Ryan White HIV/AIDS Program

Part B Manual

U.S. Department of Health and Human Services
Health Resources and Services Administration
HIV/AIDS Bureau

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HRSA
Ryan White HIV/AIDS Program

July 2023 Updates

To ensure compliance with 45 CFR 75.381**,** the due dates for the end of the year reports have changed from 120 days to 90 days after the end of the budget period to align with grant regulations. These reports include the following:

- Annual Progress Report (X07, X08, and X09)
- Expenditures Report (X07, X08, and X09)
- MAI Annual Report (X07)

The Consolidated Appropriations Act, 2023, Pub. L. 117-328, Division H, § 237 confers flexibility or administrative relief from statutory penalties and administrative requirements that would be otherwise applicable, as was similarly authorized for Fiscal Years (FYs) 2020, 2021 and 2022. The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) previously implemented this authority by permitting waivers of six provisions for FY 2020 and 2021, and three provisions for FY 2022.

After a review of the utilization of the prior waivers and the continued impact of the COVID-19 pandemic on RWHAP recipients and subrecipients, two of the three waivers available in FY 2022 will be extended into FY 2023: the expedited distribution and penalty waiver for RWHAP Part B and the unobligated balances (UOB) waiver for RWHAP Parts A and B. For FY 2023 funding, both waivers will be non-automatic and therefore only available by request.

Below is a list of penalties that may be waived, if specifically requested. If the waiver is approved, recipients will not be penalized. HRSA HAB expects these requests to be rare. RWHAP recipients will be issued a Notice of Award indicating that the penalties associated with the requested requirement(s) are waived, as applicable.

- Expedited Distribution and Penalty –
    - The requirement that recipients obligate 75 percent of the award and associated penalties may be waived upon request. Recipients are still required to submit an interim FFR. §§ 2618(c) and (d) of the Public Health Service (PHS) Act.
    - The expedited distribution requirement and penalty may be waived for FY 2023 RWHAP Part B recipients for which the COVID-19 pandemic continues to impact the recipients' ability to make timely subawards. RWHAP Part B recipients that would otherwise be penalized must request this waiver.
- Unobligated Balances Penalty –
    - Requirements regarding the timeframe for obligation and expenditure of formula and supplemental RWHAP funds within the designated timeframe and associated penalties may be waived upon request. Recipients are still required to submit a final FFR. §§ 2603(c), 2609(d)(2), and 2622 of the PHS Act. Due to the timing of the final FFR, any UOB penalties that result from formula fund UOBs reported in the final FY 2023 FFRs will be waived during the FY 2025 award cycle.
    - The unobligated balances requirement and penalty may be waived for FY 2023 RWHAP Part B recipients for which the COVID-19 pandemic continues to impact recipients' ability to obligate grant funds. RWHAP Part B recipients that would otherwise be penalized must request a waiver.

NOTE: The Maintenance of Effort waiver for RWHAP Part A, Part B, Part C, and Part F Dental Programs was not extended into FY 2023.

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Section I: Preface

The Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) Ryan White HIV/AIDS Program (RWHAP) Part B Manual (from here on referred to as the RWHAP Part B Manual) is an informational resource for RWHAP Part B recipients (i.e., those who receive funds directly from the federal government) and their subrecipients. HAB, which is one of several offices and bureaus in HRSA, administers the RWHAP. HRSA is one of the agencies within the U.S. Department of Health and Human Services (HHS). HAB awards RWHAP Part B grants to the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau (from here on referred to as state(s)/territory(ies)) to assist the state/territory in developing and/or enhancing access to a comprehensive continuum of high-quality HIV care and treatment for low-income people with HIV. Each state/territory operates a RWHAP Part B, including a RWHAP AIDS Drug Assistance Program (ADAP). RWHAP Part Bs and RWHAP ADAPs vary significantly across states/territories in administrative structure and the mechanisms used to ensure access to HIV care and HIV medications for eligible people with HIV.

The RWHAP Part B Manual serves as:

- An orientation guide for new RWHAP Part B recipient staff, with sections explaining how the RWHAP Part B and ADAP are structured at the federal and state level, and the key issues and strategies used by the RWHAP Part B and ADAP to broaden access to HIV care and treatment to persons in need;
- A reference document for RWHAP Part B recipient staff on legislative, grant regulation, and program requirements, including links to source documents;
- A tool to guide RWHAP Part B recipient staff in managing fiscal and program components; and
- A source for information about where to obtain additional information and technical assistance (TA).

Please note: The HAB Division of State HIV/AIDS Programs (DSHAP) has published a manual specific to the operations of ADAPs. The RWHAP ADAP Manual presents a comprehensive overview of ADAP-specific guidance, and that information is not repeated in this manual. Thus, the ADAP Manual and RWHAP Part B Manual should be used as companion documents. The RWHAP ADAP Manual is available at: https://ryanwhite.hrsa.gov/grants/manage/recipient-resources.

Organization

The RWHAP Part B Manual includes 10 sections, each comprised of several chapters. Each section includes the following:

- **Introduction:** Introduces the topic area for discussion in the section, including its importance.
- **Relevant Authorities:** Reviews RWHAP legislation as well as applicable regulatory requirements, grants administration policies, and program-specific policies that authorize and establish requirements for the topic.
- **Program Direction and Implementation:** Provides explanation of relevant authorities and division guidance to enhance recipient understanding of their roles and responsibilities in meeting program requirements and improving systems of HIV prevention, care, and treatment in their state/territory.
- **Technical Assistance Links and Resources:** Provides hyperlinks to tools, instructional manuals, and/or other documents that can further enhance understanding or support implementation of the topics introduced in the section.

The first sections of the manual are most helpful to those unfamiliar with the RWHAP Part B and ADAP, including new staff, as they provide a comprehensive overview and sources for additional information and assistance. Subsequent sections cover RWHAP Part B management and technical issues in more detail.

Routine Updates

HRSA HAB staff will review and update the RWHAP Part B Manual periodically. Recipients are encouraged to share recommendations for future enhancements to the manual or other feedback with their assigned HRSA HAB project officer (PO).

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

II. Chapter 1. Introduction

Since its onset in the early 1980s, the HIV epidemic has taken an enormous toll in the United States. However, with advances in science and antiretroviral therapy, HIV has become a manageable condition, and people with diagnosed HIV now can live a near normal lifespan. In the U.S., there are an estimated 1.2 million people with HIV aged 13 years and older (i.e., prevalence), of whom approximately 13 percent are unaware they have HIV.[1] The number of new HIV infections (i.e., incidence) has declined 8 percent since 2015, with an estimated 34,800 people newly diagnosed with HIV in 2019, after being relatively stable since 2013.

Congress first enacted the RWHAP legislation in 1990 to improve the quality and availability of care for low-income, uninsured, and underinsured individuals and families affected by HIV. As noted earlier, HRSA HAB administers the RWHAP. By legislation, the grant awards made under the RWHAP legislation may not be used for any item or service for which payment has been made, or can reasonably be expected to be made, under any state compensation program, under an insurance policy, or under any federal or state health benefits program (except for a program administered by or providing the services of the Indian Health Service (IHS)), referred to as "payor of last resort."

In 2020, the RWHAP provided services to 561,803,416 people, or more than half of all persons with diagnosed HIV infection in the United States. Since 2016, the RWHAP client population had a largely consistent demographic profile, with nearly three quarters of clients self-identifying as members of racial or ethnic minority groups, approximately 61 percent living at or below 100 percent of the Federal Poverty Level (FPL), and the majority of clients identify as being male (72 percent).[2] However, the RWHAP client population is aging. In 2020, people aged 50 years and older accounted for 47 percent of all RWHAP clients, an increase from 31.7 percent of clients in 2010. Clients served by the RWHAP have been shown to have better HIV-related health outcomes compared to people with HIV who do not receive services through RWHAP[3]; in 2020, 89.4 percent of RWHAP clients receiving Outpatient/Ambulatory Health Services achieved viral suppression, which exceeds the national viral suppression rate of 68.3 percent among all people diagnosed with HIV as reported by the Centers for Disease Control and Prevention (CDC).[4, 5]

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[1] Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2015–2019. HIV Surveillance Supplemental Report 2021;26(No. 1). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2021. Accessed April 2022.

[2] Health Resources and Services Administration. *Ryan White HIV/AIDS Program Annual Client-Level Data Report 2020*.https://ryanwhite.hrsa.gov/data/reports. Published December 2021. Accessed April 2022.

[3] Bradley H, Viall AH, Wortley PM, et al. Ryan White HIV/AIDS Program Assistance and HIV Treatment Outcomes. *Clin Infect Dis. 2016;62(1):90-98.*

[4] Health Resources and Services Administration. *Ryan White HIV/AIDS Program Annual Client-Level Data Report 2019*. hab.hrsa.gov/data/data-reports. Published December 2021. Accessed April 2022.

[5] Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. *HIV Surveillance Supplemental Report* 2021;26(No.2). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Published May 2021. Accessed April 2022.

II. Chapter 2. Relevant Authorities

Congress first authorized and funded the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in 1990. Since that time, it has been amended and reauthorized four times (in 1996, 2000, 2006) and, in 2009, as the Ryan White HIV/AIDS Treatment Extension Act of 2009 (codified in title XXVI of the PHS Act, 42 U.S.C. §§ 300ff-11 et seq.), from here on referred to as the RWHAP legislation.

Congress adjusted the RWHAP legislation with each reauthorization to accommodate new and emerging needs, such as an increased emphasis on funding core medical services and changes in funding formulas. The legislation provides the structure through which the RWHAP funding is distributed. Legislative provisions, called sections, address planning and decision-making, available grant types, allowable use of funds, application eligibility and submission requirements, and TA to build capacity and help programs run more effectively.

RWHAP Part B recipients must comply with all relevant authorities, including legislation, regulation, and program-specific policies. Further details on relevant authorities as they pertain to key concepts can be found in each section of this manual. The relevant authorities are:

- RWHAP Legislation: https://ryanwhite.hrsa.gov/about/legislation.
- The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, as issued by OMB and adopted by HHS, in 45 CFR Part 75 (from here on referred to as the UAR): https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=df3c54728d090168d3b2e780a6f6ca7c&ty=HTML&h=L&mc=true&n=pt45.1.75&r=PART
- HHS and HRSA Grants Administration and Program-Specific Policies:
  - HHS Grants Policy Statement (GPS): https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf
  - Notices of Funding Opportunity (NOFO): https://www.hrsa.gov/grants/fundingopportunities/default.aspx
  - Notices of Award (NoA): https://www.hrsa.gov/sites/default/files/grants/manage/awardmanagement/notice/noticeofaward.pdf
  - HRSA HAB Policy Notices: https://ryanwhite.hrsa.gov/grants/policy-notices
  - HRSA HAB Program Letters: https://ryanwhite.hrsa.gov/grants/program-letters
  - RWHAP Manuals and Reports, including this RWHAP Part B Manual and the ADAP Manual: https://ryanwhite.hrsa.gov/grants/manage/recipient-resources.
  - RWHAP technical assistance documents, including the RWHAP Parts A and B National Monitoring Standards (NMS): https://ryanwhite.hrsa.gov/grants/manage/recipient-resources.

Recipients should have a clear understanding of these authorities and all requirements and expectations therein. Further detail on each of the above can be found in Section VIII, Grants

Administration. Other sections of the RWHAP Part B Manual provide additional information about how to implement corresponding requirements.

II. Chapter 3. Overview of the Ryan White HIV/AIDS Program

The RWHAP legislation divides the program into five "Parts" as follows.

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

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

- ***RWHAP Part B HIV Care Grant Program*** (Activity Code X07), including:
  - **RWHAP Part B Base** funds to provide core medical and support services;
  - **RWHAP ADAP Base** funds to provide Food and Drug Administration (FDA)-approved medications and purchase of health care coverage for low-income people with HIV with limited or no health care coverage from private entities, Medicaid, or Medicare;
  - **RWHAP ADAP Supplemental** funds for eligible applicants who choose to apply to address a severe need for medication;
  - **Emerging Communities (EC) supplemental** funds for eligible applicants to enhance a comprehensive array of core medical and support services in metropolitan statistical areas (MSAs) reporting between 500 and 999 cumulative AIDS cases over the most recent five years; and
  - **Minority AIDS Initiative (MAI)** funds to provide education and outreach services to improve minority access to medication assistance programs, including ADAP.
- ***RWHAP Part B Supplemental Grant Program*** (Activity Code X08) for recipients with demonstrated need to supplement the HIV care and treatment services provided by the states/territories through RWHAP Part B, including ADAP.
- ***ADAP Emergency Relief Funds (ERF)*** (Activity Code X09) to help states prevent, reduce, or eliminate ADAP waitlists or implement cost-containment measures.[6]
- ***Ending the HIV Epidemic (EHE) Initiative*** – Ryan White HIV/AIDS Program Parts A and B (Activity Code UT8) to help eligible states/territories implement strategies, interventions, approaches, and core medical and support services to reduce new HIV infections in the United States.[7]

[6] Authority for ADAP ERF is 311(c) of the Public Health Service Act.
[7] Authority for Ending the HIV Epidemic is 331(c) of the Public Health Service Act.

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

RWHAP Part D – Women, Infants, Children, and Youth (WICY) with HIV and their Families:
The RWHAP Part D provides outpatient, ambulatory, family-centered primary and specialty medical care for women, infants, children, and youth with HIV. Funding also may be used to provide support services to people with HIV and their affected family members.

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

- ***The Special Projects of National Significance (SPNS) Program*** **–** Supports the development of innovative models of HIV care and treatment to respond to emerging needs of clients served by RWHAPs. The SPNS Program advances knowledge and skills in the delivery of health care and support services to underserved populations with HIV and builds health information technology (HIT) capacity within the RWHAP community to report client-level data.
- ***The AIDS Education and Training Center (AETC) Program*** **–** Supports a network of eight regional centers (and more than 130 local affiliated sites) and two national centers that conduct targeted, multidisciplinary education and training programs for health care providers treating people with HIV. The AETC Program also includes the National HIV Curriculum, a free online curriculum.
- ***Dental Programs*** **–** All RWHAP Parts can support the provision of oral health services; however, two RWHAP Part F programs focus on funding oral health care for people with HIV:
  - **The HIV/AIDS Dental Reimbursement Program (DRP)** reimburses dental schools, hospitals with postdoctoral dental education programs, and community colleges with dental hygiene programs for a portion of uncompensated costs incurred by providing oral health treatment to people with HIV.
  - **The Community-Based Dental Partnership Program (CBDPP)** supports increased access to oral health care services for people with HIV while providing education and clinical training for dental care providers, especially those practicing in community-based settings.

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

For more information on the RWHAP, see https://ryanwhite.hrsa.gov/about.
For Congressional appropriations by Part, see https://ryanwhite.hrsa.gov/about/budget.

II. Chapter 4. Context of the RWHAP

National HIV/AIDS Strategy (2022-2025)

The National HIV/AIDS Strategy for the United States (2022-2025) (NHAS) (see https://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025) is a roadmap for stakeholders across the United States to accelerate efforts to end the HIV epidemic by 2030. RWHAP promotes robust advances and innovations in HIV health care using NHAS as its framework to end the epidemic. Therefore, to the extent possible, activities funded by RWHAP focus on addressing the following four goals:

1) Prevent new HIV infections;
2) Improve HIV-related health outcomes for people with HIV;
3) Reduce HIV-related health disparities and health inequities; and
4) Achieve integrated and coordinated efforts that address the HIV epidemic among all partners and stakeholders.

To achieve these shared goals, recipients should, within the parameters of the RWHAP legislation and program guidance, align organizational efforts to ensure that people with HIV are linked to and retained in care, and have timely access to HIV treatment and the supports needed (e.g., mental health and substance use disorder services) to achieve HIV viral suppression.

Ending the HIV Epidemic in the U.S.

In February 2019, the Administration announced a new initiative, Ending the HIV Epidemic in the U.S. (EHE) (see https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview). This 10-year initiative began in fiscal year 2020 and seeks to achieve the important goal of reducing new HIV infections in the United States to less than 3,000 per year by 2030. This level of reduction would mean that HIV transmissions would be rare and would meet the definition of "ending the epidemic." Across the United States, this initiative includes four strategies to substantially reduce HIV transmissions:

- Diagnose all people with HIV as early as possible;
- Treat people with HIV rapidly and effectively to reach sustained viral suppression;

- Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs); and
- Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

II. Chapter 5. Overview of HRSA HAB

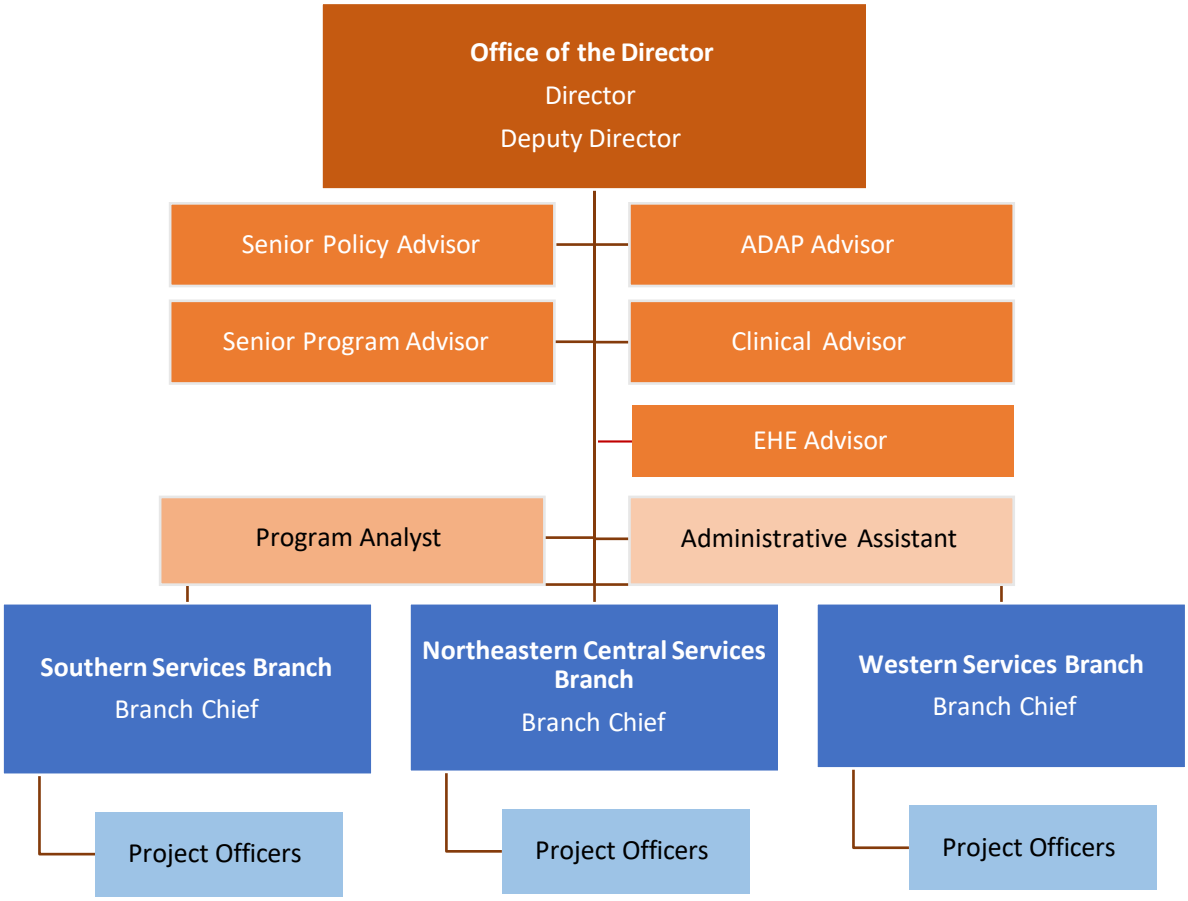
HRSA HAB administers the RWHAP. The mission of HRSA HAB is to "provide leadership and resources to advance HIV care and treatment to improve health outcomes and reduce health disparities for people with HIV and affected communities." HRSA HAB has seven offices and divisions as described below and depicted in its organizational chart, available at: https://www.hrsa.gov/about/organization/hab-org-chart.html.

- **Office of the Associate Administrator (OAA)** – Manages HAB; provides leadership and direction for HRSA's HIV programs and activities; and oversees collaboration with other national health programs.
- **Division of Metropolitan HIV/AIDS Programs (DMHAP)** – Administers the RWHAP Part A.
- **Division of State HIV/AIDS Programs (DSHAP)** – Administers the RWHAP Part B HIV Care Program, which includes RWHAP Part B Base, ADAP, ADAP Supplemental, EC, MAI, Part B Supplemental, and ADAP ERF; also administers a component of the EHE initiative.
- **Division of Community HIV/AIDS Programs (DCHAP)** – Administers the RWHAP Part C Early Intervention Services (EIS), RWHAP Part C Capacity Development, RWHAP Part D, and RWHAP Part F CBDPP and DRP.
- **Division of Policy and Data (DPD)** – Provides leadership and expertise in RWHAP data management and analysis, policy development and implementation, program evaluation, TA, publication development, and clinical quality management activities to support HRSA HAB's mission. Also administers the RWHAP Part F SPNS Program.
- **Office of Operations and Management (OOM)** – Provides administrative and fiscal guidance and support for HRSA HAB and is responsible for all budget execution tasks, personnel actions, contracting services, and facility management.
- **Office of Program Support (OPS**) – Provides grants management, information technology, communication, training, organizational development, and crosscutting clinical expertise to drive excellence, innovation, and collaboration across HRSA HAB; also administers the AETC Program.

Division of State HIV/AIDS Programs (DSHAP)

DSHAP provides leadership and support to states/territories in developing and ensuring access to quality HIV prevention, healthcare, and support services. The DSHAP organizational chart appears below (see Figure 1). See Section VIII, Grants Administration, Chapter 3, for more information on the roles and responsibilities of DSHAP staff.

Figure 1. Division of State HIV/AIDS Programs (DSHAP) Organizational Chart



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

II. Chapter 6. Overview of RWHAP Part B Funding

As outlined in Chapter 3, DSHAP administers the following four grant programs, each requiring a separate NOFO, grant application or Non-Competing Continuation (NCC) Progress Report, and NoA:

- RWHAP Part B – HIV Care Grant Program, including ADAP (HRSA Activity Code X07);
- RWHAP Part B Supplemental Grant Program (HRSA Activity Code X08);
- ADAP Emergency Relief Funds (ERF) (HRSA Activity Code X09); and
- Ending the HIV Epidemic Initiative— Ryan White HIV/AIDS Program Parts A and B (HRSA Activity Code UT8).

Throughout the remainder of this manual, references to RWHAP Part B or RWHAP Part B funding refer to the first three RWHAP Part B grant programs listed above, unless noted otherwise.

II. 6. A. Eligible Recipients

All 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands are eligible for RWHAP Part B HIV Care Grant Program Part B Base and ADAP Base funding (X07). RWHAP Part B Supplemental Grant Program (X08), RWHAP ADAP ERF (X09), and RWHAP Ending the HIV Epidemic Initiative (UT8) are competitive, and not all jurisdictions are eligible for these funds. Eligibility requirements for these grants are established in the NOFO for each grant. The governor or chief elected official of the jurisdiction accepts the award and designates the state health department or another state/territory agency to implement and manage the RWHAP funds.

II. 6. B. RWHAP Part B HIV Care Program, including ADAP

The RWHAP Part B HIV Care Program, including ADAP, grant award (X07) has, as of fiscal year (FY) 2017, a five-year period of performance, comprised of five one-year budget periods. The X07 grant award includes funds for RWHAP Part B Base, ADAP Base, ADAP Supplemental, EC, and/or MAI (see Section II, Overview of the RWHAP, Chapter 3 for a description of each component of award). In addition to the provision of services, a portion of RWHAP Part B funds can be used to cover the costs of administration, planning and evaluation, and clinical quality management (CQM).

Funding levels are determined by a legislatively mandated formula process based on cumulative cases of persons with diagnosed HIV/AIDS infection in the state/territory through the end of the

most recent calendar year, as confirmed by the director of the CDC. The formula includes the following:

- The RWHAP Part B Base formula is a weighted relative distribution that also takes into account RWHAP Part A funding.
- The ADAP Base, ADAP Supplemental, and EC formulas are based on the relative proportion of the reported number of living HIV/AIDS cases in the state/territory.
- The MAI formula is based on the relative proportion of the reported living racial/ethnic minority HIV/AIDS cases.

Emerging Communities

RWHAP Part B EC eligibility is based on the number of persons with HIV infection classified as AIDS in that jurisdiction. ECs are defined as metropolitan areas for which there have been at least 500 but fewer than 1,000 AIDS cases reported to and confirmed by the director of the CDC during the most recent five calendar years for which such data are available. An area will remain an EC unless it fails to meet both of the following requirements for three consecutive fiscal years:

1) A cumulative total of at least 500 but fewer than 1,000 cases of AIDS reported to and confirmed by the director of the CDC during the most recent period of five calendar years for which such data are available; and
2) A cumulative total of 750 or more persons with HIV infection ever classified as AIDS reported to and confirmed by the director of the CDC as of December 31 of the most recent year for which such data are available.

The geographic boundaries for ECs are those that were determined by OMB and that were in effect when initially funded.

II. 6. C. RWHAP Part B Supplemental

The RWHAP Part B Supplemental Grant (X08) is a competitive award with a one-year period of performance and a one-year budget period. Eligible states/territories must submit an application that demonstrates the need for additional RWHAP Part B funds due to the severity of the HIV epidemic in their jurisdiction. States/territories applying for funding must provide quantifiable data on HIV epidemiology, comorbidities, cost of care, the service needs of emerging populations, unmet need for core medical services, and unique service delivery challenges. An external Objective Review Committee (ORC) coordinated by HRSA's Division of Independent Review (DIR) reviews and scores each application using criteria established in the NOFO. Grant award amounts are determined using the ORC scores and the amount requested in the application within available funding ranges.

Certain penalties can prevent RWHAP Part B recipients from being eligible for Part B Supplemental funding. See Section VIII, Grants Administration, Chapter 4.5 for additional information.

II. 6. D. ADAP Emergency Relief Funds

The ADAP ERF (X09) is a competitive award with a one-year period of performance and a one-year budget period. Eligible states/territories must submit an application that demonstrates the need for additional funding to:

- Prevent, reduce or eliminate ADAP waiting lists or implement ADAP-related cost-containment measures;
- Address a current or projected increase in treatment needs aligned with ending the HIV epidemic or other unanticipated increases in the number of clients in the program due to new diagnoses, re-engagement in care, client loss of income, and/or client loss of health care coverage.

An external ORC coordinated by HRSA's DIR reviews and scores each application using criteria established in the NOFO. Grant award amounts are determined based on ORC scores and available funding.

II. 6. E. RWHAP Ending the HIV Epidemic in the U.S. Initiative

Ending the HIV Epidemic in the U.S. Initiative — RWHAP Parts A and B (UT8) are a competitive award with a five-year period of performance, comprised of five one-year budget periods. Eligible states/territories must submit an application that demonstrates their plan to implement effective and innovative strategies, interventions, approaches, and services to reduce new HIV infections in the United States. An external ORC coordinated by HRSA's DIR reviews and scores each application using criteria established in the NOFO.

II. Chapter 7. Additional Technical Assistance Links and Resources

The following links provide additional information on the RWHAP legislation and policies, HRSA HAB, and other related federal health care programs relevant to people with HIV.

- **HRSA HAB:** https://www.hrsa.gov/about/organization/bureaus/hab/index.html. For more information about HRSA HAB and the implementation of the RWHAP.
- **RWHAP Legislation:** https://ryanwhite.hrsa.gov/about/legislation. For more information about the RWHAP legislation as well as links to the PHS Act, Title XXVI.
- **RWHAP Program & Grants Management:** https://ryanwhite.hrsa.gov/grants/manage/recipient-resources. For resources available to support RWHAP-funded recipients in implementing federal grants and delivering HIV care and treatment services.
- **TargetHIV:** https://targethiv.org. TargetHIV is the central repository for TA resources for the RWHAP. The site is the one-stop shop for accessing tools, training materials, manuals, and guidelines developed by and with support from HRSA HAB. Suggested key word search list for this section includes: legislation, RWHAP Part B, imposition of charges, ADAP, Ryan White Services Report (RSR) and ADAP Data Report (ADR).
- **HIV in the United States at a Glance:**

https://www.cdc.gov/hiv/statistics/overview/ataglance.html. This website, hosted by the CDC, summarizes data on HIV prevalence and incidence in the United States.

Section III: HIV Service Delivery System

III. Chapter 1. Introduction

The RWHAP serves over half a million people with HIV each year.[8] It is the single largest federal program designed specifically to provide care and treatment for people with HIV in the United States, and is also the third largest source of federal funding for HIV care in the U.S., following Medicare and Medicaid.[9] The RWHAP requires states/territories to develop comprehensive HIV care and treatment service delivery systems for low-income people with HIV by establishing and maintaining collaborative relationships on the state and local levels among multiple sources of HIV testing, treatment, care, and prevention services agencies. RWHAP Part B recipients must use data to create systems that engage those populations most at risk for exposure to HIV and poor HIV health outcomes.

III. Chapter 2. Relevant Authorities and Legislative and Programmatic Requirements

The RWHAP, under Title XXVI of the PHS Act, includes formula and supplemental grants designed to assist states/territories in developing comprehensive HIV service delivery systems that include both essential core medical services and appropriate support services. These services provide the support that people with HIV need to access and remain engaged in HIV care and treatment services, with an ultimate goal of achieving viral suppression. While the legislation allows recipients latitude in choosing which core medical or support services to fund, it requires recipients to:

- Ensure that eligible people with HIV in the state/territory have uniform and equitable access to funded services,
- Have a planning process that includes a data-driven approach and input of people with HIV, and
- Collaborate with other funding sources that provide HIV care and treatment.

HHS develops the HHS Treatment Guidelines (https://hivinfo.nih.gov/) on the appropriate administration of HIV treatments, including antiretroviral therapies and medications for the prevention and treatment of opportunistic infections. The guidelines are regularly updated using the latest scientific research findings by expert panels. State ADAPs and other RWHAP recipients that provide medications to treat people with HIV must ensure clients receive medication therapies consistent with current HHS Treatment Guidelines

[8] Health Resources and Services Administration. *Ryan White HIV/AIDS Program Annual Client-Level Data Report* 2020. https://ryanwhite.hrsa.gov/data/reports. Published December 2021. Accessed April 2022.

[9] Kaiser Family Foundation. *U.S. Federal Funding for HIV/AIDS: Trends Over Time*. Available at: http://kff.org/global-health-policy/fact-sheet/u-s-federal-funding-for-hivaids-trends-over-time. Accessed April 2022

III. 2. A. Comprehensive Plan, Statewide Coordinated Statement of Need (SCSN), and the Integrated HIV Prevention and Care Plan

Comprehensive Plan Requirement

According to Section 2617(b)(5) of the PHS Act, recipients must develop a comprehensive plan that does the following:

- Establishes priorities for funding allocation;
- Includes a strategy that identifies individuals who know their HIV status but are not receiving HIV care services;
- Includes a strategy for coordinating the provision of such services with HIV prevention and substance use disorder treatment and prevention services;
- Describes the services and activities to be provided that maximize clinical quality;
- Describes how services will be coordinated with other available services;
- Describes how allocation and utilization of funds are consistent with the SCSN; and
- Includes key outcomes to be measured.

SCSN Requirement

Sections 2617(b)(6) and (7) of the PHS Act address the importance of full participation of key providers and users of the HIV care and treatment service delivery system in program planning 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/territory will periodically convene a meeting of individuals with HIV/AIDS, members of a federally recognized Indian tribe as represented in the state/territory, representatives of recipients 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/territory that (A) the public health agency that is administering the grant for the state/territory 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."*

Integrated HIV Prevention and Care Plan

In 2015, HRSA collaborated with the CDC to create the Integrated HIV Prevention and Care Plan Guidance, including the SCSN, CY 2017- 2021. Updated guidance for CY 2022-2026 builds on the CDC and HRSA's efforts to:

- Further reduce the reporting burden and duplicative efforts for recipients;
- Streamline the work of state and local health department staff and HIV planning bodies; and

- Promote collaboration and coordination in the use of data while simultaneously allowing recipients to meet the submission requirements outlined in Sections 2617(b)(6) and (7) of the PHS Act.

The Integrated HIV Prevention and Care Plan Guidance, including the SCSN, CY 2022- 2026, can be found at: https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/integrated-hiv-dear-college-6-30-21.pdf.

For more information about the Integrated HIV Prevention and Care Plan Guidance, including the SCSN, CY 2022- 2026, see Section IX, Planning Requirements for RWHAP Part B.

III. 2. B. Collaboration with Key Points of Access

Section 2617(b)(7)(G) of the PHS Act outlines requirements for the state/territory regarding collaboration with important points of access and components of the health care system for people with HIV.

> *"(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."*

III. 2. C. Early Identification of Individuals with HIV/AIDS

The RWHAP legislation requires states/territories to engage in efforts that support the early identification of individuals with HIV/AIDS (EIIHA). Sections 2617(b)(2) and (b)(3) of the PHS Act require states/territories to determine the size and demographics of the population of individuals with HIV in the state/territory, as well as the needs of such population. Section 2617(b)(8) of the PHS Act requires the state to assess the needs of persons with HIV who are unaware of their status and address those needs through a comprehensive plan.

To meet EIIHA requirements, recipients must develop a comprehensive plan to:

1) Increase the number of individuals who are aware of their HIV status;
2) Increase the number of people with HIV who are in medical care; and
3) Increase the number of HIV-negative individuals referred to prevention services.

The EIIHA Plan must include epidemiological data on the number of individuals with HIV, the estimated number of individua ls with HIV who do not know their status, and activities that will be

undertaken to meet EIIHA goals. The EIIHA Plan should align with the current Integrated HIV Prevention and Care Plan, including the SCSN. RWHAP Part B recipients must submit EIHAA plans with their grant application or Program Terms Report (PTR). See Section V, Reporting Requirements, Chapter 4 for more information.

III. 2. D. Allowable RWHAP Service Categories for HIV Care and Treatment

Recipients must coordinate RWHAP funds with other payer sources to create an HIV service delivery system that ensures people with HIV can access essential core medical services. The RWHAP legislation specifies 13 allowable core medical services. Per legislation, support services are those services needed for people with HIV to achieve positive medical outcomes defined as, "outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS." HRSA HAB has defined and provided guidance on these 13 core medical services and 17 support services. See PCN #16-02, Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds.

Core Medical Services

- AIDS Drug Assistance Program Treatments
- AIDS Pharmaceutical Assistance
- EIS
- Health Insurance Premium and Cost Sharing Assistance for Low-Income Individuals
- Home and Community-Based Health Services
- Home Health Care
- Hospice
- Medical Case Management, including Treatment Adherence Services
- Medical Nutrition Therapy
- Mental Health Services
- Oral Health Care
- Outpatient/Ambulatory Health Services
- Substance Use Outpatient Care

Support Services

- Child Care Services
- Emergency Financial Assistance
- Food Bank/Home Delivered Meals
- Health Education/Risk Reduction
- Housing
- Legal Services
- Linguistic Services
- Medical Transportation
- Non-Medical Case Management Services
- Other Professional Services
- Outreach Services

- Permanency Planning
- Psychosocial Support Services
- Referral for Health Care and Support Services
- Rehabilitation Services
- Respite Care
- Substance Abuse Services (residential)

Per PCN #16-02, in order "to ensure consistent quality care is provided to all HRSA RWHAP-eligible clients," recipients need to have service standards, which are sometimes referred to as standards of care. Service standards are principles and practices for the delivery of health and social services that are accepted by recognized authorities and used widely. They often are informed by guidelines, clinical research, and patient experiences. Service standards for HIV care are based on specific research (when available) and the collective opinion of experts. RWHAP service standards outline the elements and expectations a service provider follows when implementing a specific service category, to ensure that all service providers offer the same fundamental components of the given service category across the service area. They establish the minimal level of service or care that a RWHAP Part B-funded agency or provider may offer within a jurisdiction. See: https://targethiv.org/sites/default/files/file-upload/resources/Service%20Standards%20HRSA%20HAB%20Guidance%2012_14.pdf.

III. 2. E. Core Medical Services Requirement

RWHAP Part B legislation (Section 2612(b) of the PHS Act) requires recipients to expend 75 percent of the grant funds, minus the amount reserved for administrative and CQM activities, on core medical services (i.e., the 75/25 Core Medical Services Requirement). In addition to core medical services, recipients may fund key support services needed to achieve medical outcomes. Section 2612(c) of the PHS Act defines support services as those, "that are needed for individuals with HIV/AIDS to achieve their medical outcomes."

Waiver of Core Medical Services Requirement

The RWHAP legislation (Section 2612(b) of the PHS Act) allows recipients to request a waiver of the 75/25 Core Medical Services Requirement, if the recipient can demonstrate the availability of core medical services for all identified and eligible people with HIV in the service area, and if there is not an ADAP waiting list in the state. Applicants may submit a one-page HRSA RWHAP Core Medical Services Waiver Request Attestation Form to HRSA HAB, attesting that the underlying statutory and policy requirements for requesting a core medical services waiver have been met, at any time prior to submission of the grant application or NCC Progress Report, with the grant application or NCC Progress Report, or up to four months after the start of the grant budget period. For more information on the Core Medical Services Waiver, refer to Policy Notice 21-01, Waiver of the Ryan White HIV/AIDS Program Core Medical Services

Expenditure Requirement, at https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/pn-21-01-core-medical-services-waivers.pdf.

Important Note:

This requirement was waived, if specifically requested, due to the COVID-19 public health emergency for awards funded in Fiscal Years 2020 and 2021. Although Congress provided the same waiver authority for funds awarded in Fiscal Years 2022 and 2023, HAB discontinued this waiver. All RWHAP Part B recipients are required to expend 75 percent of their grant funds on core medical services or obtain a waiver to utilize additional funds on support services because all core medical services are available to eligible clients in the state.

III. 2. F. RWHAP Part B Client Eligibility

Per PCN #21-02, Determining Client Eligibility & Payor of Last Resort in the Ryan White HIV/AIDS Program, eligibility for RWHAP services is based on HIV status, low-income status (as defined by the recipient), and residency (as defined by the recipient). HRSA HAB expects all RWHAP recipients and subrecipients to establish, implement, and monitor policies and procedures to determine client eligibility based on these three factors. This expectation includes procedures and required documentation for initial eligibility determinations and that eligibility confirmations of all enrolled clients are conducted to verify whether individuals remain eligible. States/territories must establish eligibility and certification requirements and procedures for both RWHAP Part B services and for RWHAP ADAP.

Some states/territories coordinate client eligibility determination at the state level, while others assign this responsibility to their subrecipients. RWHAP Part B eligibility must be consistently applied across the state/territory. As such, all RWHAP Part B recipients must devise, implement, and rigorously monitor the use of consistent eligibility standards across all entities involved in determining and confirming RWHAP eligibility.

States/territories are encouraged to coordinate eligibility requirements for RWHAP Part B services and ADAP with other RWHAP-funded recipients in their jurisdiction to maximize access to care for people with HIV and to reduce administrative burden for direct service providers and clients. Recipients also are strongly encouraged to align recertification processes with other health care coverage eligibility and enrollment processes that may exist with the evolving heath care environment (for more information, see PCN 13-03, Ryan White HIV/AIDS Program Client Eligibility Determinations: Considerations Post-Implementation of the Affordable Care Act, and PCN #21-02, Determining Client Eligibility & Payor of Last Resort in the Ryan White HIV/AIDS Program). Establishing data-sharing agreements with other RWHAP recipients, RWHAP subrecipients, and federal programs can further reduce burden in eligibility and eligibility confirmation procedures.

III. Chapter 3. Developing a Comprehensive Service Delivery System for People with HIV

In order to plan, establish, implement, and maintain a comprehensive HIV service delivery system, HRSA HAB expects RWHAP recipients to build collaborations, partnerships, and coordination mechanisms among multiple sources of HIV prevention, testing, treatment, and care service providers. Recipients and subrecipients may establish agreements with key points of entry to enable referral and linkage of people with HIV to medical care and support services upon HIV diagnosis.

III. 3. A. Coordinating RWHAP Part B Services with Other RWHAP Parts and Payors

Recipients fund a set of RWHAP core medical and support services as part of a comprehensive service delivery system for people with HIV to improve retention in medical care and viral suppression. To achieve these goals, recipients must coordinate RWHAP Part B services with services from a variety of other payor sources that support medical, behavioral health, and supportive services. A comprehensive service delivery system also includes data collection and analysis mechanisms that allow providers to track the progress of individual clients, make data-informed health care decisions for those clients, and analyze the community-level impact of services.

Additional components of a comprehensive service delivery system include the following:

- Client-centered care that includes coordination among different treatment providers;
- Use of data to increase access to services and decrease health disparities among those groups identified by the state/territory as most at-risk for poor health outcomes, which may include but are not limited to:
  - People with HIV from communities of color;
  - People with HIV experiencing unstable housing;
  - Youth ages 13 to 24;
  - Men who have sex with men (MSM);
- Coordinated HIV prevention and care services that identify individuals unaware of their HIV status and immediately link those new HIV diagnosis into medical care; and
- Support services such as medical transportation, housing, and psychosocial support services that employ evidence-based interventions to improve retention in medical care and treatment adherence.

III. 3. B. Using Data to Inform Integrated Service Delivery Systems

HRSA and CDC's Division of HIV Prevention (DHP) support integrated data sharing, analysis, and utilization for the purposes of needs assessments, unmet need estimates, program planning, resource allocation, reporting, evaluation, continuous quality improvement, the development of

the HIV care continuum, and public health action. HRSA HAB strongly encourages RWHAP Part B recipients to do the following:

- Follow principles and standards in the "Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action" (see https://www.cdc.gov/nchhstp/programintegration/docs/pcsidatasecurityguidelines.pdf); and
- Establish data sharing agreements between surveillance and HIV programs to allow data sharing and utilization.

Integrated HIV data sharing, analysis, and utilization approaches by state and territorial health departments can help further progress in reaching the national goals to end the HIV epidemic and improve outcomes on the HIV care continuum.

HIV Care Continuum

The HIV care continuum consists of five stages, including: HIV diagnosis, linked to care, engaged or retained in care, prescribed antiretroviral therapy, and viral suppression.[10] The HIV care continuum provides a framework that depicts the series of stages a person with HIV engages in from initial diagnosis through their successful treatment with HIV medication. It shows the proportion of individuals with HIV who are engaged at each stage. The HIV care continuum allows recipients and planning groups to measure progress and to direct HIV resources most effectively. RWHAP recipients are encouraged to assess the outcomes of their programs along this continuum of care.

Recipients should work with HIV surveillance programs, community partners, and other federally funded programs to create a full data set that measures outcomes for people with HIV across the HIV care continuum. Additionally, HRSA recommends using variables (e.g., age, gender, race/ethnicity, and housing status) to stratify the data across the HIV care continuum as a means of identifying those subpopulations less likely to achieve positive health outcomes.

Data to Care

CDC developed a public health strategy called, "Data to Care," which details ways to use HIV surveillance data, pharmacy fill data, clinic appointment data, and other treatment and care data sources to identify individuals with diagnosed HIV who are not in care, to link them to care, and inform the HIV care continuum.[11] CDC's Data to Care website has a variety of resources to assist state and local health departments in using individual-level data to offer linkage and reengagement to care services when appropriate (see https://www.cdc.gov/hiv/effective-interventions/respond/data-to-care?Sort=Title%3A%3Aasc&Intervention%20Name=Data%20to%20Care). Together, these resources provide additional examples of the ways in which recipients can use data to inform strategies to create a comprehensive system of care across the HIV care continuum.

Integrated HIV Prevention and Care Planning

Since 2015, HRSA has collaborated with CDC to create the Integrated HIV Prevention and Care Plan Guidance, including the SCSN (see https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/integrated-hiv-dear-college-6-30-

21.pdf for the guidance released in June 2021). The CDC and HRSA intentionally structured the guidance to require recipients to compile data to inform planning goals. Integrated data sets included HIV surveillance data, HIV care continuum data, client-level needs assessments, SCSN data, RWHAP data, and other relevant data sources as appropriate. Integrated Guidance for Developing Epidemiologic Profiles, developed by CDC and HRSA, provides one set of guidance to assist recipients in developing integrated epidemiologic profiles using available data. (See https://www.cdc.gov/hiv/pdf/guidelines/cdc-hiv-guidelines-developing-epidemiologic-profiles-2022.pdf.) Section IX, Planning Requirements for RWHAP Part B, has more information about integrated HIV prevention and care planning.

III. Chapter 4. Additional Technical Assistance Links and Resources

The following links provide additional information on the RWHAP legislation and policies, and other related federal healthcare programs relevant to people with HIV.

- **HAB Policy Notices and Program Letters:** https://ryanwhite.hrsa.gov/grants/policy-notices and https://ryanwhite.hrsa.gov/grants/program-letters. HRSA HAB develops policies regarding legislation and provides guidance to recipients in understanding and implementing legislative requirements.
- **Integrated HIV Prevention and Care Plan Guidance, including the SCSN, CY 2022 – 2026:** https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/integrated-hiv-dear-college-6-30-21.pdf. Sets parameters for jurisdictional planning for RWHAP Part B recipients.
- **Access, Care, and Engagement (ACE) Technical Assistance (TA) Center:** https://targethiv.org/ace. Helps RWHAP recipients and subrecipients support their clients, especially people of color, to help them navigate the health care environment through enrollment in health coverage and improved health literacy. Develops practical tools and resources to support engagement, education, and health care coverage enrollment and renewal activities, helping to ensure RWHAP remains a payor of last resort.
- **Integrated HIV/AIDS Planning (IHAP) Technical Assistance (TA) Center**: https://targethiv.org/ihap. Helps RWHAP Part A and Part B recipients, CDC's DHP-funded grantees, and their respective planning bodies with integrating planning, including the implementation and monitoring of their Integrated HIV Prevention and Care Plans. Provides national and targeted TA and promotes peer-to-peer sharing.
- **National HIV Care Continuum Data, HHS, HIV.gov:** https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum. Information on the HIV care continuum and the five stages people with HIV go through from diagnosis to achieving and maintaining viral suppression.
- **CDC Data to Care Interventions:** https://effectiveinterventions.cdc.gov/en/2018-design/data-to-care/group-1/data-to-care. Information on data to care interventions, including essential elements, resources, and tools, as well as TA.

Section IV: Reporting Requirements

IV. Chapter 1. Introduction

All recipients 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 recipients, that agency is HRSA HAB. In addition, the RWHAP legislation requires some specific reports from recipients that HRSA HAB must collect and review. The review and approval process for recipient reporting is determined by the types of report:

- **Programmatic reports** (e.g., the PTR) are reviewed and approved by the DSHAP PO;
- **Fiscal reports** (e.g., the Federal Financial Report (FFR)) are reviewed and approved by a Grants Management Specialist (GMS) in the Division of Grants Management Operations; and
- **Data reports** (e.g., Ryan White HIV/AIDS Program Services Report (RSR) and AIDS Drug Assistance Program Data Report (ADR)) are reviewed by HRSA HAB's Division of Data and Policy and by DSHAP.

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

- To assure recipient compliance with requirements mandated by Congress on the use of RWHAP Part B funds. For example, RWHAP legislation requires RWHAP Part A and Part B recipients to use a proportionate amount of the grant funding to provide services to WICY living with HIV. Recipients must submit WICY Expenditures Reports or waiver requests with the Annual Progress Report (APR).
- To monitor the fiscal and programmatic integrity of the grant program, as required by legislation and policy, including the HHS GPS. For example, HRSA grant recipients must submit a program budget after receiving the NoA. Similarly, recipients are required to submit fiscal and programmatic information about subrecipients, including the RWHAP Part B Consolidated List of Contractors (CLC) and the Contract Review Certification (CRC).
- To monitor and track program activities and trends, prepare HRSA HAB reports on program accomplishments, and respond to inquiries from Congress, the OMB, the media, and the public at large. HRSA HAB is responsible for the fiscal and program integrity of RWHAP Part B recipients. HRSA HAB staff must be able to monitor and report on recipients' fiscal status, services provided, clients served, program accomplishments, and TA needs. Reports also are used by HRSA HAB to assess client outcomes and understand service utilization. For example, the RSR and ADR are reporting requirements that support HRSA HAB to meet these needs.

HRSA HAB also provides the software package CAREWare at no monetary charge 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, recipients and service providers can use CAREWare to generate their annual reports for submission to HRSA HAB.

[10] HIV.gov. *What is the HIV Care Continuum?* https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum Last updated June 21, 2021. Accessed April 2022.
[11] Centers for Disease Control and Prevention Data to Care website at: https://www.cdc.gov/hiv/effective-interventions/respond/data-to-care?Sort=Title%3A%3Aasc&Intervention%20Name=Data%20to%20Care.Accessed April 2022.

IV. Chapter 2. Relevant Authorities

Legislative Requirements Regarding Use of Funds

To meet RWHAP legislative, regulatory, and programmatic requirements, recipients must submit reports regarding the use of funds in accordance with applicable provisions. Some examples of legislatively mandated reporting requirements include the RWHAP Part B Unobligated Balance (UOB) Estimate and Estimated Carryover Request, the Interim FFR, and the WICY Expenditures Report.

Uniform Administrative Requirements and HHS Grants Policy Statement

The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR part 75, provides the basis for systematic and periodic collection of information on all federal financial assistance programs. The HHS GPS makes the general terms and conditions of HHS discretionary grant and cooperative agreement awards available in a single document. These general terms and conditions are common across all HHS Operating Divisions (OPDIVs) and apply as indicated in the HHS GPS, unless there are legislative, regulatory, or award-specific requirements to the contrary. All other reporting requirements for the RWHAP Part B are mandated by the UAR and/or grants policy. These include the Final FFR and the MAI Annual Report.

General and award-specific requirements are outlined on NoAs as Grant Specific Term(s), Program Specific Term(s), Standard Term(s), Reporting Requirement(s), Condition(s), and/or Remark(s). All requirements (general and award-specific) are described in the NoA. Grant-specific terms set criteria or limits on how grant funds may be used.

Failure to comply with the NoA's general and award-specific requirements may result in enforcement actions, including a drawdown restriction being placed on the recipient's Payment Management System (PMS) account, the disallowance of funds, and/or other conditions. The Grants Management Officer (GMO), in collaboration with the DSHAP PO, may include award-specific conditions to require correction of identified financial or administrative deficiencies, including submission of corrections or missing reports. When specific award conditions are imposed, the GMO and/or the DSHAP PO will notify the recipient of the nature of the condition(s), the reason why the condition(s) is being imposed, the type of corrective action(s) needed, the time allowed for completing the corrective action(s), and the method for requesting reconsideration of the condition(s). For additional information, see 45 CFR 75.207.

IV. Chapter 3. Overview of RWHAP Part B Reporting Requirements

Recipients are required to submit reporting requirements for each award received, including the following RWHAP Part B-specific awards: RWHAP Part B HIV Care Program, including

ADAP Base (X07); RWHAP Part B Supplemental Grant Program (X08); and RWHAP Part B ADAP ERF (X09) awards.

The following tables provide a summary of required reports for each award.

RWHAP Part B HIV Care Program, Including ADAP (X07) Reporting Requirements Summary Table	
Reporting Requirement	**Components**
Program Terms Report Due 90 days after final award.	Revised SF-424A RWHAP Part B and MAI Allocations Report RWHAP Part B Budget Narrative Spreadsheet RWHAP Part B Implementation Plan RWHAP Part B Consolidated List of Contractors RWHAP Part B Contract Review Certification Early Identification of Individuals with HIV/AIDS Plan
Non-Competing Continuation Progress Report Due date specified in the Electronic Handbooks (EHBs).	Required Form SF-PPR Required Form SF-PPR2 Program-Specific Form
Minority AIDS Initiative Plan and Annual Report Template Due 90 days after final award.	RWHAP Part B MAI Plan and Annual Report Template
Interim Federal Financial Report Due 150 days after final award.	Interim FFR (SF-425)
Unobligated Balances Estimate and Estimated Carryover Request Due January 31. (This requirement was waived for Fiscal Year 2020 and 2021 due to the COVID-19 public health emergency.)	RWHAP Part B UOB Estimate and Estimated Carryover Request
RWHAP Services Report Due last Monday in March.	RSR Grantee Report RSR Provider Reports RSR Client-Level Data Report
ADAP Data Report Due first Monday in June.	ADR Grantee Data Report ADR Client-Level Data Report
MAI Plan and Annual Report Template - Updated Due 90 days after the end of the budget period.	RWHAP Part B MAI Plan and Annual Report Template

RWHAP Part B HIV Care Program, Including ADAP (X07) Reporting Requirements Summary Table	
Reporting Requirement	**Components**
Annual Progress Report Due 90 days after the end of the budget period.	RWHAP Part B Implementation Plan Update RWHAP Part B Progress Report Narrative Early Identification of Individuals with AIDS Update Certification of Aggregate Administrative Cost RWHAP WICY Report Integrated HIV Prevention and Care Plan Update CQM Update
Expenditures Report Due 90 days after the end of the budget period.	RWHAP Part B and MAI Expenditures Report
Final Federal Financial Report Due 90 days after the end of the budget period.	RWHAP Part B Final FFR (SF-425)
Carryover Request Due within 30 days of the Final FFR due date.	RWHAP Part B UOB/Carryover Request

RWHAP Part B Supplemental Grant Program (X08) Reporting Requirements Summary Table	
Reporting Requirement	**Components**
Program Terms Report Due 90 days after final award.	Revised SF-424A RWHAP Part B Supplemental Allocations Report RWHAP Part B Supplemental Budget Narrative Spreadsheet RWHAP Part B Supplemental Implementation Plan RWHAP Part B Supplemental Consolidated List of Contractors (CLC) RWHAP Part B Supplemental Contract Review Certification (CRC)
RWHAP Services Report (RSR) Due last Monday in March.	RSR Grantee Report RSR Provider Reports RSR Client-Level Data Report
Annual Progress Report (APR) Due 90 days after the end of the budget period.	RWHAP Part B Supplemental Annual Progress Report
Expenditures Report Due 90 days after the end of the budget period.	RWHAP Part B Supplemental Expenditures Report

RWHAP Part B Supplemental Grant Program (X08) Reporting Requirements Summary Table	
Reporting Requirement	**Components**
Federal Financial Report (FFR) Due 90 days after the end of the budget period.	RWHAP Part B Supplemental Final FFR (SF-425)
Carryover Request Due within 30 days of the Final FFR submission.	RWHAP Part B Supplemental UOB/Carryover Request

ADAP Emergency Relief Fund (X09) Reporting Requirements Summary Table	
Reporting Requirement	**Components**
Programs Terms Report Due 90 days after final award.	Revised SF-424A RWHAP ADAP ERF Allocations Report RWHAP ADAP ERF Budget Narrative Spreadsheet RWHAP ADAP ERF Work Plan and Work Plan Narrative RWHAP ADAP ERF CLC RWHAP ADAP ERF CRC
Semi-Annual Report Due 30 days after the first six months of the budget period.	RWHAP Part B ADAP ERF Semi-Annual Report
ADAP Data Report Due first Monday in June.	ADR Grantee Data Report ADR Client-Level Data Report
Annual Progress Report Due 90 days after the end of the budget period.	RWHAP Part B ADAP ERF Annual Progress Report
Expenditures Report Due 90 days after the end of the budget period.	RWHAP Part B ADAP ERF Expenditures Report
Federal Financial Report Due 90 days after the end of the budget period.	RWHAP Part B ADAP ERF Final FFR (SF-425)
Carryover Request Due within 30 days of the Final FFR submission.	RWHAP Part B ADAP ERF UOB/Carryover Request

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

Below is a description of each RWHAP Part B reporting requirement, its purpose, and the general due date. Guidelines and submission instructions for all reporting requirements are provided via the HRSA EHBs and are available through the DSHAP PO. Please refer to the NoA and the EHBs for budget period specific requirements and exact due dates.

Program Terms Report (X07, X08, and X09)
Due 90 days after final award.

The PTR requires the recipient to update information provided in the full grant application (in year one of the five-year grant period of performance) or the NCC Progress Report (in years two through five of the grant period of performance) once the final grant award amount is issued. The submitted PTR must follow reporting guidelines and submission instructions. Instructions indicate when provided templates are required to be used. When templates are not required, information in the templates is still required. For X07 and X08 awards, the PTR guidelines and instructions are provided in the Grant Contract Management System (GCMS) PTR web application. For X09 awards, the PTR guidelines and instructions are provided in the EHBs.

The report must include the following seven items:

1) **Revised SF-424A (X07, X08, and X09): Budget Information—Non-Construction Programs**
   The SF-424A submitted with the RWHAP Part B grant application (X07, X08 or X09) must be revised and resubmitted as part of the PTR. The SF-424A must reflect budget allocations based on the final award. The SF-424A must reflect the final grant award, be based on priorities established by the recipient in the Integrated HIV Prevention and Care Plan, including the SCSN, and be prepared using applicable cost principles and HRSA HAB program policies. The recipient should follow the budget guidance provided in the corresponding NOFO or NCC Progress Report Instructions. Funds are subject to certain requirements, restrictions, and limitations as described in the NOFO, NoA, and the RWHAP legislation.

2) **Allocations Report (X07, X08, and X09)**
   The Allocations Report is submitted on an OMB-approved form and indicates the categories and priority areas (core medical and support service categories) provided by the recipient for the current budget period and the funding dollar amount for each service category. It must reflect the amount of funds awarded in the final NoA. For X07 and X08 awards only, recipients must demonstrate compliance with the 75/25 core medical services requirement in this report.

3) **Budget Narrative Spreadsheet (X07, X08, and X09)**
   The Budget Narrative Spreadsheet is the descriptive information used to explain and justify the amounts budgeted within each program budget category. It must reflect budget

allocations based on the final award for the one-year budget period. A categorical budget and narrative justification are required for the amounts requested for each line in the budget. The Budget Narrative Spreadsheet should specifically describe how each item will support the achievement of proposed objectives. The recipient should follow the budget guidance provided in the corresponding NOFO and in the PTR instructions. Funds are subject to certain requirements, restrictions, and limitations as described in the NOFO, NoA, and the RWHAP legislation.

4) **Implementation Plan (X07 and X08) or Work Plan (X09)**
The Implementation Plan or Work Plan outlines how the recipient will ensure people with HIV have access to a comprehensive continuum of HIV care and must address each utilized service category and the specific amount to be funded by the corresponding grant award for the current budget period. For X07, it should include RWHAP Part B Base, ADAP Base, ADAP Supplemental (if applicable), MAI (if applicable), and EC (if applicable) funding. All core medical and support services and funding amounts identified in this plan must be consistent with the Allocations Report. HRSA HAB recommends that the Implementation Plan or Work Plan be submitted on the suggested template provided.

5) **Consolidated List of Contracts (CLC) (X07, X08, and X09)**
The CLC identifies the name, contract amount, and service/activity to be provided for all core medical and support services subawards, contracts, or other legal agreements using grant funding. HRSA HAB uses this information to monitor and track the use of grant funds for compliance with program and grant policies and requirements.

6) **Contract Review Certification (CRC) (X07, X08, and X09)**
The CRC is used to certify all RWHAP Part B direct core medical and support service contracts administered by the recipient. Both the recipient project director and the budget (fiscal) officer must sign the CRC to certify that all core medical and support service contracts have been reviewed by program and administrative/fiscal staff to ensure compliance with HRSA HAB policies.

7) **Early Identification of Individuals with HIV/AIDS Plan (EIIHA) (X07)**
The EIIHA Plan is a document that describes the process for linking people identified in the EIIHA data to both prevention (for HIV-negative clients) and care services (for clients with diagnosed HIV infection).

<u>Non-Competing Continuation (NCC) Progress Report (X07)</u>
Due date specified in EHBs.

The NCC Progress Report is a required report that must be submitted through the EHBs for continued funding during years two through five of the five-year X07 period of performance. The elements reported in the programmatic sections of the NCC Progress Report are used for the RWHAP Part B formula funding calculations.

The NCC Progress Report includes three components: the SF-PPR, the SF-PPR2, and one program-specific form. These forms are completed in the EHBs. NCC Progress Report user guides and instructions are available in the EHBs.

Failure to submit the NCC Progress Report by the established deadline or submission of an incomplete or nonresponsive NCC Progress Report may result in a delay in NoA issuance.

MAI Plan (X07)
Due 90 days after final award.

The RWHAP Part B MAI Plan is submitted on the RWHAP Part B MAI Plan and Annual Report template to document the planned use of RWHAP Part B MAI funds for the budget period. For this submission, the following tabs must be completed:

- Contact information;
- Outreach (if applicable), including Section I, Section II items #9 through #10, and Section III items #13 and #14; and
- Education (if applicable), including Section I, Section II items #9 through #10, and Section III items #13 and #14.

Semi-Annual Report (X09)
Due 30 days after the first six months of the budget period.

The Semi-Annual Report documents expenditures by service category, unit, and number of clients, and for cost-containment measures for the first six-month period of the budget period.

Interim FFR (X07)
Due 150 days after the final award.

The Interim FFR is submitted using form SF-425 to document total expenditures and projected obligations from April 1 to 120 days after the final grant award amount is issued. Recipients must follow the deadlines and reporting periods provided in the EHBs.

The recipient reports the amount of RWHAP Part B funds for the current budget period that have been expended and that have been obligated and made available for expenditure during the required reporting period. The recipient can use Line F on the Interim FFR to report any unliquidated obligations (please note that this line cannot be used on the Final FFR). Unliquidated obligations can be reported on either a cash or an accrual basis. On a cash basis, unliquidated obligations include obligations that have been incurred but not yet paid. On an accrual basis, unliquidated obligations include obligations that have been incurred but the actual amount to be paid has not yet been verified.

Important Notes:

The expedited distribution requirement and penalty may be waived for FY 2023 RWHAP Part B recipients for which the COVID-19 pandemic continues to impact the recipients' ability to make timely subawards. RWHAP Part B recipients that would otherwise be penalized must request this waiver. Even if a waiver is granted, recipients are still required to submit an interim FFR.

UOB Estimate and Estimated Carryover Request (X07)
Due 60 days before the end of the budget period.

The RWHAP Part B UOB Estimate and Estimated Carryover Request provide an estimate of potential unobligated funds and the intended use of those funds. The recipient must submit by January 31 an estimate of its projected unobligated balance for the current budget period and an estimated carryover request, including the intended use of funds.

Important Notes:

If a UOB estimate for X07 is not submitted by January 31, no carryover request (except for MAI carryover) will be permitted.

This financial penalty was automatically waived due to the COVID-19 public health emergency for awards funded in Fiscal Years 2020 and 2021. HAB has discontinued this waiver for Fiscal Years 2022 and 2023.

RWHAP Services Report (RSR)
Due last Monday in March.

The purpose of the RSR is to collect information on recipients, subrecipient providers, and clients served by the RWHAP (excluding ADAP) during a calendar year. Since 2010, client-level RSR data have been used to understand demographic characteristics, service utilization, and clinical outcomes of clients receiving RWHAP services.

The RSR includes three main components: the Recipient Report, the Provider Report, and the Client-Level Data Report. The Recipient Report collects general information on the recipient and identifies each funded subrecipient. The Provider Report collects basic information about both the provider and the services the provider delivered under each of its RWHAP contracts. The Client-Level Data Report contains information on demographic characteristics, HIV clinical information, and service utilization for RWHAP clients who received core medical or support services during the reporting period. All client-level data are de-identified, and all measures have been taken on the part of HRSA HAB to protect the data.

All RWHAP recipients are responsible for coordinating with and ensuring reporting of each funded subrecipient. RWHAP Part B consortia must submit one RSR for each subrecipient provider. All RWHAP recipients are responsible for training service providers and any other reporting entities on collecting and reporting data for the RSR. Recipients also are responsible for the following:

- Reviewing service provider reports to ensure accuracy prior to submitting to HRSA

HAB;
- Submitting completed data reports to HRSA HAB by the deadline provided; and
- Cooperating in verification of data following submission.

Information and instructions on completing these reports can be found in the RSR Instruction Manual located at https://targethiv.org/library/rsr-instruction-manual. HRSA HAB supports TA providers and provides tools that can assist both recipients and subrecipients in addressing issues related to the RSR, the ADR, CAREWare and EHBs. For more information on RWHAP data support, visithttps://ryanwhite.hrsa.gov/grants/manage/reporting-requirements.

ADAP Data Report
Due the first Monday in June.

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

- Monitor the clinical outcomes of clients receiving medication assistance through ADAP;
- Monitor the use of ADAP funds in addressing the HIV epidemic in the United States;
- Monitor the support provided by ADAP to the most vulnerable communities, especially minorities;
- Address the data needs of Congress and the Department of Health and Human Services (HHS) concerning the HIV epidemic and the RWHAP; and
- Monitor progress toward the national goals to end the HIV epidemic.

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

All RWHAP B recipients are responsible for the following:

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

Instructions for completing the ADR can be found in the ADR Instruction Manual located at https://targethiv.org/library/adr-instruction-manual. HRSA HAB supports TA providers and provides tools that can assist both recipients and subrecipients to address issues related to the ADR. For more information on RWHAP data support, visit https://ryanwhite.hrsa.gov/grants/manage/reporting-requirements.

MAI Annual Report (X07)
Due 90 days after the end of the budget period.

The RWHAP Part B MAI Annual Report is submitted using the RWHAP Part B MAI Plan and Annual Report template to document the use of RWHAP Part B MAI funds for the budget period. For this submission, the following tabs must be completed:

- Outreach (if applicable), including Section II items #11 and #12, Section III items #15 through #17; and
- Education (if applicable), including Section II items #11 and #12, Section III items #15 through #17.

Recipients must update the same MAI Plan and Annual Report template that was submitted 90 days after the start of the budget period.

Annual Progress Report (X07, X08, and X09)
Due 90 days after the end of the budget period.

The APR documents accomplishments and challenges experienced during the budget period in a progress report narrative. The APR also includes the Certification of Aggregate Administrative Cost for recipients to attest to subrecipient administrative expenditures, and the WICY Expenditures Report. Recipients must also update and submit the RWHAP Part B Implementation Plan and EIIHA Plan that was submitted 90 days after the start of the budget period.

Expenditures Report (X07, X08, and X09)
Due 90 days after the end of the budget period.

The Expenditures Reports are submitted to update information submitted on the Allocations Report to reflect actual expenditures of grant funds during the budget period. For X07 and X08, recipients demonstrate compliance with the 75/25 core medical services requirement through this report. The amount reported on the Expenditures Report must match the expenditures reported on the Final FFR, and expenditures by category must match those reported in the RWHAP Part B Implementation Plan Update submitted with the APR. For X07 and X08, the report must be submitted on an OMB-approved form using the format provided.

Final FFR (X07, X08, and X09)
Due 90 days after the end of the grant period.

The Final FFR is submitted using form SF-425 provided in the PMS to report the cumulative expenses within the budget period. The Final FFR must not include unliquidated obligations and must reconcile with the PMS report of disbursements for the budget period being reported and is identified by the document number. The Final FFR will not be accepted unless the information provided matches the information in the PMS exactly (to the penny).

Reporting State Matching Funds (X07, if applicable)
Items 10i (Total Recipient Share Required) and 10j (Recipient Share of Expenditure) of the SF-

425 document indicate when the required state match for the grant has been met (i.e., the requirement is met when the amount on line 10i matches the amount entered on line 10j). If a state has both a state match and ADAP Supplemental match, the recipient must specify in the "Remarks" section how the match reported in lines 10i and 10j meets each of the required match amounts.

Reporting Program Income
Total program income earned by the recipient is reported on line 1 of the SF-425. Recipients must not report program income earned by subrecipients in the FFR.

Because program income is only additive and not deductive for the RWHAP, nothing should be entered on line "m." The amount of program income that was added to funds committed to the total project costs and expended to further eligible program activities is entered on line "n." The amount of program income that was earned but not expended is automatically calculated and appears on line "o."

For more information on program income, see Section VIII, Grants Administration, Chapter 4.3.

Reporting Pharmaceutical Rebates
HRSA has provided the following guidance for how rebates should and should not be reported on the FFR:

- Rebates should be reported in the "Ryan White Rebate Funding" section of the FFR supplemental form. HRSA requires that the following information is reported:
  - Total Rebates Available (which include any unspent rebates from previous budget periods);
  - Expended Rebate Amount;
  - Unexpended Rebates (calculated automatically); and
  - Expended Rebate amount to be used to reduce a UOB.
- Rebates should not be included on line 10j of the FFR, unless they are counted as part of the recipient's required state match under "Recipient Share."

- Rebates are not considered program income and should not be reported as such on an FFR.
- Rebates should never be recorded as a UOB on the FFR.

In Section 2622(d) of the PHS Act, there is a specific exemption from the UOB penalty provision that applies when a recipient is unable to expend grant funds because pharmaceutical rebates must be spent first. To avoid a financial penalty when a UOB is due to spending pharmaceutical rebates first, recipients must provide the amount of expended rebates to be used in reducing the UOB in the Final FFR supplemental form in the section entitled, "Ryan White Rebate Funding," specifically the line called, "Expended Rebate Amount to be used to reduce UOB."

For more information on RWHAP Part B penalties, see Section VIII, Chapter 4.6. For more information on pharmaceutical rebates, see Section VIII, Chapter 4.3 in this manual, the RWHAP ADAP Manual (see https://ryanwhite.hrsa.gov/grants/manage/recipient-resources), and PCN #15-04, Utilization and Reporting of Pharmaceutical Rebates.

Intent to Request Carryover
The recipient can indicate in the Final FFR "Remarks" section whether it intends to submit a request to carryover UOB into the subsequent budget period.

Unobligated Balance/Carryover Request (X07, X08, and X09)
Due within 30 days of the Final FFR submission.

The UOB/Carryover Request is a request by the recipient to carryover actual UOB into the subsequent budget period, including the planned use of those funds. The carryover request cannot exceed the UOB reported in the approved Final FFR. Recipients must submit their Final FFR prior to submitting a carryover request. If a recipient chooses to submit a carryover request, it can be submitted at the same time as the Final FFR or submitted within 30 days of the final FFR due date via the Prior Approval Module in the EHBs (see UOB/Carryover Request below for more information). HRSA HAB will not review a carryover request until after the Final FFR is accepted. See Section VIII, Grants Administration, Chapter 4.4, Unobligated Balance and Carryover Request, for additional information on carryover request requirements.

IV. Chapter 5. EHBs

In an effort to increase the efficiency and effectiveness of its management of recipient records, HRSA developed an electronic record keeping system, the HRSA EHBs, which provide a one-stop grants management online tool for POs and recipients. The EHBs provide online NOFOs, grant applications, NoAs, non-competing continuation applications, reporting requirements, and other types of post-award reports and requests. The EHBs allow recipients and POs to view award history, view past NoAs, and monitor report activity as well as deadlines, and access reports such as the ADR and the RSR.

Any information and data required from the recipient, such as applications, drawdown restriction requests, reports, waivers, and exemptions must be submitted via the EHBs using the format specified by HRSA HAB. The HRSA HAB EHBs reporting formats help to assure that correct information is reported across all RWHAP recipients. This allows HRSA HAB to track and report national program trends, identify TA needs, and prepare aggregate summary reports to Congress, recipients, and the public at large.

To access the recipient's grant portfolio in the EHBs, a recipient must register in the EHBs and authorize recipient staff to have certain roles on behalf of the recipient. The EHBs system is available at: https://grants.hrsa.gov/webexternal/login.asp.

Recipients having problems accessing the EHBs should contact the HRSA Call Center at:

Toll-Free Help Line: 1-877-464-4772
Hours: Monday – Friday, 7 a.m. – 6 p.m., Eastern Time
Email: HRSAEHBTier2Support@hrsa.gov
Submit a Request: http://www.hrsa.gov/about/contact/ehbhelp.aspx

IV. Chapter 6. Training and Technical Assistance Links and Resources

Training and TA for the ADR and RSR

HRSA HAB provides training and TA resources to RWHAP recipients and subrecipients to support RSR and ADR submissions. ADR and RSR instructions, trainings, and tools are available on the HRSA HAB website and TargetHIV website.

- **Data-related TA** is available at: https://www.targethiv.org
- **Report Administration** – RWHAP Data Support addresses RSR- and ADR-related content and submission questions:
  Toll-free Help Line: 1-888-640-9356
  Hours: Monday – Friday, 10 a.m. – 6:30 p.m., ET
  Email: RyanWhiteDataSupport@wrma.com
- **Data Infrastructure** – Assistance in addressing questions regarding significant assistance to meet data reporting requirements, data quality, and providing TA on the Encrypted Unique Client Identifier (eUCI) Application (see https://targethiv.org/library/encrypted-unique-client-identifier-euci-application-and-user-guide):
  Email: Data.ta@caiglobal.org
- **CAREWare** – An overview of CAREWare is available at: https://ryanwhite.hrsa.gov/grants/manage/careware. The CAREWare Help Desk addresses issues pertaining to the CAREWare data collection system:
  Toll-Free Help Line: 1-877-294-3571
  Hours: Monday, Wednesday, Friday, 12:00 p.m. – 5:00 p.m., ET
  Tuesday, Thursday, 10:30 a.m. - 6:30 p.m.
  Email: cwhelp@jprog.com
- **Grants/EHBs Support** – The HRSA Contact Center addresses EHBs and RSR-related questions.
  Toll-Free Help Line: 1-877-464-4772
  Hours: Monday – Friday, 7 a.m. – 6 p.m., ET
  Submit a Request: http://www.hrsa.gov/about/contact/ehbhelp.aspx

Additional TA Links and Resources

Additional references for reporting requirements mentioned in this section and information needed to complete them are provided below.

- **Ryan White Care and Treatment Extension Act of 2009 (RWHAP Legislation):** https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/about-program/legislation-title-xxvi.pdf
- **HHS Grants Policy Statement:** https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf
- **Information and instructions on the SF-424 budget forms:** https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf
- **HRSA HAB Policy Notices:** https://ryanwhite.hrsa.gov/grants/policy-notices
- **HRSA HAB Program Letters:** https://ryanwhite.hrsa.gov/grants/program-letters

Section V: Recipient and Subrecipient Monitoring

V. Chapter 1. Introduction

Monitoring, whether HRSA monitoring of recipients, recipient monitoring of subrecipients, or the recipient and subrecipient monitoring of contractors, is a critical component of the RWHAP. This section provides a high-level overview of the oversight and monitoring responsibilities of recipients and subrecipients, as well as information regarding useful tools that will assist with providing oversight of both subrecipients and contractors.

V. Chapter 2. Relevant Authorities

Definitions and Roles

The UAR establishes the following relevant definitions in 45 CFR § 75.2 pertaining to awarding of federal funding:

- **Federal awarding agency**, defined as "the Federal agency that provides a Federal award directly to a non-Federal entity."
- **Recipients**, defined as "an entity, usually but not limited to non-Federal entities, that receives a Federal award directly from a Federal awarding agency to carry out an activity under a Federal program. The term recipient does not include subrecipients."
- **Pass-through entities**, defined as "a non-Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program." A pass-through entity may be a recipient or subrecipient.
- **Subrecipients**, defined as "a non-Federal entity that receives a subaward from a pass-through entity 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."
- **Contractors**, defined as "an entity that receives a contract," which is defined as "a legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award."

Please note that the RWHAP legislation uses the term "subcontractor" in reference to entities that receive funding directly from the recipient, or from a lead agency or consortia acting on behalf of the recipient.

The UAR also clarifies the role of the recipient and subrecipient with regard to the following:

- Procurement standards (45 CFR §§ 75.326 – 75.340, particularly 45 CFR § 75.326 – 75.329);
- Performance and financial monitoring and reporting (45 CFR §§ 75.341-75.343);
- Access to records related to a federal award (45 CFR § 75.364);

- Distinguishing subrecipients from contractors (45 CFR § 75.351); and
- Subrecipient monitoring and management/requirements for pass-through entities (45 CFR § 75.352).

Oversight and Monitoring

All RWHAP Part B recipients are responsible for adequate oversight and monitoring of all activities supported by the federal award, including subawards and contracts. Per 45 CFR § 75.342(a):

> *"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."*

All RWHAP Part B recipients, subrecipients, and contractors must ensure proper procedures and oversight in the procurement of subawards and contracts and ensure that all requirements under the grant are satisfied across subrecipients and contractors.

Per general procurement standards in 45 CFR § 75.326:

> *"When procuring property and services under a Federal award, a state must follow the same policies and procedures it uses for procurements from its non-Federal funds. The state will comply with §75.331 and ensure that every purchase order or other contract includes any clauses required by §75.335. All other non-Federal entities, including subrecipients of a state, will follow §§75.327 through 75.335."*

Subrecipients must use their own procurement procedures that reflect applicable state/territory and local laws and regulations. Contracts must contain the clauses necessary to ensure all requirements under the grant will be satisfied. A full list of required contract clauses is contained in 45 CFR Appendix II to Part 75.

Access to all applicable records and staff is required to ensure appropriate oversight and monitoring. Per 45 CFR § 75.364:

> *"The HHS awarding agency, Inspectors General, the Comptroller General of the United States, and the pass-through entity, or any of their authorized representatives, must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts. The right also includes timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents."*

Distinguishing between Subrecipients and Contractors

All RWHAP Part B recipients, subrecipients, and contractors should review 45 CFR § 75.351 in its entirety and use judgment in classifying legal agreements as subawards or contracts based on the substance of the agreement or relationship. Per 45 CFR § 75.351:

> *"a subaward is for the purpose of carrying out a portion of a Federal award and creates a Federal assistance relationship with the subrecipient,"* and
>
> *"a contract is for the purpose of obtaining goods and services for the non-Federal entity's own use and creates a procurement relationship with the contractor."*

Furthermore,

> *"In determining whether an agreement between a pass-through entity and another non-Federal entity casts the latter as a subrecipient or a contractor,* ***the substance of the relationship is more important than the form of the agreement****."*

Therefore, pass-through entities must use the **substance of a legal agreement or relationship** to determine whether the non-federal entity with whom it has a legal agreement is a subrecipient or a contractor, regardless of the type of legal agreement or the term used when referencing the legal agreement.

Subrecipient Monitoring

As was noted earlier, all RWHAP Part B recipients are responsible for adequate oversight and monitoring of all activities supported by the federal award, including subawards and contracts. As such, the recipient must ensure that subrecipient monitoring requirements are met.

Per 45 CFR § 75.352, all RWHAP Part B recipients must ensure that any RWHAP Part B subaward (including those made by a lead agency or consortium) is clearly identified as a subaward and includes information regarding all federal requirements pertaining to the award. The subaward must also include any additional requirements imposed by the pass-through entity to meet is responsibilities to the HHS awarding agency (i.e., HRSA HAB).

All RWHAP Part B recipients also are responsible for ensuring the following and related activities:

- The evaluation of subrecipient risk for non-compliance;
- The monitoring of subrecipient activities to ensure compliance and that performance goals are met;
- Verification of subrecipient auditing; and
- Enforcement action is taken as appropriate to address noncompliance.

V. Chapter 3. Subrecipients

Subrecipients are all entities receiving a RWHAP Part B subaward from the RWHAP Part B recipient or a lead agency, consortia, or direct service provider. Subrecipients may also include entities receiving a RWHAP Part B contract if the substance of the relationship aligns with the definition of a subaward (i.e., for the purpose of carrying out a portion of a federal award). The RWHAP Part B recipient is accountable to HRSA HAB for adequate oversight and monitoring of all activities supported by the federal award, including through subawards and contracts. Common RWHAP Part B subrecipients are described below.

V. 3. A. Consortia

A consortium is an association of public and nonprofit healthcare and support service providers and community-based organizations with which the state/territory establishes a legal agreement to conduct specific activities outlined in the RWHAP legislation for a specific region(s) or the entire state/territory, including:

1) Needs assessment, including identifying key populations and service delivery needs;
2) Planning, including alignment of developed plans with RWHAP Part B recipient developed plans (e.g., SCSN);
3) Delivery of comprehensive health and support services, either directly by the consortia or by subaward/contract;
4) Program and fiscal monitoring, including evaluation; and
5) Reporting, including required reports submitted to the RWHAP Part B recipient and HRSA HAB.

Consortia must provide all five activities to meet requirements established in RWHAP legislation. Consortia can be pass-through entities that issue subawards or contracts for direct service delivery to people with HIV. Within a state/territory, the recipient may have one or more consortia specific to a defined region(s), in addition to one or more lead agencies specific to remaining regions.

The RWHAP Part B recipient must ensure it monitors consortia as it would other subrecipients.

For more information on requirements related to consortia, see Section X, The Role of Consortia, in the RWHAP Part B.

V. 3. B. Lead Agency

A lead agency is an entity with which the state/territory establishes a legal agreement to do one or more of the following: conduct needs assessments, engage in planning activities, manage procurement processes, ensure delivery of comprehensive services to people with HIV, and/or conduct program and fiscal monitoring. The state/territory may fund the lead agency to conduct

these activities for a specific region(s) or for the entire state/territory. Lead agencies are often pass-through entities that issue subawards or contracts to direct service providers. Lead agencies may also receive a subaward from the recipient to deliver direct services to people with HIV.

The RWHAP Part B recipient must ensure it monitors lead agencies as it would other subrecipients.

V. 3. C. Direct Service Provider

A direct service provider is an entity with which the state/territory, lead agency, or consortium establishes a legal agreement to provide RWHAP core medical and support services to people with HIV. Direct service providers may include ambulatory medical clinics, public health departments, institutions of higher education, state and local governments, nonprofit organizations, faith-based and community-based organizations, and tribes and tribal organizations. Direct service providers for RWHAP Part B may also be the RWHAP recipient or subrecipient from other RWHAP Parts or an entity that serves as a lead agency or consortia. Direct service providers may include for-profit entities when they are the only available providers of quality HIV care in a jurisdiction.

The RWHAP Part B recipient must ensure it monitors all direct service providers as subrecipients. If an entity is both a direct service provider and a lead agency, the recipient must ensure that each legal agreement is appropriately monitored.

V. 3. D. Fiduciary Agent

A fiduciary agent is an entity with which the state/territory establishes a legal agreement to do one or more of the following: manage grant funds; manage procurement processes; manage payment of invoices; ensure funds are used for allowable purposes and in accordance with applicable legislative, regulatory, and programmatic requirements; and/or execute award requirements related to non-compliance.

Fiduciary agents typically conduct fiscal activities on behalf of the recipient in an administrative capacity and do not provide direct services to people with HIV or have a direct relationship with direct service providers. In addition, fiduciary agents are typically not involved in programmatic decision-making (e.g., planning, priority-setting, eligibility determination).

Depending on the substance of the relationship, a fiduciary agent may be a subrecipient or a contractor. Recipients should use the content of the legal agreement, including the statement of work, to determine whether subrecipient monitoring is required.

V. Chapter 4. RWHAP Part B National Monitoring Standards

The NMS are a TA resource to support recipients and subrecipients in meeting federal requirements for program and fiscal management, monitoring, reporting, and oversight of the RWHAP Parts A and B, and to improve program efficiency and responsiveness.

The NMS consolidate requirements set forth in relevant authorities and outline suggested standards for how recipients and subrecipients can meet those requirements. As such, the NMS do not establish or impose legislative, regulatory, or programmatic requirements; but rather provide guidance on how recipients, lead agencies, and consortia can meet requirements and monitor those who have been issued subawards.

The NMS include Program, Fiscal, and Universal components. There are separate NMS for RWHAP Parts A and B. The Universal component addresses general requirements for both the RWHAP Parts A and B. The NMS are organized by legislative, regulatory, and programmatic requirements. For each requirement, suggested standards for meeting the requirement are provided, including performance measures/methods and recipient and subrecipient responsibilities. Performance measures/methods provide guidance on how to meet each requirement. Recipient and subrecipient responsibilities outline approaches for meeting or verifying compliance with the requirement. HRSA HAB's provision of the NMS does not supplant the recipient or subrecipient responsibility for reading and complying with all current and relevant authorities.

The NMS can support recipients and subrecipients in the following ways:

- Preparing for recipient or subrecipient site visits conducted by HRSA HAB, the recipient, a lead agency, or a consortia;
- Developing subrecipient monitoring protocols and tools; and
- Ensuring recipients and subrecipients meet legislative, regulatory, and programmatic requirements.

During annual subrecipient monitoring site visits conducted by the recipient, lead agency, or consortia, the NMS can be used to assess subrecipient compliance with legislative, regulatory, and programmatic requirements. Therefore, recipient and subrecipient fiscal and program staff should be familiar with all components of the NMS. If there are questions regarding the content of the NMS, please contact the DSHAP PO.

V. Chapter 5. Monitoring of RWHAP Part B Recipients by DSHAP

DSHAP provides federal monitoring and oversight of the RWHAP Part B, including ADAP. Federal monitoring and oversight include assessing recipient operations and performance, promoting economy and efficiency in recipient operations, and ensuring recipient compliance with RWHAP Part B and ADAP legislative, regulatory, and programmatic requirements.

The scope of federal monitoring and oversight includes all administrative, fiscal, and program activities under RWHAP Part B, including ADAP, and applies to any project, program, function, or activity supported by the RWHAP Part B award directly or through subaward, contract, or other legal agreement. Therefore, federal monitoring applies to all directly funded RWHAP Part B and ADAP non-federal entities in their roles as recipients of federal awards, in their role as a pass-through entity, and/or in their implementation of subawards, contracts, or other legal agreements. DSHAP monitoring does not extend to subrecipients.

Site Visits to RWHAP Part B Recipients

Site visits are a key component of DSHAP oversight of RWHAP Part B and ADAP recipients to verify and ensure compliance with RWHAP Part B legislative, regulatory, and programmatic requirements; provision of high-quality HIV clinical care in accordance with PHS guidelines; and administrative and fiscal integrity.

HRSA HAB conducts four types of site visits: comprehensive, diagnostic, TA, and Resource Innovation Team (RIT) site visits. HRSA HAB has implemented a risk-based strategy for scheduling recipient site visits and for choosing the appropriate type of site visit. Following a site visit, a site visit report is generated by the DSHAP PO and provided to the recipient.

Comprehensive Site Visit

The purpose of a Comprehensive Site Visit (CSV) is to:

1) Assess legislative, regulatory, and programmatic compliance of RWHAP Part B, including ADAP;
2) Review and ensure the recipient makes progress in planning and implementing proposed programs/projects;
3) Provide recommendations for areas of improvement; and
4) Identify best practices.

During the site visit, a team of internal HRSA HAB staff and/or external consultants conducts an assessment of the entire RWHAP Part B, including program administration, ADAP, CQM, and financial systems management. This assessment may result in the identification of legislative and/or programmatic findings, performance improvement options, and programmatic strengths. The site visit team may also provide on-site TA and/or identify TA needs to assist recipients in meeting legislative and regulatory requirements and program expectations. Following the visit, recipients will receive a Site Visit Report documenting all findings identified and discussed during the CSV Exit Conference.

When a legislative, regulatory, or programmatic finding (i.e., area of non-compliance) is identified during a site visit, the recipient must create a Corrective Action Plan (CAP), in conjunction with the DSHAP PO, to address deficiencies and bring the program into compliance. The designated DSHAP PO will work with recipients to resolve deficiencies. A recipient may request TA to support implementation of the CAP. CSVs are scheduled for all RWHAP Part B recipients at least once every three to five years.

Diagnostic Site Visits

The purpose of a diagnostic site visit is to address a significant concern or issue identified, including through DSHAP PO monitoring, recipient self-assessment, and/or audit findings. Concerns or issues that may lead to a diagnostic site visit include:

- A previously identified programmatic, fiscal, or administrative deficiency that the recipient has failed to correct within a specified time frame;
- An emerging issue or situation that may lead the recipient to be unable to meet the terms of the award;
- Persistent recipient non-compliance with conditions of award, program terms, or reporting requirements; or
- The result of an audit finding.

During the site visit, a team of internal HRSA HAB staff and/or external consultants examines and analyzes factors contributing to identified concerns or issues. The team may also review previous Comprehensive Site Visit Reports and corresponding CAPs submitted by the recipient. Following the visit, recipients will receive a Diagnostic Site Visit Report outlining the assessment provided, any findings, and recommendations for improvement. The designated DSHAP PO will work with recipients to resolve findings.

Diagnostic site visits are scheduled by DSHAP as needed.

Technical Assistance (TA) Site Visits

The purpose of a TA site visit is to provide tailored training, capacity-building assistance, instruction, or staff orientation around an identified area of need for a specific RWHAP Part B recipient. The need for TA may be identified through DSHAP PO monitoring, during application review, during a site visit, or by the recipient. TA may address any legislative or programmatic area (e.g., CQM, fiscal, administrative, or ADAP) and may focus on a range of topics (e.g., succession planning, quality management, management information systems, strategic planning, governance, etc.).

TA site visits are most often conducted by HRSA HAB external consultants. During the TA site visit, external consultants work with the recipient's administrative staff, program staff, or program directors to address the identified need. The site visit may result in the identification of areas for performance improvement, best practices, or innovative practices. Following the visit, recipients will receive a TA Site Visit Report outlining the TA provided and any additional recommendations for improvement.

TA site visits are scheduled as needed and as prioritized by DSHAP.

Resource Innovation Team Site Visits

The primary goal of the RIT is to support recipients in implementing innovative strategies that will lead to greater impact of the RWHAP Part B and related resources (e.g., grant funding, rebates, and program income) in every state and territory to meet the goals of the RWHAP, including ending the HIV epidemic. As such, the purpose of an RIT Site Visit is to:

1) Explore innovative strategies that can maximize the utilization of available resources in a state/territory to meet the goals of the RWHAP, including addressing service gaps and unmet needs;
2) Increase DSHAP's understanding of the internal and external factors impacting a state's/territory's ability to utilize all available resources;
3) Increase DSHAP's understanding of a forecasted decrease in the amount of resources that have been available to support a state's/territory's established system of HIV care and treatment; and/or
4) Identify additional TA and other support needed to reduce a state's/territory's UOB.

During an RIT site visit, a team of internal HRSA HAB staff and/or an external consultant engage in discussions with recipient staff and other state/territory health department staff regarding challenges associated with utilizing available resources from RWHAP Part B and ADAP to meet the goals of the RWHAP. These challenges may be related to budgeting, accounting, legal constraints (e.g., state regulation), coordination across RWHAP Parts, workforce, the evolving health care environment, or other factors. Site visit participants also explore innovative strategies to address identified challenges, maximize the utilization of resources, and address any service gaps and unmet needs. Following the visit, recipients receive an RIT report summarizing site visit discussions, recommendations for addressing challenges and improving utilization of resources, and opportunities for improvement. RIT site visits are scheduled as needed and as prioritized by DSHAP.

V. Chapter 6. Monitoring of RWHAP Part B Subrecipients

The RWHAP Part B recipient is held accountable by HRSA HAB for all subawards, contracts, or other legal agreements awarded through the RWHAP Part B grant, including ADAP. For example, in the case of an OIG finding that results in repayment of federal dollars, the recipient, not the subrecipient or contractor, is responsible for repaying the debt out of non-federal dollars.

Recipients should use their monitoring process and legal agreement language to establish expectations and to reinforce and underscore mutual obligations between the recipient and the subrecipient. The recipient should have an established monitoring process that designates a person or team to review fiscal and program reports, conduct site visits, interact on an ongoing basis with contracted providers, and implement a CAP or other corrective action, if necessary. If a recipient chooses to distribute monitoring functions across its organization, the recipient should ensure appropriate communication between those responsible for programmatic and fiscal monitoring. Recipients may choose to assign monitoring functions to a lead agency or consortia.

The monitoring process for subrecipients should be standardized, transparent, and encompass the full range of monitoring and oversight activities required, including: drafting and ensuring compliance with scopes of work, conducting desk compliance audits, analyzing performance reports, training recipient and subrecipient staff, and other required program and fiscal monitoring activities. In addition, it should describe and outline the process to be followed prior to, during, and after a monitoring site visit (see next section for more information).

Subrecipient monitoring requirements are outlined in 45 CFR § 75.352.

Site Visits to RWHAP Part B Subrecipients

Recipients must ensure that all RWHAP Part B subrecipients receive an annual monitoring site visit unless the recipient has an approved annual subrecipient site visit exemption from DSHAP.

Recipients and other pass-through entities (e.g., lead agencies, consortia) should establish a structured process or protocol, and develop corresponding fiscal and program tools for annual site visits to each subrecipient to ensure review of the subrecipient's obligations in sufficient detail. A sound practice is to model the fiscal and program tools after the NMS. Site visits might include staff interviews, observation of services, review of client records or charts, a facility tour, and a review of various documentation to validate subrecipient operations are compliant with requirements. Desk audits are not a substitute for annual subrecipient site visits.

Review of client records or charts is one method by which recipients can assess compliance with service category definitions and established service standards and to validate services are provided within eligibility time periods. This review does not need to include all records or charts. A sufficient review can be accomplished by using an established random sampling methodology. Established protocols and tools should define and describe the sampling methodology based on the number of clients served, number and complexity of data to be reviewed in each client record or chart, and the methodology used for data review, extraction, and/or documentation.

Following a site visit, each subrecipient must receive a Site Visit Report, including any legislative, regulatory, and/or programmatic non-compliance findings. The recipient, lead agency, or consortia must ensure a CAP is developed to resolve all findings. The recipient, lead agency, or consortia must monitor the CAP to ensure its satisfactory completion.

Annual Subrecipient Site Visit Exemption

Recipients may submit a request for an exemption to providing annual subrecipient site visits (see https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/rwhap-site-visit-exemption-dcl-2019.pdf). To receive an exemption, the recipient must demonstrate that sufficient monitoring of subrecipients will continue to occur to ensure compliance with all RWHAP Part B legislative, regulatory, and programmatic requirements.

To submit a request for an exemption from the annual site visit requirement, recipients must notify their DSHAP PO of their intention to request an exemption. The PO will initiate a Request for Information (RFI) in the EHBs.

The recipient must respond to the EHBs task by the established due date with an exemption request that addresses the following:

- How many subrecipients does the program fund and monitor?
- What are the barriers and challenges to conducting annual site visits to all subrecipients?
- If the program is unable to conduct annual site visits, what is the frequency and/or schedule of visits that the program can conduct?
- How many years are needed to conduct a full cycle of visits to all subrecipients?
- Does the state/territory have a site visit protocol? If so, include with request.
- What is the program's monitoring plan during the years that subrecipients are not receiving a site visit?
- What is the program's process for issuing and monitoring CAPs?

Recipients can request an exemption for one year or for multiple years. If submitting a multi-year exemption, recipients must submit a site visit timeline and comprehensive monitoring plan that is appropriate for the scope and complexity of the jurisdiction's system of HIV care and treatment.

If the request is approved, the recipient will be notified. Recipients with approved waivers must provide updates on site visit monitoring activities to the designated DSHAP PO. Recipients must obtain prior approval on any changes to their approved plan. When an approved exemption expires or is terminated due to non-compliance, recipients must submit a new exemption request for any subsequent year(s).

V. Chapter 7. Technical Assistance Links and Resources

This section provides resources for recipient and subrecipient monitoring to ensure compliance with legislative, regulatory, and programmatic requirements.

- **National Monitoring Standards:** https://ryanwhite.hrsa.gov/grants/manage/recipient-resources
- **HRSA HAB Policy Notices:** https://ryanwhite.hrsa.gov/grants/policy-notices
- **HRSA HAB Program Letters:** https://ryanwhite.hrsa.gov/grants/program-letters
- **45 CFR Part 75:** https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4d52364ec83fab994c665943dadf9cf7&ty=HTML&h=L&r=PART&n=pt45.1.75#sp45.1.75.b.
- **TargetHIV:** https://targethiv.org

Section VI: Clinical Quality Management

VI. Chapter 1. Introduction

The complexity of HIV care and the RWHAP commitment to equal access to quality care for all people with HIV require systematic efforts to ensure all RWHAP-funded services are delivered efficiently and effectively. CQM programs are a requirement of the RWHAP legislation, and essential to assessing whether RWHAP-funded providers are delivering high-quality HIV care and treatment and improving their system of care.

RWHAP Part B CQM programs should use effective and proven quality management concepts and quality improvement methods in program development and implementation. By analyzing the data collected on outcomes of services, RWHAP Part B recipients can direct resources to services or expand models of care that have been proven effective in linking people with HIV to care, retaining them in care, and achieving and maintaining viral suppression (i.e., improving outcomes across the HIV care continuum).

VI. Chapter 2. Relevant Authorities

RWHAP Part B legislation, Section 2618(b)(3)(E) of the PHS Act requires:

> *"Each State that receives a grant under Section 2611 shall provide for the establishment of a clinical quality management program to assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infection, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services."*

Additional language under Section 2618, "Administrative Expenses," sets limits on the amounts to be expended for CQM, but states that the CQM costs do not count toward the 10 percent recipient 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)."*

Clinical Quality Management Policy Clarification Notice, PCN #15-02, clarifies CQM program expectations for RWHAP recipients; sets the minimum requirements for RWHAP Parts A, B, C, and D; and details the necessary components of a CQM program. It is a guiding reference for establishing and implementing the CQM program.

VI. Chapter 3. Components of CQM Programs

CQM is a systematic, structured, and continuous approach to meet or exceed established professional standards and user expectations. CQM is implemented by using tools and techniques to measure performance and improve processes. To implement a CQM program, recipients need to have the necessary infrastructure, performance measurement, and quality improvement (QI) components in place. PCN #15-02 clarifies the HRSA RWHAP expectations for CQM programs.

VI. 3. A. Infrastructure

CQM is a systematic, structured, and continuous approach to meet or exceed established professional standards and user expectations. CQM is implemented by using tools and techniques to measure performance and improve processes. To implement a CQM program, recipients need to have the necessary infrastructure, performance measurement, and quality improvement (QI) components in place. PCN #15-02 clarifies the HRSA RWHAP expectations for CQM programs.

RWHAP Part B recipients are required to have a comprehensive CQM program that includes all components, but CQM programs will vary depending on the size and scope of the RWHAP. For example:

- RWHAP Part B recipients that fund many core medical and support services may require multiple staff to administer the CQM program; a large CQM Committee that includes multiple RWHAP Part A, Part C, and Part D representatives and other stakeholders; and a consumer subcommittee that directly informs the larger CQM Committee.
- RWHAP Part B recipients that fund only a few services may have a smaller CQM program, but must still have adequate infrastructure to meet the expectations outlined in PCN #15-02.
- A RWHAP Part B in a low incidence state may have a single staff member who administers the CQM program and has other duties outside of the CQM program; a small CQM Committee; and may use other health department staff to ensure that all infrastructure is in place.

Please reference the infrastructure section of PCN #15-02 for details.

VI. 3. B. Performance Measurement

Performance measurement is the process of collecting, analyzing, and reporting data regarding patient care, health outcomes, or client satisfaction. Performance measures must be based on established procession standards, evidence-based research, or client expectations, when possible. The analysis is completed by defining the data elements used to calculate the numerator and denominator for each performance measure. Additionally, HRSA HAB recommends recipients stratify their performance measure data by subpopulation. Performance measures must be based on established professional standards and/or evidenced based research, when possible. The stratified performance measure data can assist when analyzing the data to understand disparities and identify and focus quality improvement activities.

While performance measurement is a required component of a CQM program, performance measure portfolios can also vary depending on the size and scope of the RWHAP. Performance measures should reflect the RWHAP funded service categories and local priorities. RWHAP Part B recipients in high incidence states/territories may need a larger more diverse set of performance measures in contrast to small incidence states/territories. RWHAPs should refer to PCN #15-02 to determine the number of performance measures required for each funded service category. HRSA HAB has developed a portfolio of measures that RWHAPs can use, if they choose. While HRSA HAB does not require any recipients to use any specific measure, RWHAP recipients are encouraged to use the HRSA HAB core measures for funded service categories and to adopt other measures as needed for the program.

RWHAP Part B recipients may use performance measures at a system level or at a provider level. The core measures can be used at both the system level and provider level. For example, recipients are encouraged to use the HIV viral suppression performance measure (which is also encouraged for ADAP) to assess the entire RWHAP Part B system. Likewise, a RWHAP Part B recipient may have Medical Case Management (MCM) providers track and report the HIV viral suppression for the agency, thereby using the HIV viral suppression measure to assess performance at the provider level. Recipients can also choose to use HIV viral suppression to measure MCM services at a system level by aggregating data from all the MCM providers and assessing performance over time.

HAS HAB encourages RWHAP Part B recipients to coordinate their performance measures with other RWHAP recipients in their service area. RWHAP Parts A-D recipients are required to have performance measures. Within a service area, recipients' coordination could have many benefits and reduce burden. The following are suggested areas for coordination:

- Alignment of performance measure definitions (numerator, denominators, and exclusions) for a service category to enable data analysis across the service area; and
- Agreement on performance measure reporting cycles (how often and when to report on performance measures) to reduce the reporting burden for organizations funded by more than one RWHAP Part.

VI. 3. C. Quality Improvement

Quality Improvement (QI) is a process to analyze performance measure data and implement activities to improve performance. QI is required regardless of the size and scope of the RWHAP Part B. Similar to performance measures, QI activities must focus on improving patient care, health outcomes, or client satisfaction. QI must be implemented using a defined methodology and in an organized, systematic fashion. The most common QI methodologies are the Model for Improvement and Lean, although other methodologies exist.

At minimum, RWHAP Part B recipients must implement at least one QI activity at any given time for at least one service category and document the QI activities. RWHAPs in high incidence states may be engaged in multiple QI projects at a system and provider level to ensure continuous quality improvement or to meet established benchmarks. In contrast, RWHAPs in small incidence states may be engaged in a single QI project at either the system level or the provider level.

VI. Chapter 4. Subrecipient Involvement in the Recipient CQM Program

RWHAP Part B recipients must include all subrecipients in the recipient's CQM program. Recipients are to identify the specific CQM program activities for their subrecipients. The subrecipient activities often include participating on the recipient's CQM Committee and training, providing performance measure data, and implementing QI activities. HRSA HAB encourages recipients to codify subrecipient CQM activities in Requests for Proposals (RFPs) and contracts. However, the contribution of subrecipients to the recipient's CQM program will vary depending on the service provided and the resources available. For example, given their key role in HIV care, OAHS providers should have an active role in the recipient's CQM program, such as participating in the CQM Committee, reporting performance measure data, and contributing to QI projects.

In contrast, medical transportation providers may track and report the number of clients transported in a given timeframe but would not have client-level data on patient care or health outcomes. Therefore, the medical transportation provider would not be able to assess the impact on health outcomes. However, recipients could combine client-level utilization data and clinical data to assess a retention in care performance measure.

VI. Chapter 5. HRSA HAB Monitoring of CQM

A RWHAP Part B recipient's CQM program is monitored by HRSA HAB to ensure that the legislative and program CQM requirements are met. Monitoring occurs through several mechanisms, including the following:

- Discussion of CQM programs during monthly monitoring calls;
- Review of submitted CQM plans; and
- Review of CQM programs during comprehensive site visits.

If concerns are identified during routine monitoring, the DSHAP PO may engage a CQM subject matter expert to work with recipients in addressing the concern. Recipients should contact the DSHAP PO with any questions they may have about CQM programs or plans.

VI. Chapter 6. Additional Technical Assistance Links and Resources

The following links provide additional information on CQM, the RWHAP policies, and other related information relevant to the development and implementation of a CQM program.

- **HAB Clinical Care and Quality Management Website:** https://ryanwhite.hrsa.gov/grants/clinical-care-guidelines-resources. For links to information and resources on Clinical Care Guidelines and Resources, HAB Performance Measure Portfolio, and Quality of Care. The site also includes information on how to request CQM TA.
- **HAB Policy Notices**: https://ryanwhite.hrsa.gov/grants/policy-notices
- **HAB Performance Measures - List of Performance Measures and Frequently Asked Questions (FAQ):** https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio.
- **CQM Technical Assistance:** RWHAP recipients can request TA by filling out and submitting a request available at: https://targethiv.org/ta/cqm.
- **HIV Quality Measures (HIVQM) Module:** Online data system for use by all RWHAP recipients called the HIV Quality Measures Module (HIVQM Module). The HIVQM Module's purpose is to help recipients set goals and monitor performance measures as well as quality improvement projects to better support CQM, performance measurement, service delivery, and client monitoring at both the recipient and client levels. https://targethiv.org/library/topics/hivqm.
- **Ryan White HIV/AIDS Program Clinical Quality Management Listserv:** Online user forum for RWHAP CQM staff to ask questions, seek advice, and share resources with others in the RWHAP. https://public.govdelivery.com/accounts/USHHSHRSA/signup/29907.
- **Center for Quality Improvement and Innovation (CQII):** https://targethiv.org/cqii. CQII provides training and TA on QI to RWHAP recipients and subrecipients.
- **CQM Tools and Resources:** https://targethiv.org/library/topics/clinical-quality-management.

The following are additional CQM concepts that may be helpful in the development and implementation of a CQM program.

- **Model for Improvement:** The Model for Improvement was developed by Associates in Process Improvement and is a simple yet powerful tool for accelerating improvement. This model has been used very successfully by hundreds of health care organizations in many countries to improve many different health care processes and outcomes. The model has two parts:
  1) Three fundamental questions, which can be addressed in any order.
  2) The Plan-Do-Study-Act (PDSA) cycle** to test changes in real work settings. The PDSA cycle guides the test of a change to determine if the change is an improvement.
     - **Plan** – Identify problems (including their components—not just the big picture) and then plan strategies/tests that might result in improvements.
     - **Do** – Use strategies that are designed to address problems.
     - **Study** – Collect and analyze data to see if strategies have resulted in improvements.
     - **Act** – If the strategies are effective, make them an ongoing activity. If they are not effective, return to the Plan stage. Use collected data to identify new ways to address problems.

- **Benchmarking and Best Practices**: Benchmarking is the process of comparing one's performance to that of a higher performing organization of similar characteristics, determining the best practices that have led to the higher performance, and implementing the best practices. The goal is to make changes to a process that will result in higher performance. Some organizations use their own data as a baseline benchmark against which to compare future performance.
- **Clinical Practice Guidelines:** Clinical practice guidelines are generally written by a respected authority and based on the most recently available state of knowledge, clinical research, and expert opinion. The purpose of guidelines is to provide recommendations on how to screen, treatment, and provide care and services. The "*Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents"* is one such resource, and a variety of guidelines in HIV care and treatment can be found at: https://clinicalinfo.hiv.gov/en/guidelines. Guidelines are often the basis for developing performance measures and standards of care.
- **HRSA HAB Implementation Science:** HRSA HAB has developed an implementation science framework to support this translation/adaptation process, guiding implementation and evaluation projects across the RWHAP. Implementation science has emerged as an essential field for HIV treatment and prevention, providing crucial insights for clinical effectiveness and efficacy trials, bench-to-bedside translation of clinical trial evidence into real-world intervention strategies, and routine program monitoring and evaluation. Implementation science has been described as "methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services." (Eccles and Mittman, 2006)
- **Service Standards:** Service standards, which are sometimes referred to as standards of care are principles and practices for the delivery of health and social services that are accepted by recognized authorities and used widely. Service standards for HIV care are based on specific research (when available) and the collective opinion of experts. They are often informed by guidelines, clinical research, and patient experiences. RWHAP service standards outline the elements and expectations a RWHAP service provider follows when implementing a specific service category, to ensure that all service providers offer the same fundamental components of the given service category across the service area. They establish the minimal level of service or care that a RWHAP Part B-funded agency or provider may offer within a jurisdiction.
  See:https://targethiv.org/sites/default/files/file-upload/resources/Service%20Standards%20HRSA%20HAB%20Guidance%201 2_14.pdf.

Section VII: Grants Administration

VII. Chapter 1. Introduction

RWHAP Part B recipients are responsible for the administration of the RWHAP Part B grant, including ADAP. The RWHAP legislation, the UAR, Notices of Awards, and HRSA HAB Policy Clarification Notices and Program Letters contain federal rules and guidance governing grants management for the RWHAP Part B. RWHAP Part B recipients must be familiar with these documents to ensure that they and all their subrecipients and contractors follow these grant requirements. While RWHAP Part B recipients may choose to issue subawards or contracts to other entities to lead or assist in administration of the RWHAP Part B grant, the RWHAP Part B recipient is ultimately responsible for the proper stewardship of all RWHAP Part B grant funds, including ADAP.

This section provides a high-level overview of federal grants management requirements and identifies useful tools that can assist with meeting these requirements and successfully managing awards for RWHAP Part B grants, including RWHAP Part B – HIV Care Program, ADAP (X07), RWHAP Part B Supplemental (X08), and RWHAP ADAP ERF (X09).

VII. Chapter 2. Relevant Authorities

Recipients should be familiar with and have a clear understanding of relevant authorities for RWHAP Part B and ADAP to ensure proper administration and monitoring. See Section II, Overview of RWHAP, Chapter 2, for a detailed description of relevant authorities.

VII. 2. A. RWHAP Legislation

The Parts and Sections of the legislation that apply to the RWHAP Part B are Part B of the PHS Act, Sections 2611 through 2623; Part E General Provisions, Sections 2681-2689; and Part F, Subpart III MAI, Section 2693. See https://ryanwhite.hrsa.gov/about/legislation.

VII. 2. B. OMB Circulars, as adopted by HHS, including 45 CFR Part 75

The 45 CFR Part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards ensures consistency among federal agencies and protects recipients from undue burden from the awarding federal agency. On December 26, 2013, the OMB published guidance for federal award programs, known formally as the OMB Circulars: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Guidance). In accordance with requirements imposed by the OMB, HHS adopted grant regulations, codified at 45 CFR Part 75, with an effective date of December 26, 2014. The UAR 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.

VII. 2. C. HHS Grants Administration and Program-Specific Policies and Guidance

HHS Grants Policy Statement (GPS)
The HHS GPS makes available in a single document the general terms and conditions of HHS discretionary grant and cooperative agreement awards. These general terms and conditions are common across all HHS OPDIVs and apply as indicated in the HHS GPS unless there are legislative, regulatory, or award-specific requirements to the contrary (as specified in individual NoA). The HHS awarding offices are components of the OPDIVs and Staff Divisions that have grant-awarding authority. See https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.

Notices of Funding Opportunity (NOFO)
HRSA staff develop a NOFO for each grant or cooperative agreement program. The NOFO includes the purpose of the program, amount of funding available, period of performance, eligible applicants, content and form of application submission, and other important information. HRSA NOFOs are available on the HRSA website and are posted to Grants.gov. An applicant should carefully review the NOFO prior to application submission and be aware of all requirements and restrictions applicable to the receipt of federal funding. Each RWHAP Part B grant program has a corresponding NOFO. See https://www.hrsa.gov/grants/fundingopportunities/default.aspx and https://www.grants.gov/web/grants.

Notices of Award (NoA)
A NoA is issued through the EHBs for each federal grant award. The NoA references all the legislative, regulatory, and programmatic requirements of the grant, including grant-specific terms, program-specific terms, standard terms, conditions, and reporting requirements. A recipient indicates acceptance of an award and its associated terms and reporting requirements by drawing or requesting funds from the PMS. Failure to comply with any terms and/or reporting requirements by the corresponding due date, where applicable, may result in the suspension of the recipient's ability to draw down funds, the disallowance of funds, or both.

In addition, the NoA includes a "Special Remarks" section that 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. See https://www.hrsa.gov/grants/manage-your-grant/training/how-to-manage-grant-guide.

HRSA HAB Policy Notices and Program Letters

These notices and letters provide HAB policy and guidance on understanding, adhering to, and implementing RWHAP legislative requirements. See https://ryanwhite.hrsa.gov/grants/policy-notices and https://ryanwhite.hrsa.gov/grants/program-letters.

RWHAP Manuals, Reports and Technical Assistance Documents
Various guides include this RWHAP Part B Manual and the following:

1) RWHAP ADAP Manual: https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/adap-manual.pdf. A guide for new ADAP staff, with sections explaining the purpose of ADAP, how it is structured at the federal and state/territory level, and the key issues and strategies used by ADAPs to broaden access to HIV medications to persons in need.
2) RWHAP Parts A and B National Monitoring Standards (NMS): https://ryanwhite.hrsa.gov/grants/manage/recipient-resources. A compilation of existing requirements for program and fiscal management, monitoring, and reporting into a single, comprehensive document. The NMS help RWHAP Part A and Part B recipients to meet federal requirements and to improve program efficiency. See Section V, Chapter 3, for more information on the NMS.

See https://ryanwhite.hrsa.gov/grants/manage/recipient-resources for a compilation of RWHAP recipient resources.

VII. Chapter 3. Role of HRSA HAB and Office of Financial Assistance Management

DSHAP monitors the RWHAP Part B, and the DSHAP PO is the staff person responsible for monitoring the programmatic and technical aspects the RWHAP Part B awards. DSHAP POs work with recipients to:

- Provide programmatic TA;
- Monitor post-award activities of project/program performance, including review of progress reports and making site visits; and
- Address business management and other non-programmatic aspects of the grant award in collaboration with the HRSA GMS.

HRSA's Office of Financial Assistance Management (OFAM) provides assurance of the financial integrity of HRSA's grant programs and oversees HRSA grant activities to ensure they are managed in an efficient and effective manner. OFAM handles the business management aspects of grant review, negotiation, award, and administration, as follows:

- Receiving all grant applications;
- Monitoring the objective review process;
- Performing cost analysis prior to grant award and approving changes in budgets, as necessary;
- Providing business management consultation and TA;
- 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 (financial reports, revised budgets, and other related conditions of award);
- Maintaining the official grant file; and
- Conducting continuous surveillance of the financial and management aspects of grants and resolving audit findings.

Each recipient's award has a designated HRSA GMS to help address grants management issues and/or questions that may arise. The NoA includes contact information for the designated HRSA GMS.

VII. Chapter 4. Overview of Key Legislative Requirements

In order to ensure compliance, recipients should be familiar with and have a clear understanding of the following key legislative requirements.

VII. 4. A. Payor of Last Resort

As per the RWHAP legislation, 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, with respect to that item or service under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or by an entity that provides health services on a prepaid basis (except for a program administered by or providing the services of the Indian Health Services." (Section 2617(b)(7)(F) of the PHS Act).*

PCNs #13-01 and #13-04 state that recipients are required to have policies regarding the required process for pursuit of enrollment of health care coverage for all clients, and that they need to document the steps taken during their pursuit of enrollment for all clients. This requirement applies to subrecipients and contractors as well. To ensure compliance with this requirement, the RWHAP Part B recipient and any subrecipient (including those contracted through a lead agency or consortia) must ensure that other available payors are billed appropriately. They must also consistently assess individual client eligibility for other funding sources (e.g., Medicaid, Children's Health Insurance Program (CHIP), Medicare, state-funded HIV/AIDS programs, employer-sponsored health care coverage, other private health care coverage, etc.) and vigorously pursue these other funding sources. Recipients are permitted and encouraged to continue providing services funded through RWHAP to a client that remains unenrolled in Medicaid or health care coverage "after extensive documented efforts on the part of the grantee to enroll the client."

RWHAP recipients and subrecipients may not deny services to RWHAP-eligible clients who are also eligible to receive services through the Indian Health Services (per Section 2617 (b)(7)(F) of the PHS Act) or who are eligible to receive services through Veterans Health Administration (per PCN #16-01, Clarification of the Ryan White HIV/AIDS Program (RWHAP) Policy on Services Provided to Veterans). Recipients and subrecipients must respect client choice of payor in those cases where VA, IHS, and RWHAP are the available payors.

See PCN #13-01 and #13-04 for more information.

VII. 4. B. State Match

Section 2617(d) of the PHS Act requires states/territories that have reported to the CDC more than 1 percent of total U.S. HIV cases in the two most recent fiscal years make available non-federal cash or in-kind resources to match the RWHAP Part B HIV Care Program (X07) funding they receive in the RWHAP Part B Base, ADAP Base, and EC components of the award. The non-federal cash or in-kind resources can be provided either directly or through donations to the state from public or private entities. The state match requirement does not include the ADAP Supplemental or MAI components of X07 award. The RWHAP Part B Supplemental (X08) award and the ADAP ERF (X09) award are not subject to a state match. The number of years the state/territory meets the 1 percent threshold determines the required matching rate. The state match amount begins at $1 for every $5 in federal funding and can increase to $1 for every $2 in federal funding. Please note that the amount of the federal funding awarded determines the state match amount, not the amount of grant funds actually expended by the recipient. Per RWHAP legislation, the Commonwealth of Puerto Rico is excluded from state match requirements.

Determining the Rate of State Match
Section 2617(d) of the PHS Act outlines how the rate of state match is determined for relevant recipients:

- For the first fiscal year of payments under the grant, not less than $1 for each $5 of federal funds provided in the grant;
- For any second fiscal year of such payments, not less than $1 for each $4 of federal funds provided in the grant;
- For any third fiscal year of such payments, not less than $1 for each $3 of federal funds provided in the grant;
- For any fourth fiscal year of such payments, not less than $1 for each $2 of federal funds provided in the grant; and
- For any subsequent fiscal year of such payments, not less than $1 for each $2 of federal funds provided in the grant.

All years in which a state/territory meets the condition are included in establishing the required state match, even if those years are not consecutive. Historically, a small number of states/territories have been above, and have then fallen below, the 1 percent threshold over different fiscal years. A state/territory that meets the 1 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/territory subsequently meets the threshold again, the prior years in which that state met the 1 percent threshold are counted in determining the required rate of state match

Determining the Elements that Constitute the State Match
The state matching amount includes non-federal contributions, such as cash or in-kind contributions provided directly by the state/territory or through donation from public or private entities for HIV-related services, whether or not the contributions are made specifically for RWHAP. In-kind contributions are defined as non-cash contributions that a state/territory may provide to support HIV-related services that must be fairly valued and may include equipment or services.

45 CFR 75.306 provides additional clarification on the state match requirements. Recipients are expected to ensure that non-federal contributions (direct or through donations of private and public entities) are:

- Verifiable in recipient records;
- Not used as matching for another federal program;
- Necessary for RWHAP objectives and outcomes;
- Allowable as per 45 CFR part 75, subpart E;
- Not paid by another federal award, unless authorized;
- Part of the approved budget;
- Not part of unrecovered indirect cost, unless approved;
- Apportioned in accordance with appropriate federal cost principles; and
- An integral and necessary part of the time allocated value similar to amounts paid for similar work in the recipient organization, if including volunteer services.

Recipients must ensure that federal funds do not supplant state/territory spending, but instead expand HIV-related activities. Funds that states/territories may use to demonstrate compliance with match requirements are those that have, at a minimum, an identifiable line item in state/territory budgets and expenditures reports from state/territory agencies. These funds may include:

- State/territory contributions to other RWHAP services and/or ADAP;
- Pharmaceutical rebates;
- State/territory funding used for State Pharmacy Assistance Programs (SPAP);
- State-/territory-funded salaries of RWHAP Part B staff;
- State/territory funds spent on health care coverage;
- State-/territory-funded ADAP delivery fees;
- State/territory funds used for care and treatment of inmates with HIV in the state/territory Department of Corrections;
- State/territory share of Medicaid expenditures for people with HIV;
- State/territory contributions to HIV prevention and surveillance activities; and
- State/territory contributions to HIV research.

The recipient may use the same eligible funds to meet both a recipient's state match requirement and the MOE requirement. If a state/territory is aware that it is unable to match the amount required in the legislation, HRSA HAB can reduce the RWHAP Part B grant award to an amount the recipient is able to match. If HRSA HAB discovers after the close of a grant budget period that a recipient has not
met its match requirement, HRSA HAB can recoup the difference of the award the recipient was unable to match.

Documentation of State Match Requirements

Since the Secretary may not make a grant award under RWHAP Part B unless the state/territory agrees to make available the required match, the state/territory must provide documentation with its RWHAP Part B application and the NCC Progress Report 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 and the NCC Progress Report. While the RWHAP Part B

recipient is not required to submit the specific calculations or sources for meeting the match requirements, the recipient must maintain that documentation for audit and site visit purposes.

RWHAP Part B recipients are also required to document that they met the required state match for the grant on the FFR.

Important Note:

This requirement was waived, if specifically requested, due to the COVID-19 public health emergency for awards funded in Fiscal Years 2020 and 2021. Although Congress provided the same waiver authority for funds awarded in Fiscal Years 2022 and 2023, HAB discontinued this waiver.

VII. 4. C. ADAP Supplemental Match

Section 2618(a) of the PHS Act requires that states/territories awarded funds in the ADAP Supplemental component of the X07 award match $1 for every $4 in ADAP Supplemental funding. Recipients can request a waiver for the ADAP Supplemental match requirement if they are also subject to a state match and have met the state match.

Determining the Rate of the ADAP Supplemental Match
ADAP Supplemental funding requires a state match of $1 for each $4 of federal funds provided unless a waiver is requested and approved (Section 2618(a)(2)(F)(ii)(III) of the PHS Act).

Ability to Request a Waiver for ADAP Supplemental State Match Requirement
A state/territory is eligible for a waiver from the match requirement for ADAP Supplemental funding if it also has a state match requirement for the RWHAP Part B Base and ADAP Base funding, and it meets that match requirement. A recipient requests an ADAP Supplemental Match Waiver by uploading a waiver request letter with either the annual RWHAP Part B application or the NCC Progress Report.

Documentation of ADAP Supplemental Match Requirement
The same criteria are used for determining the elements that constitute an ADAP Supplemental match as are used for a state match (see examples above). While the RWHAP Part B recipient is not required to submit the specific calculations or sources for meeting the match requirements, the recipient must maintain documentation for audit and site visit purposes. RWHAP Part B recipients are required to document that they met the required ADAP Supplemental match for the grant on the FFR.

Important Note:

This requirement was waived, if specifically requested, due to the COVID-19 public health emergency for awards funded in Fiscal Years 2020 and 2021. Although Congress provided the same waiver authority for funds awarded in Fiscal Years 2022 and 2023, HAB discontinued this waiver.

VII. 4. D. Maintenance of Effort (MOE)

Section 2617(b)(7)(E) of the PHS Act includes a requirement that a recipient maintain non-federal funding for HIV-related activities at a level that is not less than expenditures for such activities during the fiscal year prior to receiving the award.

Recipients attest their compliance with this requirement by signing Agreements and Compliance Assurances in either the RWHAP Part B application or NCC Progress Report.

Funds that states/territories may use to demonstrate compliance with MOE requirements are those that have, at minimum, an identifiable line item in state/territory budgets and expenditures reports from state/territory agencies. These funds may include:

- State/territory contributions to ADAP and/or other RWHAP services;
- Pharmaceutical rebates;
- State/territory funding used for SPAP;
- State-/territory-funded salaries of RWHAP Part B staff;
- State/territory funds spent on health care coverage;
- State-/territory-funded ADAP delivery fees;
- State/territory funds used for care and treatment for inmates with diagnosed HIV infection in the state/territory Department of Corrections;
- State/territory share of Medicaid expenditures for people with HIV;
- State/territory contributions to HIV prevention and surveillance activities; and
- State/territory contributions to HIV research.

The recipient may use the same eligible funds to meet both a recipient's state match requirement and the MOE requirement.

MOE Documentation Requirements

To demonstrate compliance with the MOE requirement, states/territories must maintain adequate systems for consistently tracking and reporting HIV-related expenditure data from year-to-year. The system must define the methodology used, be written and auditable, and ensure that federal funds do not supplant state/territory spending.

The state/territory must provide the following documentation in its RWHAP Part B grant application or NCC Progress Report:

- Documentation demonstrating that the overall level of HIV-related expenditures has been maintained year-to-year for the previous two complete fiscal years (based on the

recipient's fiscal year);
- A brief narrative explaining reductions or changes in the data set; and
- A signed assurance that they are complying with the MOE requirement.

MOE Monitoring and Compliance
Recipients are required to maintain documentation regarding MOE and provide the documentation upon request. During a CSV or at any time during the grant period of performance, HAB can request to review the following documents:

- Budget elements that document the contributions of the state/territory;
- Description of the tracking/accounting system that documents the state's/territory's contribution to core medical services and support services;
- Recipient budget for state or territory contributions; and
- The actual tracking/accounting documentation of contributions.

Important Note:

This requirement was waived, if specifically requested, due to the COVID-19 public health emergency for awards issued in Fiscal Years 2020, 2021 and 2022. This waiver was discontinued for Fiscal Year 2023.

VII. 4. E. Costs and Caps

The RWHAP legislation puts limits on administration, planning and evaluation (P&E), and CQM costs. PCN #15-01, Treatment of Costs under the 10 Percent Administrative Cap for Ryan White HIV/AIDS Program Parts A, B, and C, clarifies HRSA guidelines for the treatment of costs under the recipient administrative cost cap.

The RWHAP legislation also names allowable core medical services and allows for provision of support services. PCN #16-02, Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds, identifies and describes the allowable core medical and support services for which RWHAP funds may be used to serve eligible clients.

The Department of Defense and Labor, Health and Human Services, and Education Annual Appropriations Act (from here on referred to as the Annual Appropriations Act) includes provisions that limit the salary amount that may be awarded and charged to HRSA grants and cooperative agreements to the Executive Level II rate.

Governors (or their designees) are required to sign program assurances with the grant application or NCC Progress Report to HRSA for funding (SF-424B, Program Assurances). Included among them are assurances related to these legislative requirements. Like all other program assurances and legal requirements, compliance is subject to audit by such entities as the HHS Office of Inspector General (OIG) and the Government Accountability Office (GAO).

To assure compliance with required caps, HRSA strongly recommends that recipients require subrecipients to use a budget format that clearly identifies administrative costs.

Salary Rate Limitation
The Annual Appropriations Act provides a salary rate limitation. The law limits the salary

amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. Executive Level Pay Tables are available at: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/. Recipients, subrecipients, and contractors must ensure that salaries paid with RWHAP grant funds do not exceed the current rate. For additional information and examples of how to apply the salary limitation, see the HRSA SF-424 Application Guide.

Administrative, P&E, and CQM Caps

In accordance with Section 2618(b)(3) of the PHS Act, recipients are allowed to use in any given grant budget period up to 10 percent of any RWHAP Part B grant for the payment of recipient administrative costs. Recipients may use up to 10 percent of the RWHAP Part B grant for payment of planning and evaluation (P&E) costs in any given grant budget period. The total combined costs of recipient administrative and P&E costs cannot exceed 15 percent of the RWHAP Part B grant in any given budget period.

P&E includes recipient activities related to planning for the use of RWHAP Part B funds and evaluating the effectiveness of those funds in delivering needed services. RWHAP Part B P&E costs may include, but are not limited to, the following:

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

Please note, recipients who receive a minimum allotment in the RWHAP Part B Base component of their X07 award (per Section 2618(a) of the PHS Act) may support up to one full-time equivalent (FTE) personnel and personnel-related costs, even if the cost exceeds 10 percent of the award.

PCN #15-01, Treatment of Costs under the 10 percent Administrative Cap for Ryan White HIV/AIDS Program Parts A, B, C, and D, provides guidance on what costs must be charged to administration and where there is flexibility on charging costs toward direct service. Recipients should consult with the DSHAP PO and/or HRSA GMS if more specific guidance is needed.

CQM costs are not included in administrative or P&E costs but cannot exceed the lesser of 5 percent of the RWHAP Part B grant or $3,000,000. CQM costs may include, but are not limited to, the following:

- Capacity building to engage in CQM activities;
- Management of the CQM Program (e.g., convening a CQM Committee, working with first- or second-line subrecipients, implementing quality improvement projects, etc.);
- Data management for CQM (e.g., performance measure data collection, aggregation, analysis, and reporting);
- CQM site visits (e.g., patient chart reviews for CQM, assessment of subrecipient CQM Programs, etc.);
- Gathering information on client experience (e.g., surveys, focus groups, client interviews, etc., used for CQM); and

- Training specific to CQM.

The combined total of administrative, P&E and CQM costs cannot exceed 20 percent of the RWHAP Part B grant in any given budget period. These caps apply to the X07 and X08 awards, but do not apply to X09 awards since X09 funds cannot be used for CQM related costs.

For the X07 award, calculations for P&E costs, recipient administrative costs, and CQM costs may be done separately on each of the five components of the grant award, where applicable (i.e., Part B Base, ADAP Base, ADAP Supplemental, EC, and MAI). When using this approach, the selected percentages taken from each component of the grant award do not have to be the same but cannot exceed 10 percent in aggregate.

Funds expended from the ADAP Base and MAI components of the X07 award on recipient administrative, P&E, and CQM costs must be related to the corresponding component. Funds expended from any of the other three components of the X07 award on recipient administrative, P&E, and CQM cost do not have to be related to the corresponding component of the award.

If a RWHAP Part B recipient has a subaward or contract with a lead agency, consortium, or fiduciary agent to provide RWHAP Part B program or fiscal management on behalf of the recipient, the administration costs of that subaward or contract counts toward the 10 percent recipient administrative cap. Any costs associated with direct service delivery by the recipient or through subawards/contracts to direct service providers do not count toward the recipient administrative cap.

Aggregate Administrative Cap for RWHAP Part B Service Delivery

RWHAP Part B recipients must limit the administrative costs of subrecipients that provide services to 10 percent in the aggregate. The 10 percent aggregate administrative cap applies to all subrecipients providing services, whether funded directly by the recipient or funded through a lead agency, consortia, or fiduciary agent. Recipients may choose to allow individual subrecipients to exceed 10 percent administrative costs of their individual award, as long as the aggregate of all subrecipients does not exceed 10 percent.

If a recipient issues a subaward or contract to a lead agency or consortium to provide both RWHAP Part B management on behalf of the recipient and core medical or support services, then:

1) The administrative costs associated with RWHAP Part B management count toward the 10 percent recipient administrative cap; and
2) The administrative costs associated with the provision of core medical or support services count toward the 10 percent subrecipient aggregate administrative cap.

Documentation of Compliance with Caps

As part of the annual PTR (see Section V, Reporting Requirements), RWHAP Part B recipients are required to submit categorical budgets and narrative justifications to HRSA for approval. These budgets must clearly specify costs for personnel, recipient administrative, P&E, CQM, and direct services. The DSHAP PO and HRSA GMS review recipient budgets and determine whether the recipient's costs fall within the legislative limits.

At the end of the budget year, as part of the APR submitted to HRSA HAB, the recipient will attest to subrecipient administrative expenditures in the aggregate in the Certification of

Aggregate Administrative Costs signed by the financial officer in charge of the RWHAP Part B grant.

VII. 4. F. Imposition of Charges

In accordance with Section 2617(c) of the PHS Act, RWHAP Part B recipients and subrecipients must impose a charge for services provided to RWHAP-eligible clients with individual annual gross income above 100 percent of the FPL. No charges are to be imposed on clients with individual annual gross incomes at/or below 100 percent of the FPL. However, there is a prohibition on the denial of services due to a client's inability to pay. ADAP is not subject to the imposition of charges mandate.

The recipient and subrecipient are required to have a publicly available schedule of charges (e.g., sliding fee scale or nominal charge) to clients for services. The RWHAP legislation establishes limitations on amounts of annual aggregate charges (i.e., caps on charges) in a calendar year for RWHAP services imposed on clients, which are based on the percent of client's annual individual gross income, as follows:

- 5 percent for clients with individual annual gross incomes between 101 percent and 200 percent of the FPL;
- 7 percent for clients with individual annual gross incomes between 201 percent and 300 percent of the FPL; and
- 10 percent for clients with individual annual gross incomes greater than 300 percent of the FPL.

Recipients and subrecipients must have a written policy for imposition of charges. The policy should include:

- Publicly available schedule of charges based on a nominal fee or a varying rate (e.g., sliding fee scale). Client placement on the schedule of charges must be based on the client's individual annual gross income; although, client eligibility for RWHAP services may be based on family income, if that is the policy of the recipient. Schedule of charges indicates clients with individual annual gross incomes less than or equal to 100 percent of the FPL are not charged for RWHAP services;
- Process to impose charges for RWHAP services based on the schedule of charges;
- Process to track imposed charges by the provider and payments received from clients;
- Process to track charges imposed by other RWHAP providers toward a client's cap on charges; and
- Process to ensure charges for RWHAP services cease when a client has reached the annual cap on charges based on their annual individual gross income.

The policy must align with all RWHAP Part B requirements. HRSA HAB considers it a best practice to align such policies across the RWHAP Parts, if possible. Staff should be familiar with and trained on the policy to ensure consistency of implementation. Recipients and subrecipients should incorporate the policy in all provider agreements (e.g., subawards, contracts, fee for service agreements, other legal agreements). Recipients and subrecipients should develop materials about the imposition of charges policy for clients including tools (e.g., worksheets, business reply envelopes, etc.) to inform them of their role in the imposition of charges (e.g., tracking charges across all RWHAP providers and other out-of-pocket costs). For more information on imposition of

charges, see: https://targethiv.org/library/imposition-of- charges.

VII. Chapter 5. Pharmaceutical Rebates and Program Income

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

VII. 5. A. Pharmaceutical Rebates

HRSA HAB defines a "rebate" as a return of a part of a payment. ADAPs that purchase medications through a retail pharmacy network at a price higher than the 340B price can submit claims to drug manufacturers for pharmaceutical rebates on full pay medications or medication copayments, coinsurance, or deductibles to achieve cost savings comparable to those received by ADAPs that directly purchase medications at the 340B price.

Expenditure
Section 2616(g) of the PHS Act states:

> *"A state shall ensure that any pharmaceutical rebates received on drugs purchased from funds provided pursuant to this section [i.e., ADAP] are applied to activities supported under this subpart [i.e., RWHAP Part B], with priority given to activities described under this section [i.e., ADAP]."*

As such, all 340B rebates directly generated by a federal dollar are subject to HAB's rebate policies and rules for expenditure. All rebates generated through ADAP must be used for RWHAP Part B activities, with priority given to ADAP. HRSA HAB provides clarifications related to
pharmaceutical rebates in PCN #15-04, Utilization and Reporting of Pharmaceutical Rebates.[12]

RWHAP Part B programs should proactively project the receipt of rebates and develop a budget and expenditure plan that incorporates all available funds, including federal funds, program income (if applicable), and rebate funds. Federal regulation requires that, to the extent available, recipients must disburse all rebates, including those generated by an ADAP's participation in the 340B program, before requesting additional cash payments (45 CFR § 75.305(b)(5)). As such, RWHAP Part B recipients must spend rebates received prior to drawing down grant funds.

As noted in 45 CFR § 75.2, "expenditures" means charges made by the recipient to the RWHAP award. For recipients on an accrual basis of accounting, the expenditure is recognized at the time the cost is incurred (i.e., when the contract is awarded). If rebate funds are obligated for a contract awarded during the budget period, the expenditure has been recognized (i.e., rebate funds have been spent). Neither the contract's period of performance nor when the funds are actually paid (i.e., liquidated) is a factor. For recipients on a cash basis of accounting, the expenditure is recognized at the time the payment is remitted. The expenditure is not recognized until such time funds are actually paid (i.e., liquidated).

The recipient must expend rebates received at the end of the budget period prior to the expenditure of new RWHAP Part B funds awarded in the subsequent budget period. For any ADAP receiving rebates on medication purchases, the RWHAP legislation has a specific exemption from the UOB penalties provision that applies when a recipient is unable to expend grant funds because rebates must be spent first. See Section VII. 6. B, 5 Percent UOB Limit, for more information.

Rebates are not subject to the RWHAP recipient cost caps for administration, planning and evaluation, and CQM costs, or the 75/25 core medical services requirement, but the salary rate limitation still applies (see VII. 2. E. Costs and Caps for more information). Pharmaceutical rebates must be used for costs allowed under the RWHAP legislation. However, costs (e.g., purchasing a vehicle) do not require prior approval, even if such use of federal grant funds *would* require prior approval.

PCN #15-04 includes clarifications on allowable uses of rebates. While the RWHAP Part B cannot "share" or give money to EMAs and TGAs for unrestricted use, it may issue RWHAP subawards funded with rebates to RWHAP Part A recipients to provide services for eligible RWHAP clients. RWHAP Part B recipients can use rebates to pay for health care coverage-related costs for a client (i.e., health care coverage premium costs), but rebates cannot be transferred to an insurance plan to cover administrative costs. Instructing a drug company to remit a portion of a rebate to the state/territory and a portion of the rebate to another entity is also not allowable.

Tracking and Reporting

Recipients are required to track and account for all pharmaceutical rebates in accordance with 45 CFR § 75.302(b)(3). Recipients must report the amount of pharmaceutical rebates available and expended during the grant budget period in the "Ryan White Rebate Funding" section of the Final FFR. Recipients also must report in the annual ADR the amount of pharmaceutical rebates reinvested into the RWHAP ADAP in the "Funding" section of the Recipient Report, and the amount of pharmaceutical rebate expenditures in the "Expenditures" section of the Recipient Report.

Because pharmaceutical rebates are not part of the recipient's RWHAP Part B award, they should not be included in any X07, X08 or X09 program reports (e.g., the RWHAP Part B PTR, Planned Allocations Report, or Expenditures Report).

For more information on reporting pharmaceutical rebates on the Final FFR, see Section V, Reporting Requirements, Chapter 4. For more information on reporting pharmaceutical rebates on the ADR, see the ADR Instruction Manual, available at: https://targethiv.org/library/adr-instruction-manual.

[12] Because PCN #15-04 was written prior to X07 becoming a multi-year period of performance, rebates need to be expended prior to the end of the budget period, and not the end of the period of performance.

VII. 5. B. Program Income

Program income means gross income earned by the non-federal entity that is directly generated by a supported activity or earned as a result of the federal award during the period of performance except as provided on 45 CFR § 75.307(f). Except as otherwise provided in federal statutes, regulation, or the terms and conditions of the federal award, program income does not include pharmaceutical rebates, credits, discounts, and interest earned on any of them. The primary source of program income for RWHAP Part B recipients is from charges to RWHAP Part B clients or to insurance companies for services performed.

Expenditure

In order to meet the requirements of expenditure of program income as stated in PCN #15-03, Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income, RWHAP Part B programs should proactively project the receipt of program income and develop a budget and expenditure plan that incorporates all available funds, including federal funds, program income, and rebate funds. [13]

45 CFR 75.305(b)(5) requires that, to the extent available, recipients and subrecipients must disburse funds available from program income and interest earned on such funds before requesting additional cash payments through the PMS. As such, RWHAP Part B recipients must spend program income received prior to drawing down grant funds. As noted in 45 CFR Part § 75.2, "expenditures" means charges made by the recipient to the RWHAP award. For recipients on an accrual basis of accounting, the expenditure is recognized at the time the cost is incurred (i.e., when the contract is awarded). If program income funds are obligated for a contract awarded during the budget period, the expenditure has been recognized (i.e., program income funds have been spent). Neither the contract's period of performance nor when the funds are actually paid (i.e., liquidated) is a factor. For recipients on a cash basis of accounting, the expenditure is recognized at the time the payment is remitted. The expenditure is not recognized until such time funds are actually paid (i.e., liquidated). Program income received at the end of the budget period must be expended by the recipient prior to the expenditure of new RWHAP Part B funds awarded in the subsequent period. The legislative exemption from UOB penalties for recipients that expend rebate dollars before requesting additional grant RWHAP funds does not extend to UOBs accrued as a result of expending program income.

Program income funds are not subject to the RWHAP recipient cost caps for administration, planning and evaluation, and CQM costs, or the 75/25 core medical services requirement, but the salary rate limitation still applies (see VII. 2. E. Costs and Caps for more information). Use of program income for allowable costs (e.g., purchasing a vehicle) does not require prior approval, even if such use of federal grant funds would require prior approval.

Tracking and Reporting

Recipients are required to track and account for all program income in accordance with 45 CFR § 75.302(b)(3). Recipients must report their program income (but not that of their subrecipients) on the Final FFR. Supporting documentation is not required with the FFR but may be requested during an audit or a site visit.

PCN #15-03 gives guidance on the required documentation and tracking of program income. In order to meet the requirements of PCN #15-03, recipients should require financial and performance reports necessary to ensure that the subaward, and any income generated by it, is used for authorized purposes, in compliance with federal statutes, regulations, and the terms and

conditions of the award. Subrecipients should retain program income for additive use within their own programs. Program income must be used for the purposes for which the award was made and may only be used for allowable costs under the award. Recipients should not report program income generated by subrecipients on the FFR.

For more information on reporting recipient program income on the Final FFR, see Section V, Reporting Requirements, Chapter 4.

[13] Because PCN #15-04 was written prior to X07 becoming a multi-year period of performance, program income needs to be spent prior to the end of the budget period, and not the end of the period of performance.

VII. Chapter 6. Unobligated Balance and Carryover Request

Section 2622 of the PHS Act, RWHAP legislation and requirements, and the UAR address the impact of the UOB on future funding. States/territories with UOB greater than 5 percent of the grant award may be subject to a financial penalty. HRSA HAB PCN #12-02 explains the UOB requirements and potential penalties imposed on recipients that do not comply with the requirements contained in Section 2622 of the PHS Act.

VII. 6. A. UOB Estimate and Estimated Carryover Request

RWHAP Part B recipients are required to submit a UOB Estimate and Estimated Carryover Request for their RWHAP Part B HIV Grant Program (X07) in the EHBs 60 days before the end of the grant budget period (i.e., January 31). Failure to submit a UOB Balance Estimate and Estimated Carryover Request will result in a recipient being ineligible to request carryover funds for their X07 award. Recipients are not required to submit a UOB Estimate and Estimated Carryover Request for RWHAP Part B Supplemental Grant Program (X08) or RWHAP ADAP Emergency Relief Funds (X09).

By law, pharmaceutical rebates generated under the RWHAP Part B are not considered part of the grant award and thereby are not subject to UOB provisions. Unexpended rebate funds should never be recorded as UOB on any FFR.

VII. 6. B. Carryover Requests

The Division of Grants Management Operations (DGMO) requires a carryover request of UOB be submitted at the same time as the Final FFR or within 30 days after the final FFR due date. Recipients must submit carryover requests through the "Prior Approval" module of EHBs.

Please note the following regarding carryover for RWHAP Part B awards:

- Recipients must track separately any UOB in each of the five components of X07 awards, where applicable. Recipients may request carryover of UOB on Part B Base, ADAP Base, and MAI components of X07 awards. If UOB is due to properly expended

pharmaceutical rebates, recipients may also request carryover of UOB on the RWHAP ADAP Supplemental and EC components of awards. If a UOB Estimate and Estimated Carryover Request is not submitted by January 31, carryover of X07 funds will not be permitted, excluding any UOB in the MAI component of award.

- For X08, recipients may only request carryover if the UOB is due to properly expended rebates and there is a subsequent project period into which funds can be re-obligated.
- For X09, recipients may only request carryover if there is a subsequent project period into which funds can be re-obligated.

Approvable carryover requests must include the following information:

1) The UOB amounts and the reason(s) funds were not obligated or expended during the grant budget period for each of the following:
   a. Recipient administration;
   b. Recipient planning and evaluation;
   c. Clinical quality management; and
   d. Each funded core medical and support service category.
2) The proposed use of carryover in the new grant budget period (e.g., new or expanded services, continuing or one-time activity).
3) For each proposed service or activity, provide the following:
   a. Amount of carryover budgeted;
   b. Number of clients to be served;
   c. Number of service units to be provided; and
   d. Status of the proposed service (continuing, expanded, or new) or completing the activity.
4) The capacity of the recipient to expend carryover funds during the next grant budget period, if approved.

Please note, to maintain compliance with Section 2618 (b) of the PHS Act, carryover funds may not be used for administration, planning and evaluation, or CQM.

VII. 6. C. Approval and Monitoring of Carryover Requests

DGMO must reconcile the Final FFR with financial reports in PMS and accept the FFR prior to review of carryover requests. HRSA will return to the recipient any carryover request that exceeds the amount available for carryover or does not include all required information. In reviewing requests for approval of carryover funds, HRSA will also assess the following:

- History of expenditures and carryover requests;
- Intended purpose and budget justification for the request;
- Performance issues; and
- Timeliness of FFR submission, if relevant.

Requests for carryover will be considered on a case-by-case basis. Where appropriate, HRSA will exercise its authority to offset future grant awards. If a recipient's carryover request is approved by HRSA, the recipient will be issued the carryover funds in an NoA and will be able to expend the approved UOB in accordance with the purpose stated in the carryover request. If funds are not expended in the carryover year, they cannot be used in a subsequent year.

For more information on carryover requests and other programmatic and fiscal reporting requirements, see Section V, Reporting Requirements. If there are questions regarding carryover requests, recipients should consult with their designated DSHAP PO and/or OFAM GMS.

VII. Chapter 7. RWHAP Part B Financial Penalties

Per RWHAP legislation, recipients can incur a financial penalty for not demonstrating compliance with one or more of the following four statutory requirements.

VII. 7. A. 75 Percent Obligation Requirement

Recipients must obligate 75 percent of their full RWHAP Part B HIV Care Program Award (X07) within 120 days after receipt of their final award. Recipients must use the Interim FFR (Form SF-425) to report the amount of RWHAP Part B funds for the current budget period that have been expended and/or that have been obligated and made available for expenditure from the start of the budget period (April 1) to 120 days after the full award. The recipient should report any unliquidated obligations on Line F on the Interim FFR, whether on a cash or an accrual basis. On a cash basis, unliquidated obligations include obligations that have been incurred but not yet paid. On an accrual basis, unliquidated obligations include obligations that have been incurred, but the actual amount to be paid has not yet been verified.

Recipients that do not meet the 75 percent obligation requirement will receive a financial penalty equal to the difference between the amount that should have been obligated within 120 days of final award and the amount that was obligated within 120 days of final award. This difference will be de-obligated from the recipient's current X07 award and added to the pool of funds awarded under the RWHAP Part B Supplemental Grant Program (X08). In addition, the recipient is ineligible for funding in the ADAP Supplemental component of the X07 award in the following year.

Important Note:

This requirement and the associated financial penalty were automatically waived due to the COVID-19 public health emergency for awards funded in Fiscal Years 2020, 2021 and 2022. However, HAB is requiring recipients to specifically request this waiver for Fiscal Year 2023.

VII. 7. B. 5 Percent Unobligated Limit

Recipients whose combined RWHAP Part B and ADAP Base UOB is greater than 5 percent of their combined RWHAP Part B and ADAP Base components of their X07 award (as documented on the Final FFR) will receive two penalties:

1) A reduction in the RWHAP Part B Base and ADAP Base components of the future year X07 award equal to the amount of the UOB minus any amount approved for carryover; and
2) Ineligible for RWHAP Part B Supplemental Grant Program funds.

If a recipient has a UOB greater than 5 percent due to the required expenditure of pharmaceutical

rebates before grant dollars, the recipient may request that the amount of UOB be reduced by the amount of expended pharmaceutical rebates. If the resulting UOB amount is less than 5 percent, the recipient would not incur a UOB penalty.

Important Note:

This financial penalty was automatically waived due to the COVID-19 public health emergency for awards funded in Fiscal Years 2020 and 2021. Congress provided the same waiver authority for funds awarded in Fiscal Years 2022 and 2023. However, HAB is requiring recipients to specifically request this waiver for Fiscal Year 2023

VII. 7. C. State and ADAP Supplemental Match Requirement

Where applicable, recipients must meet state match and ADAP Supplemental match requirements to avoid penalties (see Section VIII Grants Administration, Chapter 4.2, for detailed information about match requirements). If HRSA HAB discovers after the close of a grant budget period that a recipient has not met the state match or ADAP Supplemental match requirement, the recipient will be required to pay back the amount of unmatched funds under the corresponding components of the X07 award. Improperly obligated funds will be recouped by the HRSA OFAM Division of Financial Integrity (DFI).

Important Note:

This requirement was waived, if specifically requested, due to the COVID-19 public health emergency for awards funded in Fiscal Years 2020 and 2021. See Section I, Preface, Summary of Changes for more information on COVID-19 waivers. Although Congress provided the same waiver authority for funds awarded in Fiscal Years 2022 and 2023, HAB discontinued this waiver.

VII. 7. D. Summary of RWHAP Part B Financial Penalties

The table below provides a summary of RWHAP Part B financial penalties.

RWHAP Part B HIV Care Program, including ADAP (X07) Financial Penalties Table		
Requirement	**Documentation**	**Financial Penalty**
75 percent Obligation Obligate 75% of the full X07 award within 120 days of the full award.	Interim FFR (SF-425)	1) Financial reduction in current X07 award. 2) Ineligible for ADAP Supplemental component of X07 award in the following year.
5 percent UOB Obligate 95 percent of the RWHAP Part B Base and ADAP Base components of X07 award.	Final FFR (SF-425)	1) Financial reduction in ADAP Base and/or RWHAP Part B Base components of future X07 award, depending on the component(s) for which the UOB existed. 2) Ineligible for RWHAP Part B Supplemental Grant Program award (X08).
State Match Match $1 for every $5 in federal funds, with increases up to $1 for every $2 in federal funds, as stated on the NoA.	Final FFR (SF-425)	1) Must pay back improperly obligated funds under the RWHAP Part B Base, ADAP Base, and EC components of the X07 award.
ADAP Supplemental Match Match $1 for every $4 in federal funds. *May request a waiver if state match is met.*	Final FFR (SF-425)	1) Must pay back improperly obligated funds under the ADAP Supplemental component of the X07 award.

VII. Chapter 8. Additional Technical Assistance Links and Resources

This section provides resources for recipient and subrecipient monitoring to ensure compliance with legislative, regulatory, and programmatic requirements.

- **RWHAP Program Manuals and Reports, including the RWHAP ADAP Manual:** https://ryanwhite.hrsa.gov/grants/manage/recipient-resources.

- **45 CFR Part 75:** https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4d52364ec83fab994c665943dadf9cf7&ty=HTML&h=L&r=PART&n=pt45.1.75
- **HHS Grants Policy Statement:** https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf
- **HHS HRSA HAB Notices of Funding Opportunity (NOFO):** Search for NOFOs on HRSA HAB website at https://www.hrsa.gov/grants/find-funding?status=All&bureau=644 or Grants.gov https://www.grants.gov/
- **RWHAP Recipient Resources:** https://ryanwhite.hrsa.gov/grants/manage/reporting-requirements
- **HRSA HAB:** https://ryanwhite.hrsa.gov/
- **TargetHIV:** https://targethiv.org

Section VIII: Planning Requirements for RWHAP Part B

VIII. Chapter 1. Introduction

Planning is an essential part of determining how to use all available RWHAP Part B resources to provide a comprehensive system of high-quality HIV care and treatment. RWHAP Part B recipients are required to have a planning process that includes needs assessment, priority setting, and resource allocation activities as integral parts.

VIII. Chapter 2. Relevant Authorities

The RWHAP legislation contains numerous references to needs assessment and planning requirements for RWHAP Part B-funded recipients.

Needs Assessment
References to recipient requirements regarding needs assessment appear in the following sections of the legislation:

- Section 2617(b)(3) of the PHS Act requires 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.
- EIIHA:
  - Sections 2617(b)(2) and (b)(3) of the PHS Act require 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.
  - Section 2617(b)(8) of the PHS Act requires the state to assess the needs of persons with HIV/AIDS unaware of their status through a comprehensive plan.
- Section 2621 of the PHS act requires that the state/territory submit a detailed description of the severity of need and the manner in which the state/territory will use amounts received under the EC component of the RWHAP Part B X07 award.

RWHAP Part B Responsibility for Convening a Public Planning Processes and Required Participants
States/territories are required to establish a planning body for the purpose of developing a SCSN, as outlined in Section 2617(b)(6) and (7) of the PHS Act.

Consortia
Section 2613 of the PHS Act references planning body requirements for RWHAP Part B consortia. For more information about consortia, see Section X, The Role of Consortia in the RWHAP Part B.

Comprehensive Plan
The requirement for states/territories to develop a comprehensive plan are outlined in Section 2617(b)(5) of the PHS Act.

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 of the PHS Act.

RWHAP Part B Responsibility for Convening the SCSN
Sections 2617(b)(5)(F) and 2617(b)(6) of the PHS Act require the state to convene the SCSN for all RWHAP part recipients.

VIII. Chapter 3. Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need

VIII. 3. A. Historical Background

Since 1996, RWHAP Part B recipients have been required to convene a planning body to develop and submit an SCSN and a comprehensive plan. The planning body should include representation from a variety of stakeholders, including, but not limited to, representatives from any RWHAP Part A recipients funded in the jurisdiction and each of the remaining RWHAP Parts. The RWHAP legislation also requires RWHAP Part A recipients to convene a planning body and submit a comprehensive HIV care plan, and to participate in the development of the RWHAP Part B SCSN. Since 1993, the CDC has funded HIV prevention planning processes at state/territory health departments that include the establishment of an HIV prevention planning group (HPG) and the development of jurisdictional HIV prevention plans.

In July 2015, HRSA HAB and CDC DHP developed and released the first joint guidance to support submission of an Integrated HIV Prevention and Care Plan, including the SCSN (from here on referred to as the Integrated Plan). This guidance allowed dually funded recipients to develop and submit a single plan to both HRSA and CDC that meets all corresponding legislative and programmatic requirements. In addition to reducing the reporting burden, the Integrated Plan supports development of a comprehensive, jurisdiction-wide strategy or roadmap for ending the HIV epidemic. The guidance supports collaboration, coordination, efficiency, and leveraging across stakeholders, resources, and planning activities across the jurisdiction. HRSA HAB and CDC DHP released updated guidance in June 2021: https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/integrated-hiv-dear-college-6-30-21.pdf

VIII. 3. B. Integrated Plan Development

The implementation and development of the Integrated Plan is a joint effort between jurisdictions and planning bodies that engages persons at higher risk for HIV infection, people with HIV, service delivery providers, and other community stakeholders. It sets forth the jurisdiction's commitment to collaboration, efficiency, and innovation to achieve a more coordinated response to the HIV epidemic, and establishes the blueprint for achieving HIV prevention, care, and treatment goals and objectives.

Major components of the Integrated Plan include:

- The SCSN, which includes an epidemiologic overview; HIV care continuum; financial and human resources inventory; assessment of needs, gaps, and barriers; and data access, sources, and systems;
- The Integrated HIV Prevention and Care Plan, which outlines strategies to address the HIV prevention and care needs, existing resources, barriers, and gaps within the jurisdiction; collaborations, partnerships, and stakeholder involvement; and people with

HIV and community engagement; and
- The expectations for monitoring the implementation of the plan and improvement in the system of care.

Recipients should refer to the most recent guidance issued by CDC and HRSA for specific expectations regarding Integrated Plan development and implementation.

VIII. 3. C. Statewide Coordinated Statement of Need

The SCSN has specific requirements outlined in the RWHAP legislation and is a critical component of the Integrated Plan. The purpose of the SCSN is to provide a collaborative mechanism to identify and address significant HIV care issues related to the needs of people with HIV, and to maximize coordination, integration, and effective linkages across the RWHAP Parts. The SCSN must reflect, without replication, 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 care and service delivery in the state/territory. 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 infection, a comprehensive understanding of primary care and treatment in the state/territory, and a consideration of all available resources.

In the development of the SCSN, RWHAP Part B recipients must facilitate a process to identify significant issues related to the needs of people with HIV in the state/territory in order to develop a document reflecting the need and input of all stakeholders. RWHAP Part B recipients are required to include representatives from HIV prevention and surveillance, substance use, mental health, Medicaid, Medicare, Community Health Centers, U.S. Department of Veterans Affairs (VA), Housing and Urban Development (HUD), other entities involved in HIV service delivery, people with HIV, members of a federally-recognized Indian tribe as represented in the state, providers, and public agency representatives.

The SCSN provides an essential opportunity to coordinate needs assessment efforts among RWHAP Parts and between the RWHAP and HIV prevention planning processes. For example, RWHAP Part A planning councils and Part B planning bodies can collaborate within a regional service area, multiple consortia within a state can cooperate or collaborate on individual needs assessments, or RWHAP Parts C or D can participate in RWHAP Part A and Part B needs assessment efforts.

RWHAP Part B recipients are encouraged to streamline various planning processes to ensure the SCSN aligns with other components of the Integrated Plan

VIII. 3. D. Ensuring Data-Informed Planning Processes

RWHAP Part B recipients are strongly encouraged to use data-informed planning processes to ensure the success of Integrated Plans and other efforts to improve quality of care, cost-effectiveness, and outcomes across the HIV care continuum.

A large and diverse set of HIV-related data provides an evidence-based rational for planning, priority-setting, and resource allocation decisions. RWHAP Part B recipients can maximize the amount and diversity of data available by sharing and integrating data across HIV surveillance, HIV prevention, RWHAP, Housing Opportunities for Persons with AIDS (HOPWA), Medicaid and Medicare, other public health programs, and private entities. Analyzing data from multiple entities can increase the extent to which different populations are represented within a data set, lead to a more comprehensive understanding of the needs of different populations with HIV and help identify findings that may warrant special attention in Integrated Plans.

Sharing data also can reduce burden on people with HIV by avoiding multiple programs requesting similar data from the same individuals and can avoid or reduce the costs of new data collection. At a data systems level, integration can reduce information technology costs, enhance system interoperability, facilitate data transfers, and generate more robust data reports that can be used to inform and educate key stakeholders. Written agreements and related training are essential to ensuring clarity about the purpose of data sharing and integration, the appropriate use and protection of available data, and related policies and procedures.

For additional information on data sharing, see Section III, Chapter 3 of this manual. For additional information about data integration and use, see HRSA HAB Program Letter titled, Integrating and Using the Housing Opportunities for Persons with AIDS and Ryan White HIV/AIDS Program Data Sets and Integrated Guidance for Developing Epidemiologic Profiles HIV Prevention and Ryan White HIV/AIDS Programs Planning.

VIII. 3. E. Integrated Plan Submission and Review Process

The first Integrated Plan was submitted in September 2016, covering calendar years 2017 through 2021. HRSA and CDC determined that recipients would submit an Integrated Plan every five years. Recipients should refer to the most recent guidance issued by CDC and HRSA for details regarding the submission process.

RWHAP Part A and Part B recipients and CDC DHP-funded health departments are required to submit an Integrated Plan to HRSA HAB and CDC DHP by the designated date to meet the legislative and programmatic requirements of both federal agencies. HRSA HAB and CDC DHP conduct a joint review of submitted plans and provide joint feedback to corresponding recipients as appropriate to the type of plan submitted. In addition, the DSHAP PO reviews each Integrated HIV Prevention and Care Plan submitted, including the SCSN, and provides comments back to their assigned RWHAP Part B recipients. This review allows HAB DSHAP to identify crosscutting issues across jurisdictions.

VIII. 3. F. Integrated Plan Monitoring and Oversight

Recipients will report the progress on achieving the objectives presented in the Integrated Plan on a periodic basis through the CDC DHP and HRSA HAB reporting requirements (e.g., grant

application, NCC Progress Report, Implementation Plan, APR). These reporting requirements may vary slightly across federal agencies and RWHAP Parts. For more information about RWHAP Part B reporting requirements pertaining to Integrated Plans, see Section V, Reporting Requirements.

DSHAP POs will review and assess alignment across various planning documents listed in the introduction above. Feedback on how to improve alignment and coordination will be provided during routine monitoring. Recipients should request TA from the DSHAP PO as needed to ensure planning requirements are met.

VIII. 3. G. Ensuring Participation of People with HIV in Planning Processes

RWHAP Part B recipients must ensure people with HIV are members of planning bodies and ensure developed plans are responsive to identified needs. The perspectives of people with HIV are critical to ensuring that the HIV service delivery system improves outcomes along the HIV care continuum.

Recruitment procedures are needed to secure representation of people with HIV on planning bodies, and recipients should use a variety of methods to identify, recruit, and retain members. Participating people with HIV should reflect the diversity of the local epidemic, which provides for a range of perspectives that contributes to informed decision-making. Retention processes are needed to help people with HIV stay engaged and participate fully in planning bodies, such as orientation and training, mentoring, and financial support for the costs of participating.

VIII. Chapter 4. Technical Assistance Links and Resources

HRSA HAB funds the Integrated HIV/AIDS Planning Technical Assistance Center (IHAP TAC) to help RWHAP Part A and Part B recipients, CDC's DHP-funded grantees, and their respective planning bodies with integrating planning, including the implementation and monitoring of their Integrated HIV Prevention and Care Plans. IHAP TAC provides national and targeted TA and promotes peer-to-peer sharing. For more information, see https://targethiv.org/ihap.

The following links provide additional information on planning requirements, including sources for TA and a more extensive description of the Integrated Plan.

- **HRSA HAB Program Letter, HRSA CDC Integrated HIV Prevention and Care Plan Guidance, June 30, 2021:** https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/dear-colleagues-letter-6-30-21.pdf
- **Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2022- 2026:** https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/integrated-hiv-dear-college-6-30-21.pdf
- **Integrated HIV Prevention and Care Plan Guidance, including the Statewide Coordinated Statement of Need, CY 2022- 2026, Frequently Asked Questions:** https://ryanwhite.hrsa.gov/grants/program-letters/integrated-hiv-prevention-care-plan-guidance-faq
- **HRSA HAB Program Letter, Integrating and Using the Housing Opportunities for**

Persons with AIDS and Ryan White HIV/AIDS Program Data Sets, August 29, 2017: https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/hab-hopwa-data-sharing-letter-8-29-17.pdf

- **Building Leaders of Color (BLOC)-** People with HIV of Color Leadership Training including Transgender Women of Color and Youth of Color Living with HIV: www.BLOCHIV.org
- **Engaging Leadership through Employment, Validation, and Advancing Transformation and Equity for persons with HIV (ELEVATE):** https://targethiv.org/elevate
- **Ending Stigma through Collaboration and Lifting All to Empowerment (ESCALATE):** https://targethiv.org/escalate
- **Integrated Guidance for Developing Epidemiologic Profiles -** HIV Prevention and Ryan White HIV/AIDS Programs Planning: https://www.cdc.gov/hiv/pdf/guidelines_developing_epidemiologic_profiles.pdf
- **Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action:** https://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf)

Section IX: Consortia and the RWHAP Part B

IX. Chapter 1. Introduction

The RWHAP legislation indicates that a recipient may choose to establish a consortium to perform certain functions on behalf of the recipient. A consortium is an association of public and nonprofit healthcare and support service providers and community-based organizations with which the state/territory establishes a legal agreement. For a specific region(s) or the entire state/territory, the consortium provides:

- Needs assessment, including identifying key populations and service delivery needs;
- Planning, including alignment of developed plans with RWHAP Part B recipient developed plans (e.g., SCSN);
- Delivery of comprehensive health and support services, either directly by the consortia or indirectly by subaward/contract;
- Program and fiscal monitoring, including evaluation;
- Reporting, including required reports submitted to the RWHAP Part B recipient and HRSA HAB.

All direct services to people with HIV provided by or through the consortia are considered support services and must be counted as part of the maximum 25 percent of funds that may be expended for such services. Regional and statewide RWHAP Part B consortia vary in size and composition based on the region served. The RWHAP Part B allows states/territories to use RWHAP Part B funds to establish consortia within areas most affected by HIV to provide a comprehensive continuum of care to individuals and families with HIV. When states choose to establish consortia, specific requirements must be met as outlined in RWHAP legislation.

IX. Chapter 2. Relevant Authorities

Section 2613 of the PHS Act defines consortia and describes consortia requirements for RWHAP Part B recipients who choose to establish them:

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/territory 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/territory'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 organizations 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.

Definitions
Section 2613(a) of the PHS Act provides the definition for consortia, as noted above.

Assurances
Under Section 2613(b) of the PHS Act, consortia must, as the single coordinating entity, provide the state/territory with certain assurances related to its serving underserved populations of individuals with HIV and their families, and establishing a service plan consistent with the state's/territory's comprehensive plan under Section 2617(b)(4) of the PHS Act. 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.

Application Process
Sections 2613(b) and 2613(c) of the PHS Act outline the assurances and eligibility requirements an entity must provide to the state/territory to be funded as a consortium. Potential consortia must prepare and submit to the state/territory an application that:

(A) demonstrates that the consortium includes agencies and community-based organizations—

- *(i) with a record of service to populations and sub- populations with HIV/AIDS requiring care within the community to be served; and*
- *(ii) that are representative of populations and sub-populations reflecting the local incidence of HIV and that are located in areas in which such populations reside;*

(B) demonstrates that the consortium has carried out an assessment of service needs within the geographic area to be served and, after consultation with the entities de- scribed in paragraph (2), has established a plan to ensure the delivery of services to meet such identified needs that shall include—

- *(i) assurances that service needs will be addressed through the coordination and expansion of existing programs before new programs are created;*
- *(ii) assurances that, in metropolitan areas, the geographic area to be served by the consortium corresponds to the geographic boundaries of local health and support services delivery systems to the extent practicable;*
- *(iii) assurances that, in the case of services for individuals residing in rural areas, the applicant consortium shall deliver case management services that link available community support services to appropriate specialized medical services; and*
- *(iv) assurances that the assessment of service needs and the planning of the delivery of services will include participation by individuals with HIV/AIDS;*

(C) demonstrates that adequate planning has occurred to meet the special needs of families with HIV/AIDS, including family centered and youth centered care;

(D) demonstrates that the consortium has created a mechanism to evaluate periodically—

(i) the success of the consortium in responding to identified needs; and
(ii) the cost-effectiveness of the mechanisms employed by the consortium to deliver comprehensive care;

(E) demonstrates that the consortium will report to the State the results of the evaluations described in sub-paragraph (D) and shall make available to the State or the Secretary, on request, such data and information on the program methodology that may be required to perform an independent evaluation; and

(F) demonstrates that adequate planning occurred to address disparities in access and services and historically underserved communities.

Allocation of Funds

Section 2617(f) of the PHS Act states that all RWHAP Part B expenditures for service delivery, whether provided directly by the consortia or through consortia subcontractors, are classified as support services, not core medical services.

IX. Chapter 3. The Role of Consortia

Consortia must agree to use RWHAP Part B funds provided by the state/territory for *"the planning, development and delivery, through the direct provision of services or through entering into agreements with other entities for the provision of such services, of comprehensive outpatient health and support services for individuals with HIV disease."* Specifically, consortia must implement each of the following five functions for the entire state/territory or designated region of the state/territory:

1) **Needs Assessment** (Section 2613(c) of the PHS Act). The consortium must carry out an assessment of needs within the geographic area to be served, which includes participation by individuals with HIV.

2) **Planning** (Sections 2613(a) and 2613(c) of the PHS Act). The consortium must ensure the delivery of services meets identified needs, addresses disparities in access and services, and are provided in collaboration with HIV health and support service providers and other key stakeholders. Consortia should either lead or be actively engaged in the development of the state/territory Integrated Plan, including the SCSN. For more information, see Section IX, Planning Requirements for RWHAP Part B.

3) **Development and Delivery of Comprehensive Health and Support Services** (Section 2613(a)(2) of the PHS Act). The consortium must set service priorities, allocate RWHAP Part B funding, and contract with agencies to provide RWHAP Part B services for a specific designated region or the entire state/territory. The consortia may also provide RWHAP services directly.

4) **Program and Fiscal Monitoring** (Section 2613(c) of the PHS Act). Consortia are responsible for monitoring compliance of its funded service providers with all federal legislative, regulatory, and programmatic requirements. This monitoring includes the provision of annual subrecipient site visits. The consortium must evaluate its success in responding to identified needs and cost-effectiveness of service delivery mechanisms.

5) **Required Reporting** (Section 2613(c) of the PHS Act). The consortium must report to the state/territory all required data and information on its program activities to enable the state/territory to complete reports required for the RWHAP Part B grant. However, only the RWHAP Part B recipient may submit required reports to HRSA.

IX. Chapter 4. Monitoring and Oversight

The RWHAP Part B recipient determines whether there will be consortia in a state/territory and, if so, what the geographic boundaries and responsibilities of the consortia will be. The RWHAP Part B recipient retains ultimate accountability to HRSA HAB for all subawards, contracts, or other legal agreements under the RWHAP Part B grant, and must ensure that the consortium follows all requirements of the RWHAP Part B grant. The recipient must provide oversight of consortia policies, procedures, and performance, with emphasis on procurement, subcontract management, grievance policies and procedures, conflict of interest management, responsiveness to identified needs, and the cost-effectiveness of the mechanisms employed to deliver comprehensive care. Additionally, the consortium must report to the state/territory the results of the evaluations described above and make available to the state/territory or the HHS Secretary, on request, such data and information on the program methodology that may be required to perform an independent evaluation.

IX. Chapter 5. Technical Assistance Links and Resources

The following links provide more information on the role of consortia in the RWHAP Part B.

- Title XXVI of the Public Health Services Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009: https://ryanwhite.hrsa.gov/about/legislation
- Part B National Monitoring Standards (NMS): https://ryanwhite.hrsa.gov/grants/manage/recipient-resources

Section X. Technical Assistance

X. Chapter 1. Introduction

The section provides information about TA and training available through or supported by HRSA HAB, and how TA and training are provided. HRSA HAB works to ensure recipients have the TA and training they need to be successful in their administration of RWHAP Part B. TA and training are provided directly by HRSA HAB and through contracts, cooperative agreements, and/or learning collaboratives. TA and training include tools, documents, webinars, on-site and distance-based consultations, expert meetings, peer-based groups, learning collaboratives, and other specialized resources.

X. Chapter 2. Relevant Authorities

Section 2619 of the PHS Act requires the Secretary to provide TA in administering and coordinating activities, including TA for the development and implementation of the SCSN.

X. Chapter 3. Provision of Technical Assistance

TA and training are available through the following mechanisms:

- The TargetHIV website (https://targethiv.org/) provides centralized web-based access to all HAB TA resources. The TargetHIV website consists of a telephone help desk, a library of HAB- and recipient-developed TA tools, a TA calendar of upcoming events and trainings, and internet links to all recipients;
- Peer and expert consultation (individualized and on site) conducted through a national Technical Assistance Contract (TAC) and consultative meetings, site visits, and conference calls;
- Guidance in replicating successful SPNS programs to strengthen the capacity to deliver new methods of evidence-based HIV care; and
- Cooperative agreements with national organizations to deliver TA on specific topics through local and regional workshops, webcasts, web-based learning modules, conference calls, on-site trainings, and technical publications and curricula.

The three cooperative agreements within DSHAP for RWHAP Part B TA and training are:

- **Access, Care, and Engagement Technical Assistance Center:** https://targethiv.org/ace. Helps RWHAP recipients and subrecipients support their clients, especially people of color, to help them navigate the health care environment through enrollment in health coverage and improved health literacy; develops practical tools and resources to support

engagement, education, and health care coverage enrollment and renewal activities, helping to ensure RWHAP remains a payor of last resort.

- **Integrated HIV/AIDS Planning Technical Assistance Center:** https://targethiv.org/ihap. Helps RWHAP Part A and Part B recipients, CDC's DHP-funded grantees, and their respective planning bodies with integrating planning, including the implementation and monitoring of their Integrated HIV Prevention and Care Plans. Provides national and targeted TA and promotes peer-to-peer sharing.
- **RWHAP ADAP Training and Technical Assistance Program:** https://targethiv.org/ta-org/adap-technical-assistance. Provides training and TA to RWHAP ADAPs regarding the implementation of critical access, treatment, and support services. Addresses a variety of critical management topics, including 340B Drug Pricing Program policy and best practices; drug pricing; financial forecasting; interactions with other payors (e.g., Medicaid, Medicare, health care coverage); and program structure and administration.

To obtain more information about TA and training opportunities, contact the DSHAP PO. A list of TA and training products is available on the TargetHIV website (see https://targethiv.org/topics).

X. Chapter 4. Additional Technical Assistance Links and Resources

This chapter provides a compilation of resources found throughout this manual and additional references, links, and resources. See each section for other resources addressing each topic.

General References on the RWHAP Legislation, Program and Policy:

- **HIV/AIDS Bureau:** https://ryanwhite.hrsa.gov/
- **RWHAP Legislation:** https://ryanwhite.hrsa.gov/about/legislation
- **RWHAP Program and Grants Management:** https://ryanwhite.hrsa.gov/grants/manage
- **RWHAP Recipient Resources:** https://ryanwhite.hrsa.gov/grants/manage/recipient-resources
- **HRSA HAB Policy Notices:** https://ryanwhite.hrsa.gov/grants/policy-notices
- **HRSA HAB Program Letters:** https://ryanwhite.hrsa.gov/grants/program-letters
- **The National Monitoring Standards (NMS):**

https://ryanwhite.hrsa.gov/grants/manage/recipient-resources

Federal Grants Policy:

- **Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR Part 75):** https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=df3c54728d090168d3b2e780a6f6ca7c&ty=HTML&h=L&mc=true&n=pt45.1.75&r=PART.

- **HHS Grants Policy Statement (GPS):** http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf

Clinical Quality Management:

- **HAB Clinical Care and Quality Management Webpage**: https://ryanwhite.hrsa.gov/grants/quality-of-care. This website contains links to information and resources on Clinical Care Guidelines and Resources, HAB Performance Measure Portfolio, and Quality of Care. The website also includes information on how to request CQM TA.
- **HAB Performance Measures – List of Performance Measures and Frequently Asked Questions (FAQ)**: https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio.
- **CQM Technical Assistance:** RWHAP recipients can request technical assistance by filling out and submitting a request available at: https://targethiv.org/ta/cqm.
- **HIV Quality Measures (HIVQM) Module:** Online data system for use by all RWHAP recipients called the HIV Quality Measures Module (HIVQM Module). The HIVQM Module's purpose is to help recipients set goals and monitor performance measures as well as quality improvement projects to better support CQM, performance measurement, service delivery, and client monitoring at both the recipient and client levels. https://targethiv.org/library/topics/hivqm.
- **Ryan White HIV/AIDS Program Clinical Quality Management Listserv:** Online user forum for RWHAP CQM staff to ask questions, seek advice, and share resources with others in the RWHAP: https://public.govdelivery.com/accounts/USHHSHRSA/signup/29907.
- **Center for Quality Improvement and Innovation:** https://targethiv.org/cqii. CQII provides training and technical assistance on QI to RWHAP recipients and subrecipients.
- **CQM Tools and Resources:** https://targethiv.org/library/topics/clinical-quality-management.

Appendix I: List of Common Acronyms

ADAP	AIDS Drug Assistance Program
ADR	AIDS Drug Assistance Program Data Report
AETC	AIDS Education and Training Center
APR	Annual Progress Report
BLOC	Building Leaders of Color
CAP	Corrective Action Plan
CARE Act	Comprehensive AIDS Resources Emergency (CARE) Act
CBDPP	Community Based Dental Partnership Program
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CLC	Consolidated List of Contractors
CMS	Centers for Medicare and Medicaid Services
CQII	Center for Quality Improvement and Innovation
CQM	Clinical Quality Management
CRC	Contract Review Certification
CSV	Comprehensive Site Visit
CY	Calendar Year
DFI	HRSA's Division of Financial Integrity
DCHAP	Division of Community HIV/AIDS Programs
DGMO	Division of Grants Management Operations
DHP	Division of HIV Prevention
DIR	HRSA's Division of Independent Review
DMHAP	HAB's Division of Metropolitan HIV/AIDS Programs
DPD	HAB's Division of Policy and Data
DRP	HIV/AIDS Dental Reimbursement Program
DSHAP	HAB's Division of State HIV/AIDS Programs
eUCI	encrypted Unique Client Identifier
EC	Emerging Communities
EHB	Electronic Handbooks
EHE	Ending the HIV Epidemic Initiative
EIIHA	Early Identification of Individuals with HIV/AIDS
EIS	Early Intervention Services
EMA	Eligible Metropolitan Area
ERF	ADAP Emergency Relief Fund or X09
FDA	Food and Drug Administration
FFR	Federal Financial Report
FPL	Federal Poverty Level
FTE	Full-Time Equivalent
FY	Fiscal Year
GAO	Government Accountability Office
GCMS	Grant Contract Management System
GMS	Grants Management Specialist
GMO	Grants Management Officer
GPS	HHS Grants Policy Statement

HAB	HIV/AIDS Bureau
HHS	U.S. Department of Health and Human Services
HIVQM	HIV Quality Measures
HIT	Health Information Technology
HOPWA	Housing Opportunities for Persons With HIV/AIDS
HPG	HIV Prevention Planning Group
HRSA	Health Resources and Services Administration
HUD	Housing and Urban Development
IHAP	Integrated HIV/AIDS Planning
IHS	Indian Health Service
MAI	Minority AIDS Initiative
MCM	Medical Case Management
MOE	Maintenance of Effort
MSA	Metropolitan Statistical Area
MSM	Men who have sex with Men
NCC	Non-Competing Continuation
NHAS	The National HIV/AIDS Strategy for the United States: Updated to 2020
NMS	RWHAP National Monitoring Standards
NoA	Notice of Award
NOFO	Notice of Funding Opportunity
OAA	HAB's Office of the Associate Administrator
OAHS	Outpatient/Ambulatory Health Services
OFAM	Office of Financial Assistance Management
OIG	Office of Inspector General
OMB	Office of Management and Budget, the White House
OOM	HAB's Office of Operations and Management
OPDIVs	HHS Operating Divisions
OPS	Office of Program Support
ORC	Objective Review Committee
PCN	Policy Clarification Notice
P&E	Planning and Evaluation
PMS	Payment Management System
PO	Project Officer
PrEP	Pre-exposure Prophylaxis
PTR	Program Terms Report
QI	Quality Improvement
RDR	Ryan White HIV/AIDS Program Data Report
RFI	Request for Information
RFP	Request for Proposal
RIT	Resource Innovation Team
RSR	Ryan White HIV/AIDS Program Services Report
RWHAP	Ryan White HIV/AIDS Program
SCSN	Statewide Coordinated Statement of Need
SPAP	State Pharmacy Assistance Program
SPNS	Special Projects of National Significance
SSP	Syringe Services Programs

TA	Technical Assistance
TAC	Technical Assistance Contract
TGA	Transitional Grant Area
UAR	Uniform Administrative Requirements
UOB	Unobligated Balance
URA	Unit Rebate Amount
USGAO	U.S. Government Accountability Office
VA	U.S. Department of Veterans Affairs
WICY	Women, Infants, Children, and Youth