a waiver of the core medical services requirement may submit a waiver request at any time prior to submission of the annual grant application, along with the annual grant application, or up to 4 months after the start of the grant year for which a waiver is being requested. More information on the Core Medical Services Waiver can be found in Policy Notice 13-07 in the HAB website (<http://hab.hrsa.gov/manageyourgrant/policiesletters.html>).

II. Chapter 6. Ryan White HIV/AIDS Program Support Services

Introduction

As of 2006, the Ryan White HIV/AIDS Program legislation requires that that no more than 25 percent of service dollars to be spent on support services that are needed for individuals with HIV/AIDS who are eligible under the RWHAP Part B. Services funded must be needed in order for PLWH to achieve medical outcomes, defined as "outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS."

Defined Support Services

The Ryan White HIV/AIDS Program legislation provides examples of allowable support services, and HRSA/HAB has supplemented that list. Grantees must ensure that RWHAP Part B services are provided within the scope of the service category definitions provided by HRSA/HAB.

1. Case management (non-medical)
2. Child care services
3. Emergency financial assistance
4. Food bank/home-delivered meals
5. Health education/risk reduction
6. Housing services
7. Legal services
8. Linguistics services (interpretation and translation)
9. Medical transportation services
10. Outreach services
11. Psychosocial support services
12. Referral for health care/supportive services
13. Rehabilitation services
14. Respite care
15. Substance abuse services—residential
16. Treatment adherence counseling

The most recent service category definitions can be found in the Ryan White Services Report Instructions Manual that is available online at: <https://careacttarget.org/library/ryan-white-hivaids-program-services-report-rsr-instruction-manual>

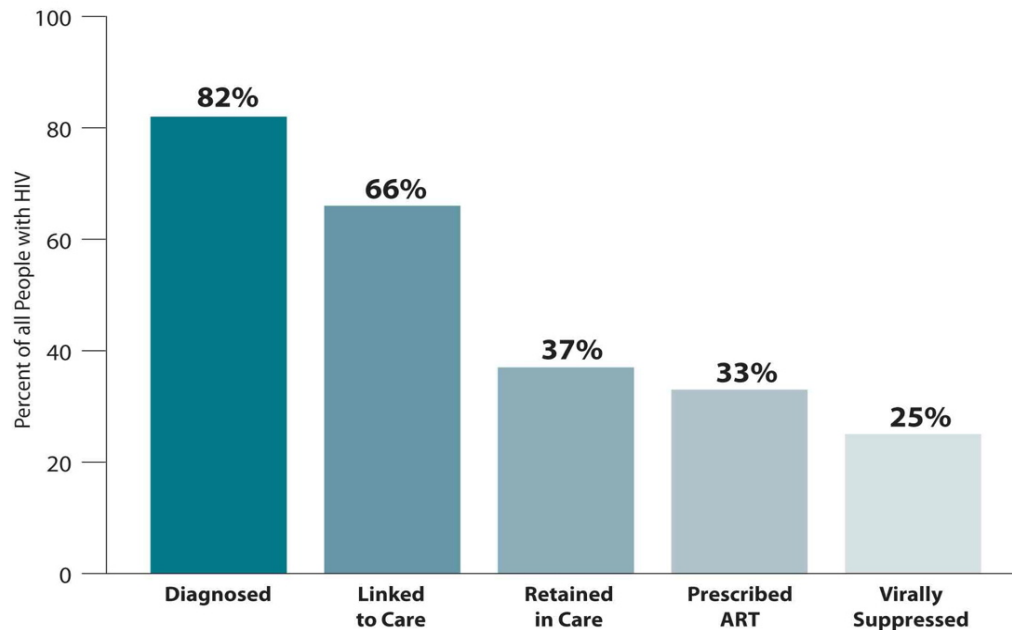
II. Chapter 7. Continuum of HIV Care

Identifying people infected with HIV and linking them to HIV primary care with initiation and long-term maintenance of life-saving antiretroviral treatment (ART) are important public health steps toward the elimination of HIV in the United States. The continuum of interventions that begins with outreach and testing and concludes with HIV viral load suppression is generally referred to as the Continuum of HIV Care or Care Treatment Cascade. The Continuum of HIV Care includes the diagnosis of HIV, linkage to HIV medical care, retention in HIV medical care, appropriate prescription of ART, and ultimately lifelong HIV viral load suppression.

The challenge of executing these lifesaving steps is difficult as demonstrated by the data from the CDC, which estimate that only 25 percent of individuals living with HIV in the United States have complete HIV viral suppression. Data from the Ryan White Service Report (RSR) indicates that there are better outcomes in Ryan White HIV/AIDS Program funded agencies with approximately 70% of individuals who received Ryan White HIV/AIDS Program funded medical care are virally suppressed. Such findings underscore the importance of supporting

effective interventions for linking HIV-positive individuals into care, retaining them in care, and helping them adhere to their combination ART regimens.

CDC Treatment Cascade (July 2012)



RWHAP grantees are encouraged to assess the outcomes of their programs along this continuum of care. Grantees should work with the community partners and other federally funded programs to improve outcomes across the Continuum of HIV Care, so that individuals diagnosed with HIV are linked and engaged in care and started on ART as early as possible. A list of CDC initiatives can be found at http://www.cdc.gov/hiv/topics/prev_prog/index.htm. In addition, CDC released a **“Data to Care: A Public Health Strategy Using HIV Surveillance Data to Support the HIV Care Continuum”** toolkit as a resource for state and local health departments to use HIV case surveillance data to improve the continuum of care in their communities, including the use of individual-level data to offer linkage and reengagement to care services when appropriate.

HAB has worked with other agencies within the Department of Health and Human Services to develop performance measures to assist in assessing outcomes along the continuum. HAB encourages grantees to use these performance measures at their local level to assess the efficacy of their programs and to analyze and address the gaps along the Continuum of HIV Care to improve the care outcomes provided. These efforts are in alignment with the support and goals and objectives of the National HIV/AIDS Strategy. More information on these performance measures can be found in Section VI: Clinical Quality Management.

II. Chapter 8. Coordination of Services and Funding Streams

Partnerships and Collaboration

The RWHAP expects to see collaboration, partnering and coordination between multiple sources of treatment, care and HIV testing, and HIV prevention service providers. In an ideal service

delivery system, collaboration between HIV testing sites, non-Ryan White HIV/AIDS Program medical and behavioral health providers, all Ryan White HIV/AIDS Program Parts (A, B, C, D, and F), Medicaid, and the Veteran's Administration (VA) should be established and maintained in the planning and implementation of services.

The RWHAP requires services to be provided in a patient-centered, coordinated, cost-effective manner that ensures that RWHAP Part B funds are the payer of last resort for HIV/AIDS services. RWHAP Part B grantee planning and service delivery efforts are coordinated with all other public funding for HIV/AIDS to: (1) ensure that RWHAP funds are the payer of last resort, (2) maximize the number and accessibility of services available, and (3) reduce any duplication.

Other Federal and local sources, including other RWHAPs must be taken into consideration in planning for the continuum of HIV/AIDS care. Sources may include but are not limited to:

- Medicaid;
- Medicare, including Medicare Part D;
- Children's Health Insurance Program (CHIP);
- Health insurance obtained through the Affordable Care Act (ACA) State and Federal Marketplaces;
- Other RWHAP Funding (Parts A, C, D and F);
- Veterans Affairs;
- Housing Opportunities for Persons With HIV/AIDS Programs (HOPWA);
- CDC Prevention;
- Services for Women and Children (e.g., Special Supplemental Food Program for Women, Infants, and Children (WIC) Program, and Substance Abuse Treatment Programs for Pregnant Women);
- Other State and local Social Service Programs (e.g., General Assistance, Vocational Rehabilitation);
- Local, State, and Federal Public Health programs; and
- Local and Federal funds for Substance Abuse/Mental Health Treatment Services including Substance Abuse and Mental Health Services Administration (SAMHSA).

Grantees are required to maintain appropriate referral relationships with entities considered key points of access to the healthcare system for the purpose of facilitating services for individuals diagnosed as being HIV positive. Many grantees require subrecipients to have active memoranda of agreement (MOA) or Memoranda of Understanding (MOU) with key points of entry. These collaborative documents enable referral and linkage of PLWH to medical care and support services upon HIV diagnosis. Grantee monitoring of these agreements helps ensure collaboration among various public health providers and strengthens the connections among the various stages of the care continuum.

Collaborative Planning Processes

The requirements for RWHAP Part B grantees to develop a Statewide Coordinated Statement of Need (SCSN) and Comprehensive Plan, and to coordinated planning efforts with all other public funding for HIV/AIDS are covered in Section VIII, Planning Requirements for RWHAP Part B. Section VIII also addresses the HRSA's and the CDC's support for integrated HIV prevention and care planning groups and activities.

II. Chapter 9. References, Links, and Resources

1. National HIV/AIDS Strategy Fact Sheet, HHS, AIDS.gov, July, 2010. <http://aids.gov/federal-resources/national-hiv-aids-strategy/nhas-fact-sheet.pdf>
2. National HIV/AIDS Strategy for the United States, White House, ONAP, July, 2010. <http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf>
3. National HIV/AIDS Strategy for the United States: Federal Implementation Plan, White House, ONAP, July, 2010: <http://www.whitehouse.gov/files/documents/nhas-implementation.pdf>
4. National HIV/AIDS Strategy: Update of 2011-2012 Federal Efforts To Implement the National HIV/AIDS Strategy, White House, ONAP, July, 2012: <http://www.aids.gov/federal-resources/national-hiv-aids-strategy/implementation-update-2012.pdf>
5. National HIV/AIDS Strategy: Implementation Progress Report 2011, HHS, May, 2012. <http://www.aids.gov/pdf/2011-nhas-progress-report.pdf>
6. HRSA/HAB Policy Notice 12-01: The Use of RWHAP Funds for Outreach Services. <http://hab.hrsa.gov/manageyourgrant/pinspals/outreachpolicy2012.pdf>

For More Information

Department of Health and Human Services: <http://www.aids.gov>

Kaiser Family Foundation: <http://www.kff.org>

Section III. AIDS Drug Assistance Programs (ADAPs)

III. Chapter 1. Introduction

ADAPs provide life-saving HIV treatments to low income, uninsured, and under-insured PLWH. In addition, some ADAPs provide insurance continuation and Medicare Part D and Medicaid wrap-around services to eligible individuals. With the implementation of the State-Based and Federally-Based health insurance marketplaces through the Affordable Care Act, more ADAPs are utilizing grant funds to cover medication co-pays and deductibles.

Please note that the DSHAP has published a manual specific to the operations of AIDS Drug Assistance Programs. The ADAP manual is designed to serve as an orientation guide for new ADAP staff, a reference document for ADAP staff on legislative and program requirements, and a tool to guide ADAPs in managing their fiscal and program components. The ADAP Manual is available online at <http://hab.hrsa.gov/manageyourgrant/adapmanual.pdf>.

All States/Territories are eligible for ADAP funding, including all 50 States, the District of Columbia, Puerto Rico, Guam, U.S. Virgin Islands and the five U.S. Pacific Territories or Associated Jurisdictions, including American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. Congress designates a portion of the RWHAP appropriation for ADAP. ADAP Base awards are based on the number of reported living cases of HIV/AIDS in the State or Territory in the most recent calendar year as confirmed by Centers for Disease Control and Prevention (CDC). Supplemental ADAP grants are awarded by the same formula as ADAP Base to States which meet any of the criteria listed in that section of the FOA for the purpose of providing medications or insurance assistance for PLWH.

Each funded State/Territory is responsible for:

- Establishing ADAP eligibility.
- Determining the type, amount, duration and scope of services.
- Developing a list of covered drugs on its formulary.
- Covering each class of drug on its formulary.
- Administering the program.

While grantees establish their own ADAP eligibility criteria, all grantees are required to implement an ADAP recertification process at least every 6 months to ensure that only eligible clients are served.

Since the Patient Protection and Affordable Care Act (ACA) (Public Law 111-148) was signed into law in 2010, ADAPs have been working to implement and preparing for areas of the law that directly impact them. Portions of health reform that impact ADAPs include:

- Medicaid eligibility expansion opportunity for states in 2014 and the expansion of the CMS Section 1115 Waiver.

- Increase in the number of individuals covered by private insurance plans through health marketplaces in 2014.
- ADAPs' Medicare Part D expenditures counting toward True Out Of Pocket (TrOOP) expenditures.
- 340B pricing transparency.

History of ADAP

ADAP started as a HRSA demonstration project to provide Zidovudine (AZT), the first drug approved by the Food and Drug Administration (FDA) to treat HIV disease, to low-income PLWH. The annual cost of this drug—about \$10,000 per year per person—placed it out of reach for many people. 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 an ADAP program nationwide. As HIV treatment advances occurred and as resources permitted, States expanded their programs to cover drugs in addition to AZT. States added therapeutics beneficial in the treatment of many of the opportunistic infections that occur in PLWH.

When ADAP became part of the newly enacted Ryan White CARE Act in 1990, States had the option to cover any FDA-approved drug that treats HIV disease or prevents the deterioration of health due to HIV. ADAPs have expanded considerably since 1990, both in terms of numbers of enrolled clients and in program resources. As a result of the dramatic increase in the cost of pharmaceutical treatment and the growing number of PLWH, the ADAP Base is now the largest portion of RWHAP spending.

III. Chapter 2. Legislative Background

ADAP Coverage of Medications

Section 2616 of the PHS Act provides specific guidelines for the ADAP program, including not only the provision of treatments, but also further defines the use of health insurance and plans:

Section 2616. [300ff–25] 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.

ADAP Coverage of Health Insurance Costs

Section 2615 provides for the use of amounts under the RWHAP Part B Program that extend private health insurance or create risk pools as follows:

Section 2615 [300ff–25] **CONTINUUM OF HEALTH INSURANCE COVERAGE.**

(a) **IN GENERAL.**—A State may use amounts received under a grant awarded under section 2611 to establish a program of financial assistance under section 2612(b)(3)(F) to assist eligible low-income individuals with HIV/AIDS in—

- (1) maintaining a continuity of health insurance; or
- (2) receiving medical benefits under a health insurance program, including risk-pools.

(b) **LIMITATIONS.**—Assistance shall not be utilized under subsection (a)—

- (1) to pay any costs associated with the creation, capitalization, or administration of a liability risk pool (other than those costs paid on behalf of individuals as part of premium contributions to existing liability risk pools); and
- (2) to pay any amount expended by a State under title XIX of the Social Security Act.”

A link to the current RWHAP legislation can be found on the HAB website at:

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

HAB provides policies, policy clarification notices, and program letters that provide guidance for the interpretation of the legislation. HAB’s policies, policy clarification notices, and program letters can be found here: <http://hab.hrsa.gov/manageyourgrant/policiesletters.html>.

III. Chapter 3. Purchasing and Dispensing Medications by ADAPs

RWHAP Part B grantees are required to secure the best price available for all products on their ADAP formularies and to achieve maximum results with these funds. A key resource available to ADAPs to meet this requirement is the 340B Drug Pricing Program.

Overview of 340B Program

The 340B Drug Pricing Program (340B Program) is a Federal drug pricing program that provides Federally-designated entities (including ADAPs and other RWHAP grantees) with access to discounted medications. The 340B Program enables eligible entities to stretch scarce resources, allowing them to reach more eligible patients and provide more comprehensive services. Manufacturers that participate in Medicaid must participate in the 340B Program and therefore

must offer participating covered entities covered outpatient drugs at or below the statutorily-defined ceiling price.

340B Pricing

The 340B ceiling price is based on quarterly pricing data reported to the Centers for Medicare & Medicaid Services (CMS) and is calculated by subtracting the Unit Rebate Amount from the Average Manufacturer Price. HRSA's Office of Pharmacy Affairs (OPA) administers the 340B Program.

340B Models

340B covered entities can secure 340B pricing through a point of purchase model (direct purchase). In 1998, the 340B program published guidelines permitting ADAPs to use a rebate model (63 Federal Register 35239, June 29, 1998).

An ADAP may pursue rebates from manufacturers for drug costs, when the ADAP has 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 340B drugs. If an ADAP makes a direct purchase of a drug at or below the ceiling price, the ADAP may not also seek a 340B rebate on that drug.

ADAPs may participate under either direct purchase or rebate options separately or a combination of the two options in order to meet the needs of their clients and maximize resources. ADAPs must 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.

340B Prime Vendor Program

The 340B Prime Vendor Program (PVP) is an optional program operated by a contractor of the HRSA OPA. The prime vendor's role is to secure sub-ceiling discounts on outpatient drug purchases and discounts on other pharmacy related products and services for participating covered entities electing to join the PVP. Purchasing pharmaceuticals through the 340B Prime Vendor Program may result in additional discounts of 20 to 50 percent of drug market prices.

More information about the 340B Drug Pricing Program and the Office of Pharmacy Affairs may be found at the OPA website: <http://www.hrsa.gov/opa>.

III. Chapter 4. Health Insurance Programs

Historically, most Americans obtained health insurance coverage through their employers under group policies, while a smaller proportion bought individual policies. Some ADAPs traditionally assisted eligible clients with Consolidated Omnibus Budget Reconciliation Act (COBRA) premium assistance when clients left their workplace.

The Affordable Care Act has provided the opportunity for many additional PLWH to access health coverage by prohibiting pre-existing condition exclusions. Section 2615 of the PHS Act allows RWHAPs to use RWHAP Part B funds to provide continuum of health insurance coverage for PLWH.

Utilizing RWHAP Part B funds to provide health insurance for eligible clients is important for the following key reasons:

- **Good Stewardship.** Paying health insurance premiums for PLWH can often be less expensive than covering medical expenses and medications directly under programs like ADAP. According to the National Alliance of State and Territorial AIDS Directors (NASTAD), States/Territories report cost savings in spending in covering health insurance premiums for persons diagnosed with HIV.
- **Expanding Access to Care.** Health insurance can improve access to care, including antiretroviral therapies and prevention and treatment of opportunistic infections.
- **Ensuring payer of last resort.** To ensure that the RWHAP is the payer of last resort, RWHAPs are encouraged to vigorously pursue and thoroughly document that eligible clients are enrolling in health insurance coverage.

Private Insurance Plans

ACA: State-Based and Federally-Based Marketplaces

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act (ACA), an effort to ensure that Americans have secure, stable, and affordable health insurance. Historically, PLWH have had a difficult time obtaining private health insurance, have been particularly vulnerable to insurance industry abuses, and have also faced barriers to obtaining care from qualified providers. Consistent with the goals of the President's National HIV/AIDS Strategy (<http://aids.gov/federal-resources/national-hiv-aids-strategy/overview>), the ACA has made considerable strides in addressing these concerns and advancing health care equality for PLWH. More information on how the ACA helps PLWH may be found here: <http://aids.gov/federal-resources/policies/health-care-reform>.

Under the ACA, beginning January 1, 2014, PLWH have private insurance coverage options available through either a State-Based or Federally-Based Health Insurance Marketplace. In States that choose to expand Medicaid, PLWH previously not eligible to obtain health insurance coverage through Medicaid may now have this option. It is within this new health insurance landscape that RWHAP Part B Programs have the option of purchasing health coverage for their clients instead of paying solely for HIV/AIDS medications. To ensure that the RWHAP is the payer of last resort, RWHAPs must vigorously pursue and thoroughly document that eligible clients are enrolling in health insurance coverage.

Depending on their state of residence, PLWH who are eligible for health insurance coverage through ACA have the option of enrolling in either a State-Based Marketplace or a Federally-Based Marketplace. Enrollment periods are set time periods with exceptions made for life-changing events; for example, birth, marriage, divorce, and other circumstances. More information about ACA, State-Based and Federally-Based Marketplaces, and enrollment may be found here: <https://www.healthcare.gov>.

HRSA has developed a number of policies that provide guidance to grantees in understanding and implementing requirements regarding ACA. These Policy Clarification Notices (PCNs) can be found here: <http://hab.hrsa.gov/manageyourgrant/policiesletters.html>. Health insurance companies offering coverage through ACA must accept third party payments from the RWHAP (Source: Federal Register, Volume 79, Number 53, Wednesday, March 19, 2014: <http://www.regulations.gov#!documentDetail;D=CMS-2014-0035-0002>).

Consolidated Omnibus Budget Reconciliation Act (COBRA)

COBRA coverage lasts 18 months plus a 20-month extension for individuals leaving employment due to a disability. More information about COBRA may be found here: <http://www.dol.gov/ebsa/publications/cobraemployee.html>.

Medicaid

Medicaid, Title XIX of the Social Security Act, is the largest source of public financing for HIV/AIDS care in the United States. Created in 1965, Medicaid is a jointly funded, jointly administered Federal-State health insurance program for low-income people who meet one or more of several categorical eligibility requirements, historically including disability. The program is administered through the Centers for Medicare & Medicaid Services (CMS). The federal government pays states for a specified percentage of program expenditures, called the Federal Medical Assistance Percentage. States have flexibility in designing their Medicaid programs. Within Federal guidelines, states determine who is eligible, what benefits are covered, how providers are paid, and other aspects of the program at the state level. All 50 states, DC, and territories have a Medicaid program.

The passage of the The Affordable Care Act expanded coverage to non-pregnant adults ages 19-64 and created a national Medicaid minimum eligibility level of 133% of the federal poverty level (FPL) for nearly all Americans under age 65. However, the Supreme Court later ruled that the Medicaid expansion is voluntary with states. As a result, some states have not expanded their Medicaid programs to cover non-pregnant adults ages 19-64 with income up to 133 percent FPL. States can expand at any time. To be eligible for Medicaid, all individuals must ensure that they satisfy the Federal and State requirements regarding income, resource, residency, and US citizenship/immigration status, and documentation of U.S. Citizenship. Medicaid coverage may, for eligible individuals, start retroactively for up to three months prior to the month of application, if the individual would have been eligible during the retroactive period, had they applied at that time. Coverage generally stops at the end of the month in which a person no longer meets the requirements for eligibility.

While not all states have opted to expand Medicaid coverage, for the first time in history, childless adults aged 18 and older who are eligible residents of states that have expanded Medicaid now have the opportunity to enroll. As a result, RWHAP clients who are newly eligible for Medicaid in states that have opted to expand Medicaid coverage must be encouraged to enroll in Medicaid. Whether in an expansion or non-expansion State, RWHAP grantees must make every effort to expeditiously enroll all eligible individuals in Medicaid and inform clients about any consequences for not enrolling. RWHAPs must vigorously pursue and thoroughly document that eligible clients are enrolling enroll in health insurance coverage through Medicaid.

Federal rules require States participating in Medicaid to cover a set of mandatory services to eligible people in order to receive Federal matching payments. States may also choose to provide optional services and receive matching payments. FDA-approved prescription drugs are an optional benefit that all States have chosen to provide. Medicaid coverage of prescription drugs includes all FDA-approved antiretroviral therapy (ART) drugs, but states may impose amount, duration, and scope limits (e.g., limit on the number of prescriptions), nominal co-payments for adults, and prior authorization controls. Other optional services that can be important for people with HIV/AIDS include case management, prevention services, tuberculosis-related services, and hospice services. States may also seek waivers to cover certain services that would not otherwise qualify for Federal matching funds, and a number have done so.

HRSA has developed a number of policies that provide guidance to grantees in understanding and implementing requirements regarding Medicaid and the ACA. These Policy Clarification Notices (PCNs) can be found here: <http://hab.hrsa.gov/manageyourgrant/policiesletters.html>. More information on Medicaid eligibility can be found here: <http://www.medicaid.gov/AffordableCareAct/Provisions/Eligibility.html>.

Medicare

Medicare (Title XVIII of the Social Security Act) is the Federal health insurance program for the elderly and disabled. It was established in 1965 and is also administered by CMS. Medicare is an important source of coverage for people with HIV/AIDS who are disabled, have sufficient work history to qualify for disability insurance, and live long enough to qualify for Medicare. As people with HIV/AIDS live longer, the number of people with HIV/AIDS on Medicare has grown, and Medicare spending has increased. Some individuals with Medicare coverage also qualify for Medicaid because of low income and are considered to be dual-eligible. For these individuals, Medicaid provides varying levels of coverage, including payment of premiums, some cost sharing, coverage of services during the waiting period (for those under 65 years), and coverage of prescription drugs. Medicare Part D has provided prescription drug benefits to Medicare enrollees since January 1, 2006. ADAPs often provide coverage for co-pays and deductibles and coverage during the “donut hole” for ADAP-eligible clients with Medicare. With the implementation of the Affordable Care Act, ADAP expenditures for Medicare Part D prescription costs now count toward the client’s True Out Of Pocket (TrOOP) costs.

More information on Medicare eligibility may be found here:
<http://medicare.gov/eligibilitypremiumcalc>.

IX. Chapter 5. References, Links, and Resources

1. **ADAP Manual:** <http://hab.hrsa.gov/manageyourgrant/adapmanual.pdf>
2. **The Ryan White HIV/AIDS Treatment Extension Act of 2009:**
<http://hab.hrsa.gov/abouthab/legislation.html>
3. **HAB Policies and Program Letters:**
<http://hab.hrsa.gov/manageyourgrant/policiesletters.html>
4. **340B Drug Pricing Program and the Office of Pharmacy Affairs:**
<http://www.hrsa.gov/opa>
5. **The President's National HIV/AIDS Strategy:** <http://aids.gov/federal-resources/national-hiv-aids-strategy/overview/>
6. **The Affordable Care Act and HIV/AIDS:** <http://aids.gov/federal-resources/policies/health-care-reform>
7. **Federal Register, Volume 79, Number 53, Wednesday, March 19, 2014:**
<http://www.regulations.gov/#!documentDetail;D=CMS-2014-0035-0002>
8. **Health Insurance Marketplace/Affordable Care Act:** <https://www.healthcare.gov/>
9. **Medicaid Eligibility:**
<http://www.medicaid.gov/AffordableCareAct/Provisions/Eligibility.html>.
10. **Medicare Eligibility:** <http://medicare.gov/eligibilitypremiumcalc>
11. **An Employee's Guide to Health Benefits Under COBRA:**
<http://www.dol.gov/ebsa/publications/cobraemployee.html>

Section IV: Reporting Requirements

IV. Chapter 1. Introduction

All grantees receiving Federal funds are required to report fiscal and program information to the agency designated to administer the particular grant program. For RWHAP Part B grantees, that agency is HRSA/HAB. In addition, the RWHAP legislation requires some specific reports from grantees that HAB must collect and review.

In general, reports are required for one or more of the following reasons:

- To assure grantee compliance with requirements mandated by Congress on the use of RWHAP Part B Program funds. Such requirements are called Conditions of Award because they set criteria or limits on how grant funds may be used.
- To monitor the fiscal and programmatic integrity of the grant program, as required by statute, regulation and policy, including the HHS Grants Policy Statement. For example, recipients of grants administered by HRSA usually must submit a revised program budget after receiving their notice of grant award, along with a narrative justification. Similarly, grantees are required to submit information about subcontracts. Examples of this type of report include the RWHAP Part B Program Consolidated List of Contractors report and the Contract Review Certification.
- To monitor program accomplishments, prepare HRSA reports on program trends, and respond to information requests from Congress, Office of Management and Budget (OMB), the media, and the public at large. As the agency responsible for the fiscal and program integrity of RWHAP Part B Program grantees, HRSA must be able to monitor and report on the grantees' fiscal status, services provided, clients served, program accomplishments, and technical assistance needs. HRSA also relies on information routinely reported by grantees to respond to inquiries from various parties such as the Congress.

IV. Chapter 2. Legislative Background

Grantees must provide progress and data reports in accordance with applicable provisions of the general grant regulations and provisions of Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87).

Submission of progress reports is one of the Conditions of Award for RWHAP Part B Program grantees. Failure to comply with any of the Conditions of Award by the specified due date may result in suspension of a grantee's ability to drawdown funds and/or the disallowance of funds.

IV. Chapter 3. The Electronic Handbook (EHB) and the Submission of Reports

In an effort to increase the efficiency and effectiveness of its management of grantee records, HRSA developed an electronic record keeping system. The HRSA Electronic Handbook (EHB) system provides a one-stop grants management online tool for Project Officers as well as grantees. The EHB makes accessible online Funding Opportunities Announcements, Grant applications, Notices of Award (NoA), Non-competing continuation applications, progress reports and other types of post-award reports and requests. EHB allows grantees and project officers to view award history, view past NoAs, monitor report activity as well as deadlines, and access reports such as the ADAP Data Report (ADR) and the Ryan White Program Services Report (RSR).

Any information and data required from the grantee, such as applications, drawdown restriction requests, reports, waivers, must be submitted in EHB using the format provided by HRSA. The HRSA EHB reporting formats help to assure that correct information is reported across all RWHAP grantees. This in turn allows HRSA to track and report national program trends, identify technical assistance needs, and prepare aggregate summary reports to Congress, grantees, and the public at large.

In order to access the grantee's grant portfolio in EHB, a grantee must register in the EHB and authorize which grantee staff will be allowed certain roles on behalf of the organization in EHB. The EHB system can be found at the following address:

<https://grants.hrsa.gov/webexternal/login.asp>

Grantees having problems accessing the EHB should contact the HRSA Call Center at:

Toll-Free Help Line: 1-877-464-4772

Hours: Monday - Friday 9AM - 5:30PM EST

E-mail: CallCenter@HRSA.gov

Reporting Deadlines

For specific reporting deadlines, grantees should refer to the Condition of Award in the NoA issued each year by HRSA/HAB and/or the deadline listed for the report in EHB. To meet the deadline, the information must be in the EHB by 11:59 p.m. EST on the due date. Grantees are expected to comply with all reporting deadlines. Once the deadline expires the EHB will close submission access and the grantee must request a deadline extension from the Project Officer or Grants Management Specialist in order to be able to submit the report. Persistent late reports may result in a special Condition of Award.

IV. Chapter 4. Overview of RWHAP Part B Reporting Requirements

Introduction

Grantees are required as a Condition of Award to provide certain program budget and fiscal reports. HRSA requirements for submitting RWHAP Part B Program programmatic and fiscal

reports are guided by grants policies established by HHS, Public Health Service (PHS), and Office of Management and Budget (OMB) guidance.

Grantees are required to submit reporting requirements for each award they receive. For example, if a grantee receives a Part B Base (X07) award and a Part B Supplemental (X08) award, the grantee would have a set of required reporting requirements in EHB for both the Part B Base and Part B Supplemental awards. The following table provides a summary of the standard reports required for the RWHAP Part B Base/ADAP Base (X07), RWHAP Part B Supplemental (X08) and RWHAP Part B ADAP Emergency Relief Funds (X09) awards. The reporting requirements are described in more detail in Chapters 5 through 7.

RWHAP Part B Reporting Requirements Summary Table		
Grant	Reporting Requirement	Components
Part B Base/ADAP Base (X07)	Program Terms Report	Revised SF 424A Revised Part B and MAI Planned Allocation Table Revised Budget Narrative Revised Implementation Plan Consolidated List of Contracts (CLC) Contract Review Certification (CRC)
	MAI Annual Plan	RWHAP Part B MAI Annual Plan
	Interim Federal Financial Report (FFR)	Interim Federal Financial Report (FFR) (SF425) demonstrating 75% obligation of grant funds
	Unobligated Balances (UOB) Estimate	RWHAP Part B UOB Estimate and Estimated Carryover Request
	RWHAP Services Report (RSR)	RSR Grantee Report RSR Provider Reports RSR Client-Level Data Report
	ADAP Data Report (ADR)	ADR Grantee Data Report ADR Client-Level Data Report
	Final Expenditure Table	RWHAP Part B & MAI Final Expenditure Table
	Annual Progress Report w/ WICY Expenditures	RWHAP Part B Annual Progress Report and WICY Expenditures Reporting
	MAI Annual Report	RWHAP Part B MAI Annual Report
	Final FFR	Final FFR and Carry Over Request
Part B Supplemental Funding (X08)	Programs Terms Report	Revised SF 424A Revised Budget Narrative Revised Implementation Plan Consolidated List of Contracts (CLC) Contract Review Certification (CRC)
	Progress Report	Part B Supplemental Progress Report Part B Supplemental Funding Table
	Final FFR	Final FFR (SF-425)

RWHAP Part B Reporting Requirements Summary Table		
Grant	Reporting Requirement	Components
ADAP Emergency Relief Funding (X09)	Programs Terms Report	Revised SF 424A Revised Budget Narrative Revised Implementation Plan Consolidated List of Contracts (CLC) Contract Review Certification (CRC)
	1 st Semi-Annual Report	RWHAP ADAP ERF Semi-Annual Report: 1st Report
	2 nd Semi-Annual Report	RWHAP ADAP ERF Semi-Annual Report: 2nd Report
	Final Funding Table	RWHAP Final ADAP ERF Funding Table
	Final FFR	Final FFR (SF-425)

IV. Chapter 5. Program and Fiscal Reports

Below is a description of the RWHAP Part B program and fiscal reports, their purpose, and the general reporting deadlines for each. Please refer to the Notice of Award and the EHB for grant year specific requirements and due dates.

Program Reports

- **Program Terms Report**

(Due 90 days after final award)

The Program Terms Report provides the grantee with the opportunity to update information provided in the grant application once the actual award amount is received in the notice of Award. The Program Terms Report is to be submitted consistent with reporting guidelines, instructions, and reporting template provided separately. The report must include the following items:

- The Ryan White Part B and MAI Planned Allocation Table* is a table that indicates in the categories and priority areas (core medical and support service categories) established by the grantee for the current grant year and the funding (dollar amount) for each service category. Grantees demonstrate compliance with the 75% core medical services requirement through this table. The amounts on the table must match the Notice of Award. **(X07 Award only)**
- The revised SF-424 budget and narrative justification* for the current grant year. This is a revision of the planned program budget submitted by the grantee with the grant application that reflects the actual amount of funds awarded on the Notice of Award. Further guidance on preparation of the revised SF-424 budget and narrative justification can be found in Chapter 6 below.
- Implementation Plan* that reflects access to a comprehensive continuum of HIV/AIDS care. It must include each service category and amounts funded by the relevant grant award (X07, X08 or X09) for the current grant year. For X07, it should include RWHAP Part B Program Base funding, ADAP Base, Minority AIDS Initiative (if

- applicable), ADAP Supplemental (if applicable), and Emerging Communities (if applicable). For X07 awards, all priorities and core and support services provided in this plan must be consistent with the Ryan White Part B and MAI Planned Allocations table.
- d. The *RWHAP Part B Program: Consolidated List of Contracts (CLC)* is a list of all contracts, fee for service, memoranda of understanding (MOU), memoranda of agreement (MOA) or letters of agreement (LOA) for service providers receiving RWHAP Part B and MAI funding. The list includes the provider name, the contract amount, and the service/activity to be provided under that contract. This summary information helps HRSA monitor and track the use of grant funds for compliance with program and grants policies and requirements.
 - e. *Consolidated Review Certification*. Grantees are required to certify for HRSA that all RWHAP Part B and MAI-funded direct service contracts have been reviewed by program and administrative/fiscal staff to ensure compliance with HRSA/HAB policies.
- **Semi-Annual Progress Reports (X09 Award Only)**
The ADAP ERF (X09) Semi-Annual Progress Reports document expenditures (by service category, unit and number of clients) and for cost-containment measures for each six-month period of the grant year.
 - **Annual Progress Report**
(Due 150 days after the end of the fiscal grant year)
The Annual Progress Report chronicles accomplishments and challenges for the twelve-month grant year. Grantees should refer to the NoA and EHB for specific instruction on the Annual Progress Report requirements for X07, X08 and X09 grants.
- For X07, the grantee must provide the final RWHAP Part B Program Implementation Plan, the EIIHA accomplishments, and the narrative report. In addition, the Final Progress Report must:
- Update the State Match report provided with the application (for applicable grantees) by including not only the dollar amount, but also describing the activities that were supported with the matching funds.
 - Document and certify the actual aggregate administrative expenditures of subrecipients/contractors.
 - Document the evaluation activities performed to measure the impact of RWHAP Part B Program funds in meeting emerging needs, ensuring access to care, coordinating with other health-care delivery systems, and evaluating the impact of Ryan White HIV/AIDS Program funds.
 - Provide information on Clinical Quality Management activities.
 - Submit the annual Women, Infants, Children and Youth (WICY) report in which grantees demonstrate that they have met the requirement to use a proportionate amount of their grant dollars to provide services to women, infants, children and youth (WICY) living with HIV/AIDS, unless a waiver is obtained (refer to the instructions and template sent annually by HAB).

- Describe any specific HRSA sponsored technical assistance activity received during the year.
- **Minority AIDS Initiative (MAI) Annual Plan (X07 Award Only)**
(Due 90 days after final award)
The MAI Annual Plan is a table and a narrative that documents the planned use of RWHAP Part B MAI funds for the grant year. Guidelines and instructions for submission of the table and narrative are provided in the EHB and through the HRSA HAB Project Officer.
- **Ryan White Part B and MAI Final Expenditure Table (X07 Award Only)**
(Due 120 days after the end of the fiscal grant year)
This table updates the Planned Allocations table (submitted with the Program Terms report) to reflect actual expenditures during the grant year. Grantees demonstrate compliance with the 75% core medical services requirement through this table. The amount reported on the Final Expenditure Table must match the expenditures reported on the Final Federal Financial Report (FFR), and expenditures by category must match those reported in the Annual Progress Report. The table must be submitted using the format provided in the EHB.
- **Minority AIDS Initiative (MAI) Annual Report (X07 Award Only)**
(Due 150 days after the end of the fiscal grant year)
The MAI Annual Report is a table and a narrative that documents the use of RWHAP Part B MAI funds during the grant year. Guidelines and instructions for submission of the table and narrative are provided in the EHB and through the HRSA HAB Project Officer.

Financial Reports

- **Unobligated Balance (UOB) Estimate (X07 Award Only)**
(Due 60 days before the end of the grant year)
By January 31st, the grantee must submit an estimate of its projected unobligated balance for the current grant year and an estimated carryover request, including the intended use of funds. IF AN ESTIMATED UOB AND CARRYOVER REQUEST ARE NOT SUBMITTED, NO CARRYOVER WILL BE PERMITTED.
- **Interim Federal Financial Report (FFR) (X07 Award Only)**
(Due 135 days after the end of the fiscal grant year)
Using form SF-425, the grantee reports for the current budget period the amount of RWHAP Part B funds that have been obligated (contracted) and made available for expenditure by August 1. The grantee is required to substantiate that 75% of the funds were obligated and can be used for the provision of services. Failure to document that 75% obligation of the RWHAP Part B award will result in a penalty.
- **Final Federal Financial Report**
(For X07 & X09, due 120 days after the end of the fiscal grant year; for X08, due January 30th)
Using form SF-425 provided in the EHB the grantee is to report the cumulative expenses within the project period. The final FFR must not include un-liquidated obligations and must

agree with the Payment Management System report of disbursements and advances for the budget period being reported and identified by the document number.

The FFR will not be accepted unless the grantee completes the required attachment providing a breakout of the awarded amounts, any approved carryover, and the respective expenditures for each of the following: Base, Emerging Communities, ADAP, MAI and Carryover amount from the prior year.

Reporting State Matching Funds (X07 Awards Only, if applicable)

Items 10b (Recipient Share of Outlays) and 10e (Recipient Share of Un-liquidated Obligations) of the FFR 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). If a state has both a Base and ADAP Supplemental Match, the grantee must specify in the remarks section how the match reported in lines i and j meets each of the required match amounts.

Reporting Rebates

Rebates are to be indicated on line 12 (the “Remarks” section) of the FFR with attachments as necessary, and must reflect the amount of rebate funds received, the amount of rebate funds expended and the amount of difference. Rebate amount should also be indicated in the “Ryan White Rebate Funding Section” of the FFR. Provide the amount of rebate expended for the current year in the “Expended Rebate Amount” Line and the amount of the rebate that will be applied to the unobligated balance in the “Expended Rebate amount to be used to reduce UOB” line. Rebate funds should never be recorded as an unobligated balance on any FFR. Rebates collected under the RWHAP Part B are not considered program income and must not be reported in section 10, Lines l-o of the FFR. HAB Policy Notice 12-02 specifies that UOB provisions do not apply to funds from drug rebates under RWHAP Part B. 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” section with the following statement: “STATE NAME has an unobligated balance due to rebate funds and is requesting to reduce the unobligated grant fund balance of \$XXX by the amount of \$XXX in rebate funds”. For more information, see HAB Policy Notice 12-02:

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

UOB and Carryover Request

If the grantee has an unobligated balance, they must do one of the following:

- Upload a carryover request within the EHBs Prior Approval module.
- Indicate in their FFR their intent to submit a carryover request separately and submit the request via the Prior Approval Module within 30 days of the FFR submission.
- Indicate on the FFR their intention to not submit any carryover request.

IV. Chapter 6. Budget and Budget Narrative Justification Guidelines

A revised SF-424 budget and narrative justification for the current grant year is submitted as a component of the Program Terms Report. This is a revision of the planned program budget submitted by the grantee with the grant application that reflects the actual amount of funds awarded on the Notice of Award. It must be based on priorities established by the grantee in the comprehensive plan and SCSN and reflect the amount of RWHAP Part B funds awarded to the State for that fiscal year (FY) only, and be prepared using applicable Cost Principles and HAB program policies. The grantee should follow the budget guidance given in the annual Funding Opportunity Announcement. RWHAP Part B funds are subject to certain requirements, restrictions, and limitations as described in the FOA and NoA, and the RWHAP legislation. For more information, see Section V: Grantee and Subrecipient Monitoring.

There are two components in a Final Program Budget:

1. **Standard Form (SF) 424-A. Budget Information—Non-construction Programs.** The (SF) 424-A that had been submitted with the annual Part B application (whether X07, X08 or X09) must be revised and resubmitted as part of the Program Terms Report. The Final RWHAP Part B Program Budget must reflect budget allocations based on the actual amount of funds awarded to the State on the Notice of Award. For X07 and X08, the grantee should label the “Grant Program, Function or Activity” columns in the SF424-A table with the following four major program budget categories:
 - a. **Administration:** This column should include all funds allocated to the following grant activities: grantee administration, planning and evaluation, and clinical quality management.
 - i. **Grantee Administration.** These are funds to be used by the grantee for routine grant administration and monitoring activities and cannot exceed 10 percent of the award. Such activities include development of the RWHAP Part B application, receipt and disbursement of program funds, the development and establishment of reimbursement and accounting systems, preparation of routine programmatic and financial reports, and costs associated with assuring compliance with grant conditions and audit requirements. Reminder: Administrative and planning evaluation costs together cannot exceed 15 percent. (See Section V. Grantee and Subrecipient Monitoring).
 - ii. **Planning and Evaluation.** These costs may not exceed 10 percent of the grantee’s award. Reminder: Administrative and planning evaluation costs together cannot exceed 15 percent. (See Section V. Grantee and Subrecipient Monitoring).
 - iii. **Clinical Quality Management.** The grantee may allocate a portion of RWHAP Part B funds awarded to the State to support Clinical Quality Management programs that assist direct-service medical providers in assuring that funded services adhere to established HIV clinical practice standards and HHS Guidelines. Grantees are allowed to allocate up to 5 percent of the total

grant award or \$3 million (whichever is less) for quality management activities.

- b. **ADAP:** This column should include all funds allocated to ADAP.
 - c. **Consortia:** This column should include all funds allocated to consortia and emerging communities.
 - d. **Direct Services:** This column should include all funds allocated to the following grant activities: state direct services, home and community-based care, MAI, and health insurance continuation. The total amount to be awarded for services through sub-grants, contracts, sub-contracts and any memoranda of understanding or other agreements should be entered on line 6f of column 1 on page 2 of the SF 424-A. Further contract information is not needed with the Final Program Budget, but will be submitted with the Consolidated List of Contractors described earlier in this chapter.
2. **Budget Narrative Justification.** A categorical budget and narrative justification is required for the amounts requested for each line in the budget. The budget justification should specifically describe how each item will support the achievement of proposed objectives. The budget period is for ONE year. The budget narrative is the descriptive information used to explain and justify the amounts budgeted within each program budget category. It must include specific information—the “who, what, where, when, and why.” All costs identified in Section B of SF 424-A of the budget must be described and justified, including those listed in the “other” category.

IV. Chapter 7. Client Level Data Reporting

Introduction

All grantees and providers funded by RWHAP Part B grantees are required to submit client level data reporting annually for services funded through RWHAP Part B. The ADAP Data Report (ADR) collects client level data for ADAP services; the Ryan White Data Report (RSR) collects client level data on non-ADAP services. All client-level data is collected via a unique encrypted unique identifier to ensure that all measures have been taken on the part of HAB to protect the data as well collect only the necessary variables required for the ADR and RSR reports.

Data reported in the ADR and RSR are used to broadly assess the impact and quality of Ryan White HIV/AIDS Program-funded programs as grantees and their providers strive to serve the vulnerable and underserved populations most severely impacted by the HIV/AIDS epidemic. RSR also provides comprehensive RWHAP information to respond to public inquiries regarding the RWHAP funded service delivery and client demographics.

The Ryan White Data Report (RSR) (Due last Monday in March)

The purpose of the RSR is to collect information on all clients who receive at least one RWHAP eligible service (excluding ADAP) during a calendar year. RSR client-level data provides information on the number and characteristics of grantee, providers and the clients served. It is the responsibility of each grantee to collect one RSR from each of the providers with which it contracts to provide RWHAP services or program support. RWHAP Part B consortia also must submit one RSR for each of the providers with which they contract.

The RSR includes three main components: the Grantee Report, the Provider Report and the Client Report (client-level data). Each section is to be answered by the appropriate Part, grantee and provider. Not all sections require a response; some sections are specific to the funded services. Entities completing the RSR should carefully review their roles and responsibilities for reporting.

The RSR eliminates Parts-specific reporting. Therefore, service providers complete one annual report that includes all RWHAP services provided and all clients served during the calendar year, regardless of which Part funded the services. The provider then submits a copy of the completed report to its grantee(s) of record. The grantee of record then submits the same report to the HAB data contractor.

The RSR must be submitted as an .xml file to HAB. The web-based system includes built-in validations and warnings to assure that the data will be internally consistent. The RSR and instructions for completing the report can be found on the TARGET Center website:

<https://careacttarget.org>.

The AIDS Drug Assistance Program Data Report (ADR) (Due second Monday in June)

RWHAP Part B grantees formerly provided information on their ADAP through the ADAP Quarterly Report (AQR), which was an aggregate data report. The AQR was retired at the end of Fiscal Year 2013, and HAB is no longer requiring grantee submission of this report. To address the limitation provided by the aggregate data collected in the AQR, HRSA began requiring RWHAP Part B grantees to collect client level data for their ADAP programs through the ADAP Data Report (ADR). The ADR provides HAB with a demographic profile of the clients served, and enough service and expense data to evaluate the impact of the program nationwide.

The ADR is comprised of two components: the Grantee Report and the Client Report (client-level data). The ADR must be submitted as an .xml file to HAB. The web-based system includes built-in validations and warnings to assure that the data will be internally consistent. The ADR and instructions for completing the report can be found on the TARGET Center website:

<https://careacttarget.org>.

IV. Chapter 8. Grantee and Provider Responsibilities for Data Reporting

Grantee Responsibilities

All Ryan White HIV/AIDS Program grantees are responsible for training their service providers and any other reporting entities on collecting and reporting data for the annual ADR and RSR.

Grantees are also responsible for:

- Ensuring that contract providers annually complete required client level data.
- Reviewing their providers' reports to ensure accuracy prior to submitting them to HAB.
- Submitting completed data reports to HAB by the deadline provided.
- Cooperating in the verification of their data following submission.

Provider Responsibilities

All Ryan White HIV/AIDS Program-funded providers must complete a Provider Report and, if it provides core medical or support services, upload client-level data.

All service providers funded by Ryan White HIV/AIDS Program grantees are responsible for:

- Establishing and maintaining a client-level data collection system that permits the compilation of all data needed to complete the RSR.
- Collecting complete data from all subrecipients.
- Submitting a completed RSR to their grantee of record by a locally established due date to permit review by the grantee.

A grantee-provider is a service provider that also is a grantee. A grantee-provider must complete a Grantee Report *and* a Provider Report. If the grantee-provider offers core medical or support services, it must also submit a Client Report.

IV. Chapter 9. Training and Technical Assistance for the ADR and RSR

HAB designated Division(s) and subrecipients are responsible for training Ryan White HIV/AIDS Program grantees on the implementation and use of the ADR and RSR, and in turn, grantees are responsible for training their service providers. ADR and RSR instructions, trainings and tools are available on the HAB website and TARGET Center website.

HAB also provides the software package CAREWare (for free) for use in collecting and reporting client-level data necessary for completion of the ADR and/or RSR. Use of CAREWare is not required. However, grantees and service providers can use CAREWare to generate their annual report for submission to HAB. HAB staff are responsible for offering CAREWare training on an as-needed basis.

HAB also provides the following training and technical assistance:

- A data-related technical assistance found at the TARGET Center website (<https://careacttarget.org>)
- A telephone helpline for assistance with completing the RSR and ADR reports.
Toll -free Help Line: 1-888-640-9356
Hours: Monday–Friday 9AM–5:30PM EST
E-mail: [Ryan White Data Support](#)
Learn More Online: [RSR Home Page](#) | [ADR Home Page](#)
- A CAREWare telephone helpline (the CAREWare Help Desk) for assistance in implementing the use of CAREWare at a grantee or service provider’s site.
Toll-Free Help Line: 1-877-294-3571
Hours: Monday–Friday 1:00–4:00 PM EST
E-mail: cwhelp@jprog.com

Learn More Online: [CAREWare Home Page](#)

- The HRSA Call Center for questions pertaining to HRSA Electronic Handbooks (EHBs) or the Web data entry system.
Toll-Free Help Line: 1-877-464-4772
Hours: Monday–Friday 9AM–5:30PM EST
E-mail: CallCenter@HRSA.gov
- Upon request, on-site data-related technical assistance from HAB’s data contractor.

IV. Chapter 10. References, Links, and Resources

1. Ryan White CAREWare: <http://hab.hrsa.gov/manageyourgrant/careware.html>
2. The RWHAP Services Report (RSR):
<http://hab.hrsa.gov/manageyourgrant/clientleveldata.html>
3. HHS Grants Policy Statement: <http://dhhs.gov/asfr/ogapa/grantinformation/hhsgps107.pdf>
4. Information and instructions on the SF-424 budget forms can be found at
<http://www.grants.gov/assets/InstructionsSF424A.pdf>

For More Information

Please refer to the HAB Target Center at <https://careacttarget.org>.

Section V: Grantee and Subrecipient Monitoring

V. Chapter 1. Introduction

Monitoring is required by HRSA to ensure compliance with statutory requirements, regulations and guidance. Monitoring activities review and test compliance with applicable laws, regulations and policies, and assess efficiency of operations and effectiveness in achieving program results. If warranted, the monitoring process makes recommendations to enhance agency operations, promote economy, efficiency, and compliance with Federal and programmatic requirements. Monitoring requirements apply to any project, program, sub-award, function or activity supported by the RWHAP Part B award. Therefore, monitoring applies to grantees, subrecipients of the State/Territory, lead agencies, fiduciaries and/or consortia subrecipients/contractors. Monitoring includes both program monitoring and fiscal monitoring. In order to facilitate program and fiscal monitoring, HRSA/HAB consolidated the monitoring requirements into the National Monitoring Standards.

One change in this revised version of the RWHAP Part B manual is the use of the term “subrecipient” instead of “subgrantee” or “subcontractor”. The term “subrecipient” is being used to be consistent with the terminology used in the new Uniform Guidance. 2 CFR Part 220.93 of the Uniform Guidance defines a subrecipient as a non-Federal entity that receives a subaward from a pass-through entity (i.e., a RWHAP Part B grantee) to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. See also 2 CFR Part 200.330.

V. Chapter 2. Legislative Background

The uniform grants rules, codified at 2 CFR Part 200, clarify the role of the grantee with regard to monitoring and reporting program performance (2 CFR Part 200.328) and sub-recipient monitoring and management (2 CFR Part 200.331). “The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities. The non-Federal entity must monitor its activities under Federal awards to assure compliance with applicable Federal requirements and performance expectations are being achieved. Monitoring by the non-Federal entity must cover each program, function or activity. See also 2 CFR Part 200.331 for subrecipient monitoring requirements.

V. Chapter 3. RWHAP Part B National Monitoring Standards

The National Monitoring Standards for the Ryan White HIV/AIDS Part A and B grantees (the Standards) were developed by HRSA/HAB to provide clear guidance to grantees regarding monitoring expectations of grantees and subrecipients. The Standards define a series of fiscal and program criteria to be monitored for compliance by consolidating the expectations of the following grant management documents. HRSA/HAB’s provision of the Standards does not preclude grantee responsibility for reading and complying with all current, relevant grant management documents.

1. Title XXVI of the Public Health Service Act, 42 U.S.C. 300ff-11, Sections 2611-23 (as amended by Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87)).
2. Code of Federal Regulations (including national policy requirements codified in Titles 2 and 45 and administrative requirements including 42 CFR Part 50, Subpart E and other applicable regulations highlighted in the HHS Grants Policy Statement and the Notice of Award).
3. 2 CFR Part 200 *Uniform Administrative Requirements, Cost Principles, and Audit Requirement for Federal Awards*.
4. HHS Grants Policy Statement.
5. HRSA/HAB policy notices, letters and guidelines.
6. RWHAP Part B Program Guidance Documents.
7. Notices of Grant Award and Conditions of Award.
8. Office of Inspector General (OIG) reports and recommendations.
9. Manuals and Guides issued by HRSA/HAB.

The Standards are included as a term of the Notice of Grant Award (NoA), and RWHAP Part B grantees are expected to comply with the RWHAP Part B Fiscal and Program Standards as well as the Universal standards (which apply to both Parts A and B). The Standards can be accessed at the following link: <http://hab.hrsa.gov/manageyourgrant/granteebasics.html>.

V. Chapter 4. Monitoring of RWHAP Part B Grantees by HAB

The Division of State HIV/AIDS Programs (DSHAP) of HRSA/HAB is responsible for overseeing the RWHAP Part B and conducting routine monitoring of RWHAP Part B grantees' performance and compliance with statutory requirements, regulations, and guidance. Routine monitoring of grantees includes regularly scheduled monthly monitoring calls, reviews of grantee reports and comprehensive site visits.

The monitoring of grantees is based upon requirements outlined in HHS guidance and the Code of Federal Regulations (CFR), as well as RWHAP legislation and policy guidance. The grantee and subrecipient assessments include adherence with Public Health Service treatment guidelines, the extent to which grantees are providing coordinated systems of care, and adherence with programmatic and fiscal requirements.

A technical assistance assessment, which may be requested by project officers or by grantees, is a byproduct of monitoring. Technical assistance can be provided using a range of modalities, including an on-site visits, tool and resource development, telephone consultation, and by webinar. If a grantee has legislative or programmatic compliance findings and does not correct them in a timely manner even with technical assistance, more intensive monitoring will result.

Site Visits to RWHAP Part B Grantees

Site visits are key component of HRSA/HAB grantee oversight and are used to verify compliance with Ryan White HIV/AIDS Program legislative and Program requirements, to verify the provision of high quality HIV clinical care and compliance with HHS guidelines, and

to verify administrative and fiscal integrity. If a site visit identifies program deficiencies, a corrective action plan must be created to address program deficiencies and brings the program into compliance.

HRSA conducts three types of site visits: comprehensive, diagnostic and technical assistance. HRSA has implemented a risk based strategy for selecting its direct grantees for site visits and for choosing which type of site visit is required. The following factors are included in the risk assessment:

- Comprehensive :
 - Conducted on a periodic basis—every 3 to 5 years.
- Diagnostic:
 - Low score on recent competitive application or poor non-competing applications.
 - Lack of communication with the Project Officer.
 - Habitual and problematic grantee staff turnover.
 - Problematic spend-down patterns (Payment Management System (PMS) requests) and/or multiple years with unobligated balances.
 - Consistently failing to meet work plan objectives.
- Technical Assistance:
 - An initial site visit for newly awarded grantees.
 - To address issues identified in a diagnostic or comprehensive site visit.
 - Assistance to improve grantee performance.

V. Chapter 5. Monitoring of RWHAP Part B Subrecipients by Grantee or Designee

The RWHAP Part B grantee retains ultimate accountability to HRSA for all contracts and/or agreements awarded through its RWHAP Part B grant. For example, in the case of an Office of Inspector General (OIG) visit that results in repayment of Federal dollars, the State or territory, not the subrecipient, is responsible for repaying the debt out of non-Federal dollars. Grantees should use the monitoring process to reinforce and underscore mutual obligations between funder and provider. The grantee should designate a person or team to review fiscal and program reports, conduct site visits, interact on an ongoing basis with contracted providers, and implement remedial steps or corrective action plans if necessary. A grantee may distribute monitoring functions across its organization. For example, fiscal monitoring activities are frequently handled by a different person, team, or even division within a health department than program monitoring activities. Communication between the fiscal and programmatic team needs to remain seamless.

The grantee must have a process to monitor subrecipients as well as assure that lead agencies/consortia have in place a process that includes annual program and fiscal site visits to monitor their subrecipients. Grantees should require their lead agencies to annually submit required Federal audits, monitoring reports and/or corrective action plans for their subrecipients. When problems with a subrecipient are noted, grantees or lead agencies/consortia must share the findings with the subrecipient and ensure that corrective actions are instituted and monitored.

When instances of legislative and/or programmatic noncompliance are discovered, the grantee or the grantee's lead agency/consortia must share the finding with the subrecipient and ensure that a corrective action plan is established to address the finding(s). The grantee must monitor the corrective action plan to ensure its satisfactory completion. The grantee or its lead agency/consortia should follow a graduated problem-solving approach, with termination of the contract as a last measure.

Grantees are encouraged to establish a monitoring manual to assist in providing a standardized and transparent process for the range of monitoring activities, including desk compliance audits, analysis of performance reports, scopes of work, staff and subrecipient training, and other required program and fiscal monitoring. In addition, the manual should describe and outline the process to be followed prior to, during and following a monitoring site visit.

See also the requirements outlined in 2 CFR Part 200.331.

Site Visits to RWHAP Part B Subrecipients

The Ryan White HIV/AIDS Program Part B National Monitoring Standards require an annual comprehensive monitoring site visits by grantees to subrecipients (see Section I.E. of the Part A and B Universal Standards). The visit must test compliance with Fiscal, Programmatic, and Universal Standards. The usefulness of desk audits and any timelines for their use are determined by the grantee. Desk audits may not be used as a substitute for comprehensive annual site visits.

The grantees or lead agencies/consortia may want to develop a fiscal and program tool to use to ensure that each subrecipient or lead agency contractual obligation is reviewed in sufficient detail. A site visit might include staff interviews, observation of services, client records or chart reviews, a facility tour, and a review of documentation and testing relating to the following compliance aspects of subrecipient operations.

There is no expectation that all client records must be reviewed during a site visit. A random sampling methodology should be established as part of the monitoring protocols. The sample size is not specified in the National Monitoring Standards, because it depends on the size of the client population being sampled and on the number and complexity of the variables being reviewed. While a specific sample size is not required, the norm to review for a client population of 50 or less is 100% of folders; 50% or less is acceptable for a population of 51 to 100. The percent to be sampled gets smaller as the population gets larger – from 10% for a client population of 500 or more to 3 to 5% for a client population of 1,000 or more.

Annual Site Visit Waiver

While grantees must maintain compliance with the monitoring of subrecipients, grantees can request a waiver from the requirement to conduct site visits annually. A waiver request letter must be submitted through the EHB prior approval portal, and must include:

- Barriers and challenges binding the program from conducting annual visits;
- Frequency and/or schedule of site visits the program can conduct;
- Site visit protocol (if available, send as attachment);
- A monitoring plan for the years the visits will not be conducted;

- Process for issuing and monitoring corrective action plans;
- Number of staff participating on the site visit team; and
- The number of providers/subrecipients that the RWHAP Part B grantee funds.

Once an annual site visit exemption request approval has been provided to the grantee, the HAB Project Officer will monitor adherence to the revised site visit timeline during monthly monitoring calls and comprehensive site visits. Grantees who are granted the exemption must provide updates on their site visit monitoring activities when responding to future X07 Funding Opportunity Announcements and must submit a continuation request for an exemption to the annual site visit requirement through the prior approval portal in EHB within thirty days after the submission of the X07 grant application.

V. Chapter 6. References, Links, and Resources

1. National Monitoring Standards:
 - Fiscal Monitoring Standards: [Ryan White Part B](#) (PDF - 301 KB)
 - Program Monitoring Standards: [Ryan White Part B](#) (PDF - 492 KB)
 - Universal Monitoring Standards: [Part A & B](#) (PDF - 117 KB)
 - [Frequently Asked Questions](#) (FAQs) (PDF - 161 KB)
2. Policies and Program Letters: <http://hab.hrsa.gov/manageyourgrant/policiesletters.html>
3. [2 CFR Part 200 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards](#)
4. Ryan White Part B Funding Opportunity Announcement HRSA 15-004, FY 2015: <http://apply07.grants.gov/apply/opportunities/instructions/oppHRSA-15-004-cfda93.917-cidHRSA-15-004-instructions.pdf>
5. GAO Report on Oversight of Part A/B Grantees: <https://careacttarget.org/library/gao-report-oversight-part-ab-grantees>

For More Information

Please refer to the HAB Target Center at <https://careacttarget.org>.

Section VI: Clinical Quality Management

VI. Chapter 1. Introduction

The RWHAP Part B Program awards grants to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality HIV care and treatment for low-income people living with HIV (PLWH). In order to assess whether RWHAP-funded services are delivering high quality HIV care, clinical quality management programs are essential. By ensuring compliance with guidelines and protocols, by employing quality improvement methods and through training and technical assistance, clinical quality management programs help grantees develop and improve their systems of care, which is demonstrated by the improved health of the PLWH.

VI. Chapter 2. Legislative Background

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

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

“(ii) USE OF FUNDS-

(I) IN GENERAL- From amounts received under a grant awarded under section 2611 for a fiscal year, a State may use for activities associated with the clinical quality management program required in clause (i) not to exceed the lesser of--

(aa) 5 percent of amounts received under the grant; or

(bb) \$3,000,000.

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

VI. Chapter 3. HAB Program Expectations

The complexity of HIV care and the Ryan White HIV/AIDS Program's commitment to equal access to quality care for all HIV-positive individuals require systematic efforts to ensure that all RWHAP-funded services are delivered efficiently and effectively. The RWHAP legislative requirements for clinical quality management apply to all RWHAP-funded core medical and support services, whether provided by a direct grantee or a subrecipient/contractor. The ADAP must be included in the quality management program as well.

RWHAP Part B clinical quality management programs should use tested quality management concepts in developing and implementing their programs. These concepts include quality assurance, quality improvement, continuous quality improvement (CQI), and outcomes evaluation that includes performance measurement. Continuous quality improvement and quality assurance are particularly relevant because of their focus on managing program quality.

At a minimum, RWHAP Part B grantee quality management program 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), contracts, Memoranda of Understanding (MOU)/Letters of Agreement (LOA), statements of work and/or State/Territory contracts, including contractors/subrecipients at the consortia and sub-recipient level.

In addition to these required components, a successful quality management program should:

- Have identified leadership, accountability, and dedicated resources available to the program.
- Use data and measurable outcomes to determine progress toward evidenced-based benchmarks.
- Focus on linkages, efficiencies, and provider and client expectations in addressing outcome improvement.
- Be adaptive to change and fit within the framework of other programmatic quality assurance and quality improvement activities (*i.e.*, Joint Commission on the Accreditation of Healthcare Organizations [JCAHO], Medicaid, and other HRSA programs).
- Ensure that data collected are fed back into the quality improvement process so that goals are accomplished and improved outcomes are realized.

The requirements of a RWHAP Part B grantee to implement a Clinical Quality Management program are covered in Section D of HAB's RWHAP Part B National Monitoring Standards. More information on the RWHAP Part B National Monitoring Standards can be found in Section V, Chapter 3. DSHAP monitors grantee compliance with clinical quality management requirements through questions in funding opportunity announcements, progress reports,

monthly monitoring calls and site visits. States must sign assurances in their annual applications attesting that appropriate quality management programs are in place.

VI. Chapter 4. Measuring Clinical Quality with Performance Measures

HAB has created performance measures that RWHAP grantees can use to monitor the quality of care and services they provide. These measures have been developed and revised to emphasis HAB's priorities and in keeping with data that is already required for grant reporting. HAB 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* and *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection*, among other Federal and national guidelines for the care and treatment of PLWH.

HAB sought and received national endorsement from the National Quality Forum (NQF) for a selection of HAB's HIV performance measures in 2012. This national endorsement is important as many payers of health care, including insurance companies and the Centers for Medicare and Medicaid Services, choose or favor nationally endorsed performance measures when selecting measures to include in their programs.

The performance measures can be used at the provider or system level. RWHAP grantees are encouraged to use the "core" measures for all funded service categories and to adopt the other measures as appropriate for their program. For example, the viral load suppression measure can be used for ADAP clients as it measures the outcome of clients who receive antiretroviral therapy attaining the goal of therapy. Another example is using the medical visit frequency measure to assess transportation services.

The performance measures can be found on the HAB website: (<http://hab.hrsa.gov/deliverhivaidscares/habperformmeasures.html>). HAB also created Frequently Asked Questions (FAQ) to assist in the use of these performance measures. The [FAQs](#) are also available on the HAB website. The following table lists the HAB performance measures and indicates which have received NQF endorsement, which are included in HAB's In+Care Campaign, and which are also Department of Health and Human Services HIV measures.

HAB Performance Measures				
Category (with Links)	Measure	NQF Endorsed	In+Care Campaign	HHS HIV Measure
Core Clinical Measures <i>(Can be used for all service categories)</i> FAQs	Viral Load Suppression	X	X	X
	Prescribed Antiretroviral Therapy	X		X
	Medical Visits Frequency	X	X	X
	Gap in Medical Visits	X	X	
	PCP Prophylaxis			

HAB Performance Measures				
Category (with Links)	Measure	NQF Endorsed	In+Care Campaign	HHS HIV Measure
Measures For All Ages	CD4 Count			
	HIV Drug Resistance Testing Before Initiation of Therapy			
	Influenza Vaccination			
	Lipids Screening			
	TB Screening			
	Viral Load Monitoring			
Adolescent and Adult Measures	Cervical Cancer Screening			
	Chlamydia Screening			
	Gonorrhea Screening			
	Hepatitis B Screening			
	Hepatitis B Vaccination			
	Hepatitis C Screening			
	HIV Risk Counseling			
	Oral Exam			
	Pneumococcal Vaccination			
	Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan			
	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention			
	Substance Use Screening			
HIV-Infected Children Measures	Syphilis Screening			
	MMR Vaccination			
HIV-Exposed Children Measures	Diagnostic Testing to Exclude HIV Infection in Exposed Infants			
	Neonatal Zidovudine Prophylaxis			
	PCP Prophylaxis for HIV-Exposed Infants			
Medical Case Management (MCM) Measures	Care Plan			
	Gap in Medical Visits	X	X	
	Medical Visit Frequency	X	X	X
Oral Health Measures	Dental and Medical History			
	Dental Treatment Plan			
	Oral Health Education			
	Periodontal Screening or Examination			
	Phase I Treatment Plan Completion			
ADAP Measures	Application Determination			
	Eligibility Recertification			
	Formulary			
	Inappropriate Antiretroviral Regimen			

HAB Performance Measures				
Category (with Links)	Measure	NQF Endorsed	In+Care Campaign	HHS HIV Measure
<u>Systems-Level Measures</u>	Waiting Time for Initial Access to Outpatient/Ambulatory Medical Care			
	HIV Test Results for PLWH			
	HIV Positivity			X
	Late HIV Diagnosis			X
	Linkage to HIV Medical Services			X
	Housing Status			X

VI. Chapter 5. References, Links, and Resources

HIV/AIDS Bureau Performance Measures

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

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

National Quality Center (NQC)

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

<http://nationalqualitycenter.org/>

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

<http://nationalqualitycenter.org/index.cfm/17263>

HRSA Quality

HRSA’s primary goal is to “Improve Access to Quality Health Care and Services” and has a longstanding commitment to improve the quality of healthcare for people who are uninsured, isolated or medically vulnerable the in the United States. HRSA is active in improving quality at the Federal, state and local levels and at the point of care. The HRSA Quality website (<http://www.hrsa.gov/quality>) provides a centralized source of information and technical assistance for HRSA grantees and the safety net population.

Agency for Health Research and Quality

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

<http://www.ahrq.gov>

Section VII. Grants Administration

VII. Chapter 1. Introduction

RWHAP Part B grantees are responsible for the appropriate administration of the RWHAP Part B grant. The Federal rules governing grants management for the RWHAP are provided in the Ryan White HIV/AIDS Program legislation, OMB guidance, the Code of Federal Regulations (CFR), and HRSA policy notices and letters. RWHAP Part B grantees are expected to be familiar with these documents to assure that all contractors and service providers follow the procedures outlined in these documents.

RWHAP Part B grantees may choose to contract with other entities to provide certain aspects of administration of the RWHAP Part B grant (i.e. the entity has entered into a vendor or procurement relationship with the state, and is acting on behalf of the state). A **“lead agency”** is an organization the grantee contracts with to sub-contract with local service providers on behalf of the grantee. The lead agency is often responsible through its contract with the grantee to provide program and fiscal monitoring of the sub-contracted providers. **“Consortia”** are associations of public and nonprofit health-care and support service providers and community-based organizations that the State contracts with to provide, for a specific region(s) or the entire State: 1) planning, 2) resource allocation and contracting, 3) program and fiscal monitoring, and 4) required reporting. The lead agency and/or the consortium members may also deliver services for PLWH in areas receiving RWHAP Part B funding (more information on Consortia can be found in Section IX). Only agencies the RWHAP Part B grantee directly contracts with (or whom lead agencies or consortia contract with on their behalf) are considered **“first-tier entities” (formerly called ‘first-line entities)**. Entities providing services under subcontracts are second-tier entities. Both first and second-tier entities are also referred to as **“subrecipients”**.

As was noted earlier, this revised version of the RWHAP Part B manual uses the term “subrecipient” instead of “subgrantee” or “subcontractor”. The term “subrecipient” is being used to be consistent with the terminology used in the new Uniform Guidance, 2 CFR 200.93 and 2 CFR 200.330. The Uniform Guidance defines a subrecipient as a non-Federal entity that receives a subaward from a pass-through entity (i.e., a RWHAP Part B grantee) to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.

The RWHAP Part B grantee is ultimately responsible for the proper stewardship of all grant funds, even if some of the program and fiscal management of those funds is shared with a contracted lead agency or consortia.

The Division of Grants Management Operations (DGMO) in the Office of Federal Assistance Management (OFAM) at HRSA oversees the grant award process to Ryan White HIV/AIDS Program Part B grantees. DGMO handles business management aspects of the review, negotiation, award, and administration of grants, as follows:

- Receiving all grant applications.

- Monitoring the objective review process.
- Performing cost analysis prior to grant award and negotiating changes in budgets as necessary.
- Providing business management consultation and technical assistance.
- Signing and issuing grant awards, amendments to awards, close out of grants and notices of suspension and termination.
- Receiving and responding to all correspondence related to business activities.
- Receiving all documentation submitted for compliance with the terms and conditions of the grant award (progress reports, financial reports, revised budgets, and other conditions of award).
- Maintaining the official grant file.
- Conducting continuous surveillance of the financial and management aspects of grants, and resolving audit findings.

VII. Chapter 2. Grants Management Regulation and Policy Documents

RWHAP Part B grantees can find relevant information regarding the administration of grants in OMB guidance, the Code of Federal Regulations (CFR), the HHS Grants Policy Statement, HRSA policy notices and letters, and the National Monitoring Standards.

• New Uniform Grant Guidance – Formerly known as OMB Circulars

On December 26, 2013, the Office of Management and Budget (OMB) published new guidance for Federal award programs, OMB Uniform Guidance: Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Guidance). The Guidance was implemented by the Department of Health and Human Services (HHS) as 45 CFR Part 75 on December 26, 2014. The Guidance supersedes and streamlines requirements from OMB Circulars A-21, A-87, A-110, A-122, A-89, A-102 and A-133 and the guidance in Circular A-50 on Single Audit Act follow-up. It is a key component of a larger Federal effort to more effectively focus Federal grant resources on improving performance and outcomes while ensuring the financial integrity of taxpayer dollars.

The effective date of 45 CFR 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards is December 26, 2014, and the requirements are applicable to grants issued on or after that date. For RWHAP Part B Grantees, this means it is effective for all FY 2015 awards and audits beginning with the FY 2015 award. For non-Federal entities that are nonprofit organizations or institutions of higher education, there is a one-year grace period for implementation of the procurement standards in 45 CFR 75.316 through 75.325.

The Uniform Guidance addresses:

- Standards for financial management systems, including payments, program income, revision of budget and program plans, and non-Federal audits,
- Property standards, including the purpose of insurance coverage, equipment, supplies, and other expendable property,
- Procurement standards, including recipient responsibilities, codes of conduct,

- competition, procurement procedures, cost and price analysis, and procurement records,
 - Reports and records, including monitoring and reporting program performance reports, financial reports, and retention and access requirements,
 - Termination and enforcement,
 - Closeout procedures,
 - Cost Principles, and
 - Audits.
- **Grants Policy Statement**
RWHAP Part B grantees should also utilize the January 1, 2007, HHS Grants Policy Statement which serves as the general terms and conditions for all HRSA grants and cooperative agreements (<http://dhhs.gov/asfr/ogapa/grantinformation/hhsgps107.pdf>).
 - **Policy Clarification Notices and Program Letters**
In addition, HRSA develops policy clarification notices (PCNs) relating to the Ryan White HIV/AIDS Program legislation, providing guidance to grantees in understanding and implementing legislative requirements. Program letters provide additional guidelines to grantees. PCNs and program letters can be found at:
(<http://www.hab.hrsa.gov/manageyourgrant/policiesletters.html>).
 - **Notice of Grant Award**
The Notice of Award (NoA) references all the legislative and programmatic requirements of the grant. The grantees are responsible for meeting all grant specific terms, program terms, standard terms and for fulfilling all reporting requirements indicated in the NoA. A recipient indicates acceptance of an award and its associated terms and conditions by drawing or requesting funds from the Payment Management System. Failure to comply with any of the special conditions and/or reporting requirements of award by the specified due date may result in the suspension of the grantee's ability to drawdown funds, the disallowance of funds, or both.

In addition, the NoA includes a Special Remarks section which contains information such as matching requirements and expenditure limitations. There is also a contact section with names, addresses, and telephone numbers of persons to contact regarding grants management issues and/or programmatic issues.

VII. Chapter 3. Costs for Administration, Planning, Evaluation, and Clinical Quality Management

The Ryan White HIV/AIDS Program legislation allows for, but puts limits on, administration, planning and evaluation and clinical quality management expenditures.

Caps on Administration, Planning, Evaluation, and Clinical Quality Management Expenditures

In accordance with Section 2618(b)(3) of the PHS Act, grantees are allowed to use up to 10 percent of RWHAP Part B funding for the payment of administrative costs in any given grant year, with a total of 15 percent of the RWHAP Part B grant used for the combination of grantee administration, and planning and evaluation activities. Clinical Quality Management expenditures are not included in the administrative or planning and evaluation costs, but are subject to a cap of the lesser of 5 percent of amounts received under the grant or \$3,000,000.

RWHAP Part B grantee administrative, planning and evaluation costs charged to the RWHAP Part B grant must fall within the limits as calculated above. The calculations for planning and evaluation, administrative costs, and clinical 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 Base must be spent on the grantee's administration, planning, evaluation, and clinical quality management costs related to the ADAP. There is no requirement that funds taken out of non-ADAP Base amount for administration costs be used in any set proportion between ADAP and other program components.

Lead Agencies/Consortia with Statewide/Regional Management and Oversight Functions

If a RWHAP Part B grantee has contracted with an entity or consortia to provide statewide or regional RWHAP management and fiscal oversight (i.e., the entity or consortia has entered into a vendor or procurement relationship with the state, and is acting on behalf of the grantee), the cost of that contract would count toward the grantee's 10% administrative cap. Providers that the lead agency or consortia have contracted with are considered to be first-tier entities (subrecipients) of the State grantee and are subject to the aggregate 10% administrative cap for subrecipients.

Administrative Cap for First-tier Entities (Subrecipients)

The Ryan White HIV/AIDS Program legislation also specifies a cap on administrative expenditures of "entities and subcontractors to which a State allocates" Part B funds. The State grantee must limit the aggregate administrative costs of its first-tier entities (subrecipients) to 10 percent of the total funds awarded to those entities.

The term "subcontractor" as used in the RWHAP legislation refers to entities that receive funding directly from the grantee or lead agency/consortia acting on behalf of the grantee. Other entities that receive funding from first-tier subrecipients are not subject to the 10 percent aggregate administrative cost cap. As such, second and third tier entities' administrative costs are not included as part of the aggregate administrative costs.

The basis for calculating the aggregate administrative cost cap for first line entities under RWHAP Part B is the total amount remaining after the grantee takes its administrative, planning and evaluation and clinical quality management 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 and 5% (\$150,000) for clinical quality management. \$2,400,000 remains for distribution. Of this \$2,400,000, a maximum of 10 percent (\$240,000) can be charged to the RWHAP Part B grant for administrative costs. In this example, 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 RWHAP Part B funds cannot exceed \$240,000. The Grantee responsibility is to monitor all administrative costs to ensure they do not exceed the allowable rate.

Allowable Costs for Administration, Planning, Evaluation, and Clinical Quality Management Administrative Costs

Please note that not all of these costs may count towards the 10% administrative cost cap. Grantees should consult with their Project Officer and/or Grants Management Specialist for more specific guidance on which costs are excluded from the cost cap.

Administration:

Grantees may charge the following administrative costs to the grant (generally subject to the 10% administrative cost limit):

- Routine grant administration and monitoring activities, including the development of applications and the receipt and disbursement of program funds
- Development and establishment of reimbursement (340B rebate, Medicaid back billing) and accounting systems
- Preparation of required programmatic and financial reports, including RWHAP 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; including the activities carried out by consortia, if they exist
- Subrecipient monitoring activities including telephone consultation, written documentation, and onsite visits
- The receipt and disbursement of pharmaceutical funds
- Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily identified but are necessary to the operations of the organization. The term "facilities and administration" is used to denote indirect costs. "Facilities" includes depreciation on buildings, equipment and capital improvement, interest on debt associated with certain buildings, equipment and capital improvements, and operations and maintenance expenses. "Administration" includes general administration and general expenses such as the director's office, accounting, personnel and all other types of expenditures not listed specifically under one of the subcategories of "Facilities." (See 45 CFR 75.414 for additional information.)

For RWHAP Part B grantees providing care, the portion of indirect or direct facilities expenses such as rent, maintenance, utilities, etc. related to core medical and support services provided to clients to meet the goals and objectives of the Ryan White HIV/AIDS Program (i.e., clinic, pharmacy and other spaces primarily utilized for patient services, including food bank services, residential substance abuse treatment facilities, etc.) would NOT count against the 10% administrative cost cap.

Subrecipients may also charge administrative costs to the Ryan White HIV/AIDS Program. The following are examples of allowable administrative costs at the subrecipient level:

- Usual and recognized overhead activities, including established indirect rates
- Management oversight of specific programs funded under RWHAP Part B
- Other types of program support such as quality assurance, quality control, and related activities

Planning and evaluation includes grantee activities related to planning for the use of Part B funds and evaluating the effectiveness of those funds in delivering needed services. Specific activities that planning and evaluation funds may support for Part B programs 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

Clinical Quality Management activities may include but are not limited to:

- Capacity building
- Management of Clinical Quality Management Program (e.g. convening a quality committee, working with first line entities, implementing quality improvement projects, etc.)
- Data management (performance measure data collection, aggregation, analysis, and reporting)
- Clinical Quality Management site visit (patient chart audits, meeting with patients, etc.)
- Estimated patient experience (surveys, focus groups, patient interviews, etc.)
- Training (clinical care and quality-related)

Documentation of Compliance with Expenditure Caps

As part of their annual application, RWHAP Part B grantees are required to submit categorical budgets and narrative justifications to the HRSA for approval. These budgets must clearly specify costs 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.

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 administrative cost cap and 10% aggregate administrative cost cap for subrecipients 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 require subrecipients to use a budget format that clearly identifies the costs for administration. In their budget justifications, grantees will be required to identify the following information for “first-tier” subrecipients:

- The aggregate amount of funds available for the entities to spend on administrative costs.
- An estimate of the total amount of administrative costs each of the 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 attested to by the financial officer in charge of the Ryan White HIV/AIDS Program grant.

VII. Chapter 4. Client Charges and Program Income

Client Charges

In accordance with Section 2617(c) of the PHS Act, a Part B program must have a sliding fee scale if clients are billed for services. The HRSA/HAB Fiscal Monitoring Standards state that, unless waived, the grantee and subrecipient should have policies and procedures that specifies charges to clients for services, which may include a documented decision to impose only a nominal charge. This expectation applies to grantees that also serve as direct service providers and/or ADAP pharmacies.

No charges are to be imposed on clients with incomes below 100 percent of the Federal Poverty Level (FPL). Charges to clients with incomes greater than 100 percent of poverty are based on a discounted fee schedule and a sliding fee scale. The cap on total annual charges for Ryan White HIV/AIDS Program services (including ADAP) is 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.

Program Income

Income made from charges to RWHAP Part B clients or to insurance companies for services performed is considered program income. Service providers must retain program income derived from RWHAP-funded services. Service providers must use program income for program purposes 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. Program income funds are not subject to the Federal limitations on administration (10%), clinical quality management (5% or \$3,000,000 whichever is less), or core medical services (75% minimum).

VII. Chapter 5. Tracking and Reporting Unobligated Balances

The Unobligated Balance (UOB) Policy 12-02 for RWHAP Part B Formula, Supplemental and MAI funds provides guidance on RWHAP Part B unobligated balances and carryover provisions. RWHAP Part B formula funds include the RWHAP Part B Base and ADAP Base formula awards; and supplemental funds include the ADAP Supplemental, Emerging Communities and RWHAP Part B Supplemental awards. Grantees must separately track Part B Base, ADAP Base, ADAP Supplemental, Emerging Communities, and MAI grant funds and carryover funds for each of these grant fund categories as applicable.

The unobligated balance provision does not apply to funds from medication rebates under RWHAP Part B. By law, medications rebate amounts are not considered part of the grant award and are not subject to the unobligated balances provisions. Rebate funds should never be recorded as UOB on any FFR.

Unobligated Balances and Carryover of Funds

Grantees are required to submit an Estimated Carryover Request together with an estimated UOB 60 days before the end of the grant year (or by January 31st). Failure to submit a timely carryover request and estimated UOB in the EHB portal will result in a grantee being ineligible to receive RWHAP Part B formula carryover funds, even if the grantee later identifies and reports unobligated RWHAP Part B formula funds in the Final Federal Financial Report (FFR). In this situation the grantee would only be able to carryover unobligated balance of Minority AIDS Initiative (MAI) funds.

The Division of Grant Management (DGMO) requires a carryover request of unobligated formula funds to be submitted with the FFR or within 30 days after the FFR has been submitted. The request must contain the following information:

- The unobligated balance at the end of the grant year.
- The amount of funds available for carryover including the methodology used for determining the carryover amount.
- Source of the unexpended carry over funds (administrative, direct service, program support, certain provider categories).
- Proposed use (existing or new service, new priority, one-time use, maintenance of enhanced levels of service, and cost annualization in future years).
- Justification for use of funds (quantification of number of clients, units of service, link/responsiveness of proposed use to identified need).
- Time period proposed for use of funds and ability to use.
- Capacity of the grantee to make funds available for use and of the entities to utilize such funds in the designated time period.

Because RWHAP Part B grantees are required to expend rebate dollars prior to grant dollars, properly expended rebates may result in UOB. If so, grantees that document expenditure of rebates may request a waiver from the UOB penalty that would otherwise be imposed.

Once a grantee's carryover request is approved by HRSA, the grantee will be issued the carryover funds in a Notice of Award and will be able to expend the approved UOB in accordance with the purpose stated in the request. If funds are not expended in the carryover year, the funds will be cancelled and cannot be used in subsequent years.

Monitoring Compliance of Carryover Requests

In reviewing requests for approval of carry over funds, HAB will assess the following:

- History of expenditures and carry over requests.
- Specific situations regarding the current year's awards.
- Submission of the final FFR on or before July 30 reconciled with the grantee Payment Management System account.
- Intended purpose and budget justification for the request.
- Performance issues, including compliance with conditions of grant award.

VII. Chapter 6. Payer of Last Resort

By statute, the RWHAP funds may not be used for any item or service "for which payment has been made or can reasonably be expected to be made" by another payment source (Sections 2605(a)(6), 2617(b)(7)(F), 2664(f)(1) and 2671(i) of the Public Health Service (PHS) Act.). This means that grantees must assure that funded providers make reasonable efforts to secure non-RWHAP funds whenever possible for services to individual clients. Grantees should ensure that eligibility for other funding sources (e.g., Medicaid, CHIP, Medicare, state-funded HIV/AIDS programs, employer-sponsored health insurance coverage, and/or other private health insurance, etc.) is consistently assessed and enrollment is vigorously pursued, to extend finite RWHAP grant resources to new clients and/or needed services.

There are exceptions in the payer of last resort requirement for veterans and for PLWH eligible for Indian Health Services (IHS). HRSA/HAB Policy 07-07 provides specific guidance that RWHAP grantees may not deny services, including prescription drugs, to a veteran who is otherwise eligible for RWHAP services. Policy 07-01 states that programs administered by or providing services of the IHS are exempt from the "Payer of Last Resort" restriction for Parts A, B, and C by persons also eligible for benefits under IHS funded programs. In both of these instances, payer coordination on behalf of clients must respect client choice of payer in those cases where VA, IHS and Ryan White are the available payers.

It is important to remember that while the RWHAP is the payer of last resort, it is also able to complete coverage for health care and supportive services not covered by public health coverage or private health insurance plans, and also to pay for such coverage, if cost effective.

In cases where the operations of the RWHAP Part B Program and/or its eligibility determinations are made through a sub-contractual relationship, the grantee must ensure that the payer of last

resort requirement is met by its subrecipient, including the responsibility to vigorously pursue other funding sources.

VII. Chapter 7. Maintenance of Effort (MOE)

MOE Requirement

RWHAP Part B funds are not intended to be the sole source of support for HIV care and treatment services for States. The Ryan White HIV/AIDS Program legislation requires RWHAP Part B Program grantees to maintain State expenditures for HIV-related activities at a level equal to the 1-year period preceding the fiscal year (FY) for which the grantee is applying to receive a RWHAP Part B grant. The maintenance of effort requirement is important in ensuring that RWHAP funds are used to supplement, not supplant, existing State expenditures for HIV-related care and treatment services and to prevent RWHAP Part B funds from being used to offset specific HIV-related budget reductions at the State level. States must submit a signed assurance that maintenance of effort has been maintained, a description of a consistent data set of local government expenditures for two previous years that are counted towards the MOE, and methodologies for calculating MOE expenditures.

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.

The same eligible funds can be used to meet both a grantee's State Match requirement and the Maintenance of Effort (MOE) requirement.

MOE Documentation Requirements

To demonstrate compliance with the MOE provision, States and Territories must maintain adequate systems for consistently tracking and reporting on HIV-related expenditure data from year-to-year. The system must define the methodology used, be written and auditable, and must ensure that Federal funds do not supplant State spending but instead expand and enrich HIV-related activities.

The State/Territory must provide the following documentation in its RWHAP Part B grant application:

- Documentation (or worksheet) proving that the overall level of HIV-related expenditures has been maintained year-to-year for the previous two complete fiscal years (based on the grantee's fiscal year).
- A brief narrative explaining any changes in the data set where HIV-related expenditures have been reduced or where the purpose of an HIV-related expenditure has changed.
- A signed assurance that they are complying with the maintenance of effort requirement.

For documentation purposes, all communication between the grantee and state government agencies regarding maintenance of effort must be in writing or electronically documented. It is not acceptable to compile information by telephone without a documentary record.

MOE Monitoring and Compliance

Grantees are required to assure that maintenance of effort has been fulfilled. During a comprehensive site visit or at any time during the grant year HAB can request for review the following documents:

- Budget elements that document the contributions of the State or Territory.
- Description of the tracking/ accounting system that documents the State or Territory's contribution to core medical services and supportive services.
- Grantee budget for State or Territory contributions.
- The actual tracking/accounting documentation of contributions.

VII. Chapter 8. State Match

State Match Requirement

Section 2617(d) of the PHS Act requires States that have reported to the CDC more than one percent of U.S. HIV/AIDS cases in the two most recent fiscal years make available non-Federal contributions to match the RWHAP Part B (X07) funding they receive (matching is not required for RWHAP Part B Supplemental (X08) and ADAP Emergency Relief Funds (X09) awards). The required matching rate is based on the number of years the State meets the one percent threshold. The match ceiling is different for RWHAP Part B formula award (\$1 for each \$2 of Federal funds) and the ADAP Supplemental grants (\$1 for each \$4 of Federal funds) and the match requirement for ADAP Supplemental funds can be waived. The RWHAP Part B formula award and ADAP Supplemental matching amounts are based on the amount of the award, not the amount of grant funds actually expended.

Determining the Rate of State Match

Section 2617(d) of the Ryan White HIV/AIDS Program legislation outlines how the rate of state match is determined for relevant grantees:

- 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);
- 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);
- 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);

- 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
- 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).

All years in which a state meets the condition are included in establishing the required match, even if those years are not consecutive. Historically, 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, the years in which that State meets the one percent threshold are counted in determining the required rate of match.

Determining the Elements That Constitute the State Match

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 for HIV-related services whether or not the contributions are made specifically for RWHAP programs. In-kind contributions are defined as non-cash contributions that a State may provide to support HIV-related services that must be fairly valued, and may include plant equipment or services.

The HRSA/HAB National Monitoring Standards, Fiscal Monitoring Standards, provides additional clarification on the State matching requirements. 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.

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 other RWHAP services and/or ADAP.
- Prescription drug rebates.
- State Pharmacy Assistance Programs.
- State-funded salaries of RWHAP Part B staff.
- State funds spent on health insurance.
- State-funded ADAP delivery fees.

- State Department of Correction expenditures on care and treatment for HIV+ inmates.
- The State share of Medicaid expenditures for PLWH.
- State contributions to HIV prevention and surveillance activities.
- State contributions to HIV research.

The same eligible funds can be used to meet both a grantee's State Match requirement and the Maintenance of Effort (MOE) requirement.

State contributions claimed as match for other Federal programs (such as Medicaid) may not be used to meet the match requirement for the RWHAP 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.

If a State is aware that it is unable to match the amount required in the legislation, HRSA can reduce the RWHAP Part B grant award to an amount the grantee is able to match. If HRSA discovers after the close of a grant year that a grantee has not met its match requirement, HRSA can recoup the difference of the award the grantee was unable to match.

RWHAP Part B Match Documentation Requirements

Since the Secretary may not make a grant award under Ryan White HIV/AIDS Program Part B unless the State agrees to make available the required match, the State must provide documentation with its RWHAP 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 RWHAP Part B Application Guidance for States. While the RWHAP 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.

RWHAP Part B grantees are also required to document that the required State match for the grant has been met on the Final FFR. In addition, States must describe the activities, personnel, and other object class categories actually supported through use of matching funds in the Final Progress Report due 90 days after the end of the budget period.

Ability to Request a Waiver for ADAP Supplemental State Match Requirement

Section 2618(a)(2)(F)(ii) of the PHS Act outlines the opportunity for a grantee to request a waiver of the supplemental drug treatment grant match requirement if the State has otherwise fully complied with a match required for the Part B Base award. The request for a waiver is made as part of the annual RWHAP Part B application.

VII. Chapter 9. Grantee and Provider Contract Requirements

According to Uniform Grant Regulations, state grantees must use their own procurement procedures that reflect applicable State and local laws and regulations. A contract must contain the clauses necessary to ensure that all requirements under the grant will be satisfied. A full list of required contract clauses is contained in 2CFR Part 200, Appendix II.

VII. Chapter 10. References, Links, and Resources

1. ADAP Manual 2012: <http://hab.hrsa.gov/Resources/adap/adapmanualfinalv9.0124d.pdf>
2. [2 CFR Part 200 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards](#)
3. HHS Grants Policy Statement, January, 2007:
<http://dhhs.gov/asfr/ogapa/grantinformation/hhsgps107.pdf>
4. U. S. Department of Health and Human Services, Health Resources and Services, HIV/AIDS Bureau, Division of State HIV/AIDS Programs, Ryan White Part B Guidance, 2012:
<http://apply07.grants.gov/apply/opportunities/instructions/oppHRSA-13-158-cfda93.917-cid5421-instructions.pdf>
5. Grantee Basics: <http://hab.hrsa.gov/manageyourgrant/granteebasics.html>

For More Information

Please refer to the HRSA HIV/AIDS Program at <http://hab.hrsa.gov>.

Section VIII. Planning Requirements for RWHAP Part B

VIII. Chapter 1. Introduction

For the RWHAP Part B, States and territories are required to undertake needs assessment, priority setting, and resource allocation activities as integral parts of the RWHAP Part B planning process. Results from the needs assessment should be used in developing the Statewide Coordinated Statement of Need and the State's Comprehensive Plan, and in crafting the annual implementation plan and specific strategies for addressing needs. Needs assessment results can also provide baseline data for evaluation and help the State and its subrecipients improve services.

Ryan White HIV/AIDS Part B grantees must ensure appropriate needs assessment and planning for the use of RWHAP Part B funds to provide essential health and support services. Whether accomplished through regional or statewide planning bodies, planning is an essential part of determining how to use limited RWHAP Part B funds in providing a system of HIV/AIDS care and to ensure that the RWHAP Part B is the payer of last resort.

The Ryan White HIV/AIDS Part B grantee can choose to oversee planning itself through Statewide or regional planning bodies, or the State can assign the responsibility to a consortia. Consortia are associations of public and nonprofit health-care and support service providers and community-based organizations that the State contracts with to provide, for a specific region(s) or the entire State, planning, resource allocation and contracting, program and fiscal monitoring, and required reporting.

Both the State and its consortia have designated responsibilities in the areas of planning and delivery of RWHAP Part B services. Regardless of the structure, planning requires broad membership involvement in order to bring diverse experience and input into such tasks as needs assessment, developing a comprehensive plan, setting priorities, and recommending the allocation of funds to service categories. While RWHAP Part B planning bodies are not responsible for service dollar allocation (as in RWHAP Part A), the RWHAP grantee should take measures to ensure that the planning body(ies) do not discuss procurement or discuss individual providers.

The RWHAP Part B legislation describes the State's responsibilities related to planning efforts, processes, and bodies. The chapters that follow will provide detailed legislative background related to relevant issues addressed.

VIII. Chapter 2. Legislative Background

The Ryan White HIV/AIDS Program Legislation contains numerous references to planning requirements for RWHAP Part B funded grantees. The following is a list of key planning-related topics and where they are referenced in the legislation:

- **Participation in Public Planning Processes**

Planning body requirements for States are outlined in Section 2617(b)(6) and (7).

- **Consortia**

RWHAP Part B planning body requirements for consortia are outlined in Section 2613.

- **Needs Assessment**

- The requirement for the State to submit a RWHAP Part B application that contains [in part] a determination of the needs of the population with HIV/AIDS in the State is outlined in Section 2617(b)(3).
- The requirement for the State to determine the size and demographics of the population of individuals with HIV/AIDS in the State as well as the needs of such population is found in Section 2617(b)(2) and (b)(3).
- The requirement for the State to assess the needs of persons with HIV/AIDS unaware of their status through a comprehensive plan is found in Section 2617(b)(8).
- Section 2618(a)(2)(F) describes the needs assessment process for awarding supplemental treatment drug grants under RWHAP Part B as including the demonstration of severe need, including factors such as eligibility standards, formulary composition, inability of State to provide therapeutics to eligible persons, and anticipated increase of eligible PLWH.
- The requirement for the State to submit a detailed description of the severity of need and the manner in which the State will use amounts received under the Emerging Communities grant is found under Section 2621.
- Section 2620(b) specifies the factors that the Secretary may consider in making awards for demonstrated need.

- **Comprehensive Plan**

The requirements for the States to develop a comprehensive plan are outlined in Section 2617(b)(5).

- **Legislative Requirements for Use of Funds**

The provisions relating to use of funds that must be factored into the priority setting and resource allocation process are found in Section 2612.

- **RWHAP Part B Responsibility for Convening the Statewide Comprehensive Statement of Need (SCSN)**

The requirement of the State for convening the SCSN for all RWHAP grantees is found in Section 2617(b)(5)(F) and Section 2617(b)(6).

VIII. Chapter 3. Needs Assessment

Introduction

RWHAP Part B needs assessment is a process of collecting information about the needs of PLWH—both those receiving care and those who are not in care. Steps involve gathering data from multiple sources on the number of HIV and AIDS cases, the needs and service barriers of PLWH, and current resources (RWHAP and other) available to meet those needs. This information is then analyzed to identify what services are needed, what services are being provided, and what service gaps remain, overall and for particular groups of PLWH.

Components of a Needs Assessment

A comprehensive needs assessment includes specific components. The needs assessment plans and timelines should be reviewed on an annual basis, and, on a periodic basis as determined by the overall timeline, the components should be expanded and/or updated, depending on trends and special issues facing the RWHAP Part B program. The major components of a comprehensive needs assessment are:

1. **Epidemiologic profile**, which describes the current status of the epidemic in the RWHAP Part B State/Territory, specifically the prevalence of HIV and AIDS overall and among defined subpopulations. The Centers for Disease Control and Prevention (CDC) and HRSA's *Integrated Guidelines for Developing Epidemiologic Profiles* provide guidance for preparing such a profile and is available on the CDC website: http://www.cdc.gov/hiv/pdf/guidelines_developing_epidemiologic_profiles.pdf. The profile should also describe demographic and geographic trends in the epidemic. Needs assessment based on analysis of epidemiologic data can provide an understanding of populations most likely to be undiagnosed, including their race/ethnicity, age, gender, risk factors, and places of residence.
2. **Assessment of service needs** (including core medical services and support services) among affected populations, including barriers that prevent PLWH both in and out of care from receiving needed services or from continuing in care. A needs assessment should gather an array of information in order to identify trends and common themes. States and territories should collect this information from multiple sources, among them PLWH and other community members, health departments, the State Medicaid agency, community-based providers and, where applicable, grantees of other Ryan White HIV/AIDS Program Parts. Information must be obtained from and about HIV-positive individuals who know their status and are not in care.
3. **Resource inventory**, which describes organizations and individuals providing the full spectrum of services available to PLWH. The goal of the resource inventory is to develop a comprehensive picture of **services, regardless of funding source**. At a minimum, the resource inventory includes for each provider a description of the types of services provided, number of clients served, and funding levels and sources. (Note: A resource inventory can often be turned into a resource for clients and providers to use in locating

services, especially online. In this format, data on number of clients served and funding levels is usually removed).

4. **Assessment of service gaps**, which brings together the quantitative and qualitative data from all the other components on service needs, resources, providers, and barriers. This should include an assessment of needs for PLWH who know their HIV status but are not in care and an assessment of service gaps for all PLWH—both in and out of care. This should include identification of both categories of service that are unavailable or insufficiently available, or service gaps for specific population groups.

Unmet Need

Unmet Need is defined by HRSA/HAB as the number of individuals for which there is no evidence of any of the following three components of HIV primary medical care during a specified 12 month time frame: viral load (VL) testing, CD4 count, or provision of anti-retroviral therapy (ART). Unmet Need is further defined as the need for HIV-related health services by individuals with HIV who are **aware** of their HIV status, but are not receiving HIV primary health care. RWHAP Part B grantees are required to provide an updated estimate of unmet need in the jurisdiction using the HRSA/HAB Unmet Need Framework in the annual RWHAP Part B application. HRSA provides guidance on Unmet Need through the document “A Practical Guide to Measuring Unmet Need for HIV-Related Primary Medical Care: Using the Unmet Need Framework”, which is available on the HRSA website at:

<ftp://ftp.hrsa.gov/hab/unmetneedpracticalguide.pdf>.

Needs Assessment Principles and Strategies

RWHAP Part B grantees and their planning bodies are expected to apply the following principles and strategies in their needs assessment efforts:

- **Needs assessment is a partnership activity** of the grantee, the planning body, and the community.
- **Needs assessment is the basis for other RWHAP Part B planning activities.**
Assessment plays an important role in the development of an array of services for PLWH. RWHAP Part B programs use their results to help prioritize service needs and allocate funds, develop a comprehensive plan, and craft strategies to address these needs through the implementation plan and appropriate service models.
- **Needs assessments focus on particular areas of need**, with an emphasis on reaching those not in care or not aware of their status, identifying disparities in care, and identifying ways to enhance the service delivery system. Areas for attention are as follows:
 - **Focus on PLWH not in care and disparities in care.** Many needs assessments have primarily targeted PLWH who were receiving HIV-related services (individuals already “in care”). The RWHAP Part B legislation requires planning bodies to expand their needs assessments to also determine the needs of those individuals who know their HIV status but are not in care and to determine strategies for identifying HIV-

- positive unaware people and ensuring that they are tested and linked to care. Particular attention must also be paid to identifying disparities in access and services among affected subpopulations and historically underserved communities.
- **Identify capacity development needs.** Capacity development needs exist when disparities in the availability of HIV-related services are identified, particularly in historically underserved communities. In planning for capacity development, State planning bodies must determine the number and characteristics of subpopulations experiencing disparities in access and services. If the needs assessment identifies gaps in its ability to reach and address the needs of underserved populations or communities (e.g., insufficient access points, cultural or language barriers), the planning council and grantee must address capacity development needs.
 - **Address coordination with HIV prevention and substance abuse prevention and treatment.** Because RWHAP resources are only one source of HIV/AIDS care, needs assessments should identify where coordination across services is needed. Of particular importance is coordination with HIV prevention and with substance abuse prevention and treatment programs, including programs that provide comprehensive substance abuse treatment. Coordination with these services can enhance efforts to identify individuals with HIV who do not know their status and individuals who know their status but are not receiving primary health care, provide risk reduction services to these individuals, enable them to access and remain in care, and result in better attention to the full range of their needs.
 - **Identify need for early intervention services (EIS).** The RWHAP Part B legislation allows RWHAP Part B grantee to fund Early Intervention Services (EIS). The EIS service category includes four components: HIV testing and targeted counseling, referral services, linkage to care, and health education and literacy training that enable clients to navigate the HIV system of care. All four components must be present in order for RWHAP funds to be used for the EIS service category. Also, in order to consider this service for funding, the entity must demonstrate to the satisfaction of the chief elected official for the State involved that Federal, State, or local funds are otherwise inadequate for the early intervention services that the entity proposed to provide; and the entity will expend funds pursuant to such paragraph to supplement and not supplant other funds available.
 - **Obtain PLWH input.** The RWHAP Part B legislation requires States to use methods such as community/public meetings for obtaining input on community need and priorities. Such input enables them to fulfill the legislative requirement to establish priorities for the allocation of RWHAP Part B funds with attention to the needs of PLWH.
 - **States should establish a needs assessment cycle.** RWHAP Part B grantees are not expected to conduct a comprehensive needs assessment each year. HAB/DSHAP recommends that the State establish needs assessment cycle that is sufficient to provide information for the HAB and CDC Comprehensive Plan and the SCSN, with a schedule

for collecting updated information to address special areas and support priority-setting and resource allocation activities. Epidemiologic data should be obtained annually, information on new populations added, and special circumstances—such as the impact of advances in medical treatments on service needs or the impact on health care reform on coordination of care—addressed promptly.

- **Needs assessment should include analysis of the impact of changes in the health care system and the HIV/AIDS continuum of care.** Especially during these times when considerable changes are occurring in the health care system and in the HIV/AIDS continuum of care and payers, needs assessment should include efforts to understand the implications of such changes on PLWH. For example, as more PLWH become eligible for Medicaid or for subsidized private insurance under the health insurance exchanges authorized by the Affordable Care Act, what are the implications for the demand for RWHAP Part B services? What services will not be available through the State Medicaid system or through the exchange, and therefore will continue to be needed from RWHAP Part B? If the transition is causing some PLWH to fall out of care, then RWHAP Part B services may need to be restructured to address this problem.

VIII. Chapter 4. Statewide Coordinated Statement of Need

Introduction

The Statewide Coordinated Statement of Need (SCSN) is a written statement of need developed through a collaborative process with other Parts of the RWHAP. The SCSN must reflect, without replicating, a discussion of existing needs assessments and should include a brief overview of epidemiologic data, existing quantitative and qualitative information, and emerging trends/issues affecting HIV/AIDS care and service delivery in the State. Important elements in assessing need include a determination of the population with HIV who are aware of their status but not in care (unmet need), individuals who are unaware of their HIV positive status, a comprehensive understanding of primary care and treatment in the State, and a consideration of all available resources. Requirements and instructions for developing and submitting the SCSN are provided to RWHAP Part B Grantees prior to the SCSN being due.

SCSN Purpose

The purpose of the Statewide Coordinated Statement of Need (SCSN) is to provide a collaborative mechanism to identify and address significant HIV/AIDS care issues related to the needs of PLWH, and to maximize coordination, integration, and effective linkages across the RWHAP Parts (A, B, C, D, and F). In addition, the SCSN process is expected to result in a document that reflects the input and approval of all RWHAP Parts. The RWHAP Part B grantees are assigned the responsibility for periodically convening a meeting for the purpose of developing a SCSN and submitting the SCSN to HRSA/HAB, Division of State HIV/AIDS Programs. However, HRSA views all RWHAP Parts equally responsible for the development of the process, their organization's participation, and the development and approval of a collaborative SCSN.

The SCSN must be developed with input from:

- (1) representatives of all RWHAPs, including administrators of the AIDS Education and Training Centers, the Dental Reimbursement Program and Special Projects of National Significance Demonstration Grants operating in the State. Part A representation should include grantee and Planning Council representatives. RWHAP Part Bs should include Consortia, direct care providers, and grantee administrators;
- (2) PLWHs;
- (3) members of a federally recognized Indian tribe as represented in the State;
- (4) providers; and
- (5) public agency representatives.

States are also encouraged to include representation from other major providers or funders of services needed by PLWH such as substance abuse, mental health, Medicaid, Medicare, Community Health Centers, Veteran's Administration, HIV prevention, as well as other entities that may be appropriate for developing a coordinated strategy to link newly identified PLWH to appropriate health and support services.

Coordination among needs assessment efforts is extremely important and is increasing, both among Ryan White HIV/AIDS Program Parts and between Ryan White HIV/AIDS Program and HIV prevention community planning processes. In particular, the Statewide Coordinated Statement of Need (SCSN) represents an opportunity to coordinate needs assessment activities that are conducted across Ryan White HIV/AIDS Program Parts. This occurs, for example, when RWHAP Part A and Part B planning bodies collaborate within a regional service area, when consortia across a State cooperate or collaborate on their individual needs assessments, or when Part C or Part D programs participate in RWHAP Part A and Part B needs assessment efforts.

HRSA encourages its grantees to use the SCSN to support HIV planning statewide. This may include using the goals outlined in the SCSN to set out measurable objectives, inform resource allocation decisions, create a statewide plan, or any other activity that would enhance HIV care and service delivery statewide. The SCSN is not intended to supplant local needs assessment, planning, and priority setting processes.

SCSN Process

The mechanism for developing the SCSN can be a series of statewide meetings, meetings organized based on epidemiologic data or some other locally developed process, as long as the criteria meets HAB/DSHAP requirements. The mechanism must ensure participation of all other Parts (A, B, C, D, and F) and the inclusion of HIV prevention program is strongly encouraged.

The SCSN process should consider all RWHAP **resources** in the State, both the amount of funds and what services the funds are supporting. Where possible, the value of non-RWHAP resources in the State should be considered in determining need. The SCSN must identify broad goals and critical gaps in life-extending care needed by PLWH both in and out of care.

In developing a SCSN, States are also expected to use **needs assessments and comprehensive plans** completed by other Parts of the RWHAP in an effort to identify cross-cutting issues in the State. The cross-cutting issues and goals identified by this process will form the basis of the SCSN. The issues and goals identified in the SCSN should not be prioritized, but assessed equally. Some examples of cross-cutting issues and/or broad goals may include access to medications, increasing the number and percentage of cervical cancer screenings provided to women living with HIV/AIDS, developing and evaluating a clinical quality management program, and decreasing unmet need.

An important element in assessing statewide need includes describing the needs of individuals who are unaware of their HIV status. The early intervention of individuals living with HIV/AIDS (EIIHA) Initiative supports all three of the National HIV/AIDS Strategy (NHAS) goals: 1) reducing the number of people who become infected with HIV, 2) increasing access to care and optimizing health outcomes for PLWH, and 3) reducing HIV-related health disparities.

HAB reviews each SCSN submitted and provides comments back to the RWHAP Part B grantee. Review of the SCSN allows HAB/DSHAP to identify cross-cutting issues across jurisdictions.

VIII. Chapter 5. Comprehensive Planning

Introduction

The Ryan White HIV/AIDS Program legislation requires RWHAP Part B grantees to submit a Comprehensive Plan. The purpose of this multi-year Plan is to assist grantees in the development of a comprehensive and responsive system of care that addresses the needs and challenges that change over time reflective of the HIV Continuum of Care in the State/Territory. The Comprehensive Plan is a living document that serves as a roadmap for grantees and should be continually updated, as needed. The Comprehensive Plan should reflect a community's vision and values regarding how best to deliver HIV/AIDS services, particularly in light of funding reductions in Federal, State, and local resources.

HRSA and CDC encourage RWHAPs and HIV prevention programs at the local and state level to integrate planning activities to help further progress in reaching the goals of the National HIV/AIDS Strategy and improving outcomes on the HIV Continuum of Care. These encompass comprehensive needs assessment, information and data sharing, cross representation on prevention and care planning bodies, coordinated/combined projects, combined meetings, and merged planning bodies. Planning groups are encouraged to streamline their approaches to HIV planning so that it increases access to and effectiveness of prevention, care and treatment services within the jurisdictions.

Requirements and instructions for developing and submitting the Comprehensive Plan are provided to RWHAP Part B Grantees prior to the Comprehensive Plan being due.

Focus of Comprehensive Plans

HAB/DSHAP expects States/Jurisdictions to develop multi-year comprehensive plans that will:

- Address disparities in HIV care, access, and services among affected subpopulations and historically underserved communities.
- Ensure the availability and quality of all core medical services.
- Address the needs of those who know their HIV status and are not in care as well as the needs of those who are currently in the care system.
- Address performance measures and other clinical and outcome measures.
- Address the goals of the National HIV/AIDS Strategy.
- Outline how efforts are coordinated with and adapt to changes in the health care system, such as those occurring because of health care reform.
- Include strategies that:
 - a. Identify individuals who know their HIV status but are not in care and inform these individuals of services and enable their use of HIV-related services.
 - b. Identify individuals with HIV/AIDS who do not know their HIV status, make them aware of their status, and enable them to use HIV-related services, with particular attention to reducing barriers to routine testing.
 - c. Provide goals, objectives, and timelines (as determined by the needs assessment).
 - d. Coordinate services with HIV prevention programs including outreach and early intervention services.
 - e. Coordinate services with substance abuse prevention and treatment programs.

The Comprehensive Plan must:

- be compatible with existing plans including the Statewide Coordinated Statement of Need (SCSN) and the CDC required HIV Prevention Comprehensive Plan;
- address the goals of the National HIV/AIDS Strategy; and
- address the objectives of Healthy People 2020.

Relationship between the Comprehensive Plan and the SCSN.

The Comprehensive Plan must be compatible with existing State and local service plans including and in particular the Statewide Coordinated Statement of Need (SCSN). The SCSN is a collaborative mechanism coordinated by the RWHAP Part B that is designed to identify and address significant HIV/AIDS care issues related to the needs of PLWH, and to maximize coordination, integration, and effective linkages across all RWHAP Parts.

VIII. Chapter 6. PLWH/Consumer Participation

RWHAP Part B planning creates a participatory planning process to ensure that local health care and social service programs are responsive to the needs of PLWH. Unique PLWH perspectives are a major benefit of consumer involvement in such terms as design of appropriate services and identification of needs.

Recruitment measures are needed to secure representation on the planning body, such as a variety of outreach methods to identify potential members. Retention measures are needed to help consumer members stay engaged and participate fully, such as orientation and training, mentoring, and financial support for the costs of participating.

Benefits of Consumer Participation

- **Consumer Perspective.** PLWH provide a critical consumer perspective on RWHAP Part B service planning, delivery, and evaluation. Consumers should reflect the diversity of the local epidemic, which provides for a range of perspectives that contributes to informed decision making.
- **Reality Check.** PLWH help keep the members of the consortium focused and on track by providing a first-hand perspective on issues facing PLWH and their families. PLWH can discuss their actual experiences in seeking and obtaining services.
- **Help in Needs Assessment.** PLWH can help ensure that needs assessments consider the needs of PLWH from differing populations and geographic locations, including those in and out of care. They can help recruit other PLWH for town halls, focus groups, and other input sessions.
- **Identifying Service Barriers.** PLWH can identify service barriers that may not be evident to others and can help consortia plan to overcome those barriers.
- **Outreach.** PLWH can help identify ways to reach the PLWH communities served, including minority and other special populations with unmet need for services.
- **Quality Management.** PLWH who are clients of Ryan White HIV/AIDS Program services can provide direct feedback on the quality of services. Their voices can help determine what services are needed, including how to improve service delivery models.
- **Community Liaison.** PLWH provide an ongoing link with the community. They can bring community issues to the group, as well as help to bring research and care information to the community.

VIII. Chapter 7. Coordination between RWHAP Parts and Programs and Other Payers

A. Introduction

RWHAP Part B planning efforts should be coordinated with all other public funding for HIV/AIDS to: ensure that RWHAP funds are the payer of last resort; maximize the number and accessibility of services available; and reduce any duplication of services. For RWHAPs, the goal of coordination is to enhance access to a range of services in order to both achieve better client health outcomes and use RWHAP resources wisely.

Coordination with other RWHAP Parts

As was covered earlier, coordination within the RWHAP community occurs through specific efforts of grantees to work together, such as the collaborative planning process to develop the Statewide Coordinated Statement of Need (SCSN) which includes input from all RWHAP Parts.

In exploring ways to work together, RWHAP Part A and B planning bodies must consider the following differences in their respective authority and autonomy.

- RWHAP Part A planning councils are public bodies established by the EMA's/TGA's chief elected official (CEO). Legislation defines their key responsibilities, such as determining service priorities, allocating resources to priority service categories, and assessing the administrative agent's timeliness in disbursing funds. The procurement process and monitoring of funded service providers are grantee responsibilities. Legislation forbids planning council participation in the procurement process.
- RWHAP Part B planning bodies are not defined in the legislation. As such, they have a more varied structure and membership than planning councils. RWHAP Part B planning bodies are shaped primarily by the grantee. They may be incorporated bodies with responsibility not only for needs assessment and planning, but—unlike planning councils—also for procurement and contract management. In some areas, a separate local lead agency fulfills those roles or the State may serve as lead agency.

Coordination with non-RWHAP Programs and Payers

RWHAP Part B Grantees are required to collaborate with other publicly funded programs in the assessment of need, priority setting and resource allocation, and development of their comprehensive plans. Among the most important are Medicaid (by far the largest public payer of HIV care), Medicare (the second largest public payer of HIV care), CHIP, and private health insurance (a source of payment accessible to PLWH through RWHAP via health insurance continuity payments, which can cover both continuation of existing policies and purchase of new ones). Others—defined by their services as well as their payer status—include Veterans Affairs, substance abuse prevention and treatment services (funded extensively through State block grants and other public and private mechanisms), maternal and child health care, and HIV prevention (including Centers for Disease Control and Prevention (CDC) HIV prevention). Also important are community health centers and providers of services to the homeless and substance abusers.

Integrated HIV Care Planning with HIV Prevention

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) and the Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP) support integrated HIV prevention and care planning groups and activities. Integrated HIV planning approaches by State and Territorial Health Departments can help further progress in reaching the goals of the National HIV/AIDS Strategy and improving outcomes on the HIV Continuum of Care.

In May 2013, HRSA and CDC issued a letter encouraging Ryan White HIV/AIDS Programs (RWHAP) and HIV prevention programs at the local and state level to integrate HIV planning activities. These integrated HIV planning activities encompass comprehensive needs assessment, information and data sharing, cross representation on prevention and care planning bodies, coordinated/combined projects, combined meetings, merged planning bodies, and joint strategic decision-making on responses to a jurisdiction's HIV epidemic. HIV planning groups are encouraged to streamline their approaches to HIV planning so that it increases access to and effectiveness of prevention, care and treatment services within the jurisdictions. A updated joint HRSA/CDC letter was issued on February 27, 2014, and is available at

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

HRSA and CDC have determined that the RWHAP Parts A and B Comprehensive Plans and the CDC Jurisdictional HIV Prevention Plan will be due in September 2016. Also due at that time will be the RWHAP Part B Statewide Coordinated Statement of Need (SCSN). HRSA and CDC are working to align the guidance(s) for the RWHAP Comprehensive Plans/SCSN and the jurisdictional HIV Prevention Plan to enable the submission of an integrated HIV Plan that is responsive to the requirements of both HRSA and CDC.

HIV prevention planning groups supported by CDC review existing resources, needs, gaps, current activities, and impacted populations for HIV prevention services and develop a jurisdictional HIV prevention plan that guides HIV prevention activities. The RWHAP planning groups supported by HRSA are required to annually plan, prioritize services and recommend allocation of resources to address the HIV service needs of people living with HIV (PLWH). Implementing comprehensive HIV prevention, care and treatment planning processes provides an opportunity for integration, synergy, and efficiency in responding to jurisdictional needs and federal requirements, and these have been successful in many states and local health departments. Good planning is imperative for effective local and state decision making to develop systems of prevention and care that are responsive to the needs of persons at risk for HIV infection and PLWH. Activities to collaborate and/or develop a joint planning body are supported by both HRSA and CDC. Community and stakeholder involvement as well as jurisdictional ownership of their HIV continuum of care data is an essential component for planning comprehensive, effective HIV prevention, care, and treatment programs in the United States.

Potential Areas of Coordination

Coordination with non-RWHAP Part B programs and payers can occur in the following areas:

- 1) **Planning.** Coordination in RWHAP planning involves consideration of other programs in such areas as assessment of needs, priority setting, and resource allocation. Required representation of other Federal programs on planning bodies is designed to ensure their participation in Part B planning. To illustrate, needs assessments should determine existing resources, regardless of funding stream, as part of efforts to identify areas of unmet need. In setting priorities, other resources must be considered in terms of how they help meet service demands so that RWHAP resources can be used to fill gaps.

Other examples of coordination between HIV prevention and care in planning include:

- Development of a single epidemiologic profile
 - Preparation of a joint resource inventory
 - Cooperation on other components of a needs assessment
 - Development of formal linkages between prevention and care providers, and
 - Development of plans for specific joint activities, such as collaborative outreach, a referral process linking HIV counseling and testing sites and primary health care facilities, or an initiative focusing on preventing perinatal transmission.
- 2) **Funding of Services.** RWHAP grantees, including RWHAP Part B programs, are required to coordinate their services and seek payment from other sources before

RWHAP funds are used. This makes the RWHAP the “payer of last resort,” meaning that funds are to fill gaps in care not covered by other resources. Major payers include Medicaid, Medicare, the Children’s Health Insurance Program (CHIP), and private health insurance.

- 3) **Service Delivery.** RWHAP requires coordination with specific services (i.e., outreach, substance abuse prevention and treatment, HIV counseling and testing, and early intervention services) that are funded by other Federal, State, and local sources. For example, HIV prevention services are 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).

Coordination between care and prevention should occur in the planning and delivery of local HIV outreach programs designed to identify PLWH and help them learn about their HIV status and enter care, and in developing outreach activities that target women of childbearing age in order to reduce HIV perinatal transmission rates.

VIII. Chapter 8. References, Links, and Resources

Continuum of Care, Planning, Program Components (RWHAP Part B Administrative Overview): <https://careacttarget.org/library/continuum-care-planning-program-components-part-b-admin-overview>

Please refer to the Needs Assessment resources on the Target Center for more detailed information on needs assessment design and implementation:
<https://careacttarget.org/category/topics/needs-assessment>

For More Information

Please refer to the HAB Target Center at <https://careacttarget.org>.

Section IX. The Role of Consortia in RWHAP Part B Grants

IX. Chapter 1. Introduction

The Ryan White HIV/AIDS Program legislation indicates that the grantee may choose to establish a consortium to perform certain functions on behalf of the grantee. Consortia are associations of public and nonprofit health-care and support service providers and community-based organizations that the State contracts with to provide, for a specific region(s) or the entire State: 1) planning, 2) resource allocation and contracting, 3) program and fiscal monitoring, and 4) required reporting. The consortium may also deliver services for Persons Living with HIV in areas receiving RWHAP Part B funding. **All services provided by or contracted through consortia are considered support services and must be counted as part of the maximum 25% of service dollars that may be expended for such services.** Regional and Statewide RWHAP Part B consortia vary in size and composition of regions served.

IX. Chapter 2. Legislative Background

The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 and subsequent reauthorizations have specified the role and responsibilities of Consortia as part of a comprehensive system of medical, therapeutic, and supportive service delivery system. The changes over the years have added provisions related to comprehensive planning and who participates in the consortia planning bodies. The current legislation provides the specific responsibilities of RWHAP Part B consortia as follows:

Definition:

Section 2613(a) describes consortia as “an association of one or more public, and one or more nonprofit private, (or private for-profit providers or organizations if such entities are the only available providers of quality HIV care in the area) health care and support service providers and community based organizations operating within areas determined by the State to be most affected by HIV disease.”

Allowable Services

Specific services that may be provided by consortia include comprehensive outpatient health and support services for individuals with HIV disease as described in Section 2613(a)(2)(A) as follows:

- “(A) essential health services such as case management services, medical, nursing, substance abuse treatment, mental health treatment, and dental care, diagnostics, monitoring, prophylactic treatment for opportunistic infections, treatment education to take place in the context of health care delivery, and medical follow-up services, mental health, developmental, and rehabilitation services, home health and hospice care; and
- (B) essential support services such as transportation services, attendant care, homemaker services, day or respite care, benefits advocacy, advocacy services provided through public and nonprofit private entities, and services that are

incidental to the provision of health care services for individuals with HIV disease including nutrition services, housing referral services, and child welfare and family services (including foster care and adoption services).”

Consortia Services as “Support Services”

Section 2617(f) defines expenditures of consortia services as support services and not core services:

- “(f) Allocation of Funds; Treatment as Support Services- For purposes of the requirement of section 2612(b)(1), expenditures of grants under section 2611 for or through consortia under this section are deemed to be support services, not core medical services. The preceding sentence may not be construed as having any legal effect on the provisions of subsection (a) that relate to authorized expenditures of the grant.”

Plan for Serving Underserved Populations

Under Section 2613(b), consortia must, as the single coordinating entity, provide the State with certain assurances related to its serving underserved populations of individuals and families with HIV disease and establishing a service plan consistent with the State’s comprehensive plan under 2617(b)(4). The legislation does include an exception to the single coordinating entity provision where subpopulations exist with unique service requirements that cannot be adequately and efficiently addressed by a single consortium serving the entire community or locality.

Consortia Membership

Consortia must assure representation in their membership as described under 2613(c) to include agencies and community-based organization with a record of service to populations and subpopulations with HIV disease requiring care within the community to be served; and that are representative of populations and subpopulations reflecting the local incidence of HIV and that are located in areas in which such populations reside.

Assessment of Need

Under Section 2613 (c) planning activities and responsibilities through consortia must demonstrate that the consortium has carried out an assessment of service needs within the geographic area to be served and that the assessment of service needs and the planning of the delivery of services will include participation by individuals with HIV disease. Consortia must also demonstrate that they have created a mechanism to evaluate periodically their success of the consortium in responding to identified needs; and the cost-effectiveness of the mechanisms employed by them in delivering comprehensive care.

IX. Chapter 3. The Role of Consortia

The following functions are allowable for a RWHAP Part B consortium:

- **Planning**
The consortium can serve as entity that meets the RWHAP Part B planning requirements for a specific region or the entire State.
- **Resource allocation and contracting****
The RWHAP Part B grantee can contract with a consortium to set service priorities, procure RWHAP Part B funding, and contract with agencies to provide RWHAP Part B services for a specific region or the entire State.
- **Program and fiscal monitoring**
The consortium can serve as the agent for subcontract management, including monitoring of fiscal and programmatic performance and of quality management. In these cases, the consortium is responsible for all required aspects of monitoring (e.g. reports, site visits, etc.) and should work with the state to ensure that the consortium members providing services are adhering to all rules, regulations and policies.
- **Required reporting**
The consortium can be assigned responsibility for completing reporting required for the RWHAP Part B grant. Only the RWHAP Part B grantee can submit required reports.
- **Service Delivery****
The RWHAP Part B allows States/Territories to use RWHAP Part B funds to support HIV care consortia within areas most affected by HIV disease to provide a comprehensive continuum of care to individuals and families with HIV disease.

****All services provided by or contracted through consortia are considered support services and must be counted as part of the maximum 25% of service dollars that may be expended for such services.**

IX. Chapter 4. RWHAP Part B Grantee Responsibilities with a Consortia Model

Consortia are responsible to the RWHAP Part B grantee, and the grantee maintains ultimate responsibility for the RWHAP Part B grant and is held responsible for compliance with all grant terms and regulations. The grantee determines whether there will be consortia, and if so, specifies their geographic boundaries and responsibilities. The roles and activities required of a consortium depend upon the responsibilities delegated through contracts and/or MOU to it by the RWHAP Part B grantee, its structure and service area characteristics, and its funding level.

The grantee must ensure that the consortium follows all requirements of the RWHAP Part B grant. The grantee must provide oversight of consortia policies, procedures, and performance, with emphasis on procurement, subcontract management, grievance policies and procedures, and

conflict of interest management. The grantee must provide evaluation of the consortium as required in the RWHAP Part B Monitoring Standards.

IX. Chapter 5. References, Links, and Resources

For more information, please refer to the following resource on the HAB Target Center:
Training Guide: A Resource for Orienting and Training Planning Council and Consortium
Members (2003): <https://careacttarget.org/content/training-guide-resource-orienting-and-training-planning-council-and-consortium-members>

Section X. Technical Assistance

X. Chapter 1. Overview

The RWHAP includes a technical assistance (TA) and training component to support the work of Program constituents, including grantees, providers, planning bodies, and consumers. Activities include provision of TA tools and documents, onsite and distance-based consultations, expert meetings, and specialized TA centers.

X. Chapter 2. Legislative Background

Section 2619 of the PHS Act requires the Secretary to “provide technical assistance in administering and coordinating the activities authorized under section 2612 [the Ryan White Part B grant], including technical assistance for the development and implementation of statewide coordinated statements of need.”

X. Chapter 3. Purpose and TA Topics

TA is provided in areas related to the legislative mandates and programmatic requirements of the Ryan White legislation. Critical topic areas include:

- Access to care
- AIDS Drug Assistance Program
- Clinical care
- Clinical program development
- Consumer development and training
- Cultural competency
- Data collection and programmatic reporting (including client-level data)
- Engagement in care: recruitment and retention
- Fiscal and program management
- Medical case management
- Needs assessment
- Patient-Centered Medical Home
- Patient flow evaluation
- Pediatric and Perinatal Guidelines facilitation
- Peer-to-Peer TA or training
- Planning body operations
- Program and capacity development
- Quality
- Stigma
- Strategic planning
- Training peers to serve in health-care teams
- Unit cost analysis
- Unmet need
- Working with consumers to help address unmet needs by engaging others in care.

X. Chapter 4. How TA Is Provided

TA and training are provided through the following methods:

- The Technical Assistance Resources, Guidance, Education, and Training (TARGET) Center Web site (<http://www.careacttarget.org>), which provides centralized, Web-based access to all HAB TA resources and facilitates networking among Ryan White Program Parts. The TARGET Center comprises a telephone help desk, a library of HAB- and grantee-developed TA tools, a TA calendar of upcoming events and trainings, and Web links to all grantees.
- Individualized and onsite peer and expert consultation through a national Technical Assistance Contract (TAC). The TAC also coordinates consultative meetings and conferences, site visits, and conference calls.
- Assisting grantees in replicating successful Special Projects of National Significance (SPNS) to strengthen their capacity to deliver new methods of evidence-based HIV care.
- An array of cooperative agreements with national organizations to deliver TA in specific topics through local and regional workshops, Webcasts, Web-based learning modules, conference calls, onsite trainings, and technical publications and curricula.
- DSHAP Monthly Technical Assistance Webinars

X. Chapter 5. How to Obtain TA

To obtain more information about TA, contact your HAB project officer. A list of TA products is available on the Technical Assistance Resources, Guidance, Education, and Training (TARGET) Center Web site (<http://www.careacttarget.org>). Additional sources of TA are discussed in other sections of this Manual.

X. Chapter 6. References, Links, and Resources

1. Ryan White Technical Assistance Program Fact Sheet, 2012: <http://hab.hrsa.gov/abouthab/files/tafacts2012.pdf>
2. 340B Prime Vendor Program: <https://www.340bpvp.com/controller.html>
3. ADAP Manual 2012: <https://careacttarget.org/content/adap-manual>
4. HRSA/HAB Glossary of Terms: <http://hab.hrsa.gov/abouthab/glossaryterms.html>

For More Information

Please refer to the HAB Target Center at <https://careacttarget.org>.

Appendix A: HIV/AIDS Bureau Organizational Chart

