



Ryan White HIV/AIDS Program AIDS Drug Assistance Program 101

Division of State HIV/AIDS Program Administrative Reverse Site Visit

October 23, 2019

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Vision: Healthy Communities, Healthy People



Health Resources and Services Administration (HRSA)

Overview

- Supports more than 90 programs that provide health care to people who are geographically isolated, economically or medically vulnerable through grants and cooperative agreements to more than 3,000 awardees, including community and faith-based organizations, colleges and universities, hospitals, state, local, and tribal governments, and private entities
- Every year, HRSA programs serve tens of millions of people, including people living with HIV/AIDS, pregnant women, mothers and their families, and those otherwise unable to access quality health care



Ryan White HIV/AIDS Program

- Provides comprehensive system of HIV primary medical care, medications, and essential support services for low-income people with HIV
 - More than half of people diagnosed with HIV in the United States – more than 550,000 people – receive care through the Ryan White HIV/AIDS Program (RWHAP)
- Funds grants to states, cities/counties, and local community based organizations
 - Recipients determine service delivery and funding priorities based on local needs and planning process
- Payor of last resort statutory provision: RWHAP funds may not be used for services if another state or federal payer is available
- 85.9% of Ryan White HIV/AIDS Program clients were virally suppressed in 2017, exceeding national average of 59.8%



Source: HRSA. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2017; CDC. HIV Surveillance Supplemental Report 2016;21(No. 4)



Learning Objectives

- Understand the federal requirements for RWHAP AIDS Drug Assistance Programs (ADAPs)
- Understand the impact of ADAPs nationally
- Identify how RWHAP recipients across Parts can collaborate to ensure the health care and medication needs of RWHAP clients are met



Agenda

- AIDS Drug Assistance Program (ADAP) 101 Presentation
 - Overview of ADAP Definition, Funding, and Impact
 - ADAP Administrative Structure and Responsibilities
 - ADAP Operations
 - ADAP Medication Assistance
 - ADAP Health Insurance Assistance
 - Technical Assistance Resources
- Break
- Small Group Activity
- Report Back to Larger Group
- Wrap Up



Overview

ADAP Definition

- State-administered program authorized under RWHAP Part B legislation
- Provides access to Food and Drug Administration (FDA)-approved medications to low-income clients who are uninsured and underserved
- Eligible ADAP clients must be living with HIV and meet income and other eligibility criteria as established by the state

Overview

National ADAP Overview

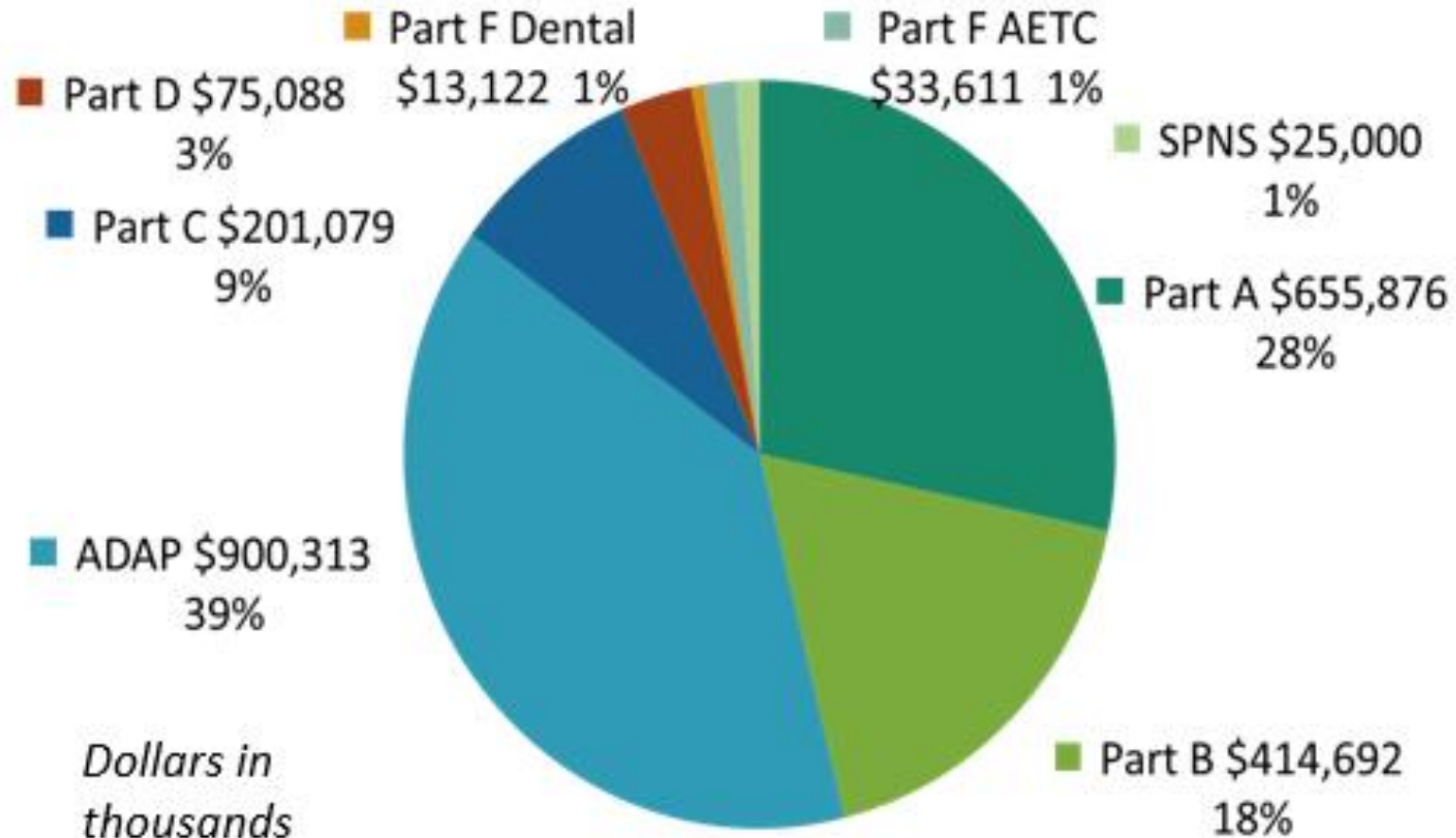
- RWHAP Part B ADAP grants are awarded to all 50 States, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands and the five U.S. Pacific Territories or Associated jurisdictions
- Wide variation in program characteristics
 - Due to differences in each state's HIV/AIDS prevalence, health care system, and administration of ADAP
 - Differences most pronounced in areas of funding, eligibility criteria, formulary size, and cost-saving strategies



Overview

Ryan White HIV/AIDS Program

- FY 2017 Full-Year Appropriation- \$2,318,781



Overview

ADAP-Specific Funding (FY 2019)

RWHAP Part B (X07)

- ADAP Base: \$808,941,062
- ADAP Supplemental: \$37,572,304

ADAP Emergency Relief Funding (X09)

- \$51,210,229 (from ADAP Base)

Other sources of ADAP Funding: State match, drug rebates, state general revenue funds, and RWHAP Part A and B contributions



Overview

ADAP's Impact

- ADAPs serve approximately one in four people with HIV in the U.S. that receive antiretroviral medications (ARV)
 - 268,174 people with HIV served through ADAPs in calendar year (CY) 2017
 - 140,401 received full-pay medication assistance
 - 116,596 received insurance assistance for premiums and/or copays

*Source: Health Resources and Services Administration. Ryan White HIV/AIDS Program ADAP Data Report, 2017



Overview

Source of ADAP Requirements

- RWHAP Legislation:
 - Section 2616. 300ff–26 PROVISION OF TREATMENTS
- HAB Guidance:
 - Policy Clarification Notices (PCNs) and Program Letters
 - RWHAP Part B and ADAP Manuals
- HHS and HRSA Grants Policy



Overview

ADAP Allowable Services

- All funding must be related to *drug assistance*
 - purchasing medications
 - providing assistance with health insurance premiums, medication co-pays, and deductibles
- ADAP Flexibility Policy allows states to redirect up to five percent of their ADAP appropriations under the Flexibility policy (10 percent in extraordinary circumstances) to:
 - improve access to medications
 - increase adherence to medication regimens
 - help clients monitor their progress in taking HIV-related medications



Overview

RWHAP Part B Minority AIDS Initiative (MAI)

- The parameters for the use of RWHAP Part B MAI outlined in the legislation are narrow
 - can only be used for education and outreach services
 - are for the specific purpose of increasing minority enrollment in ADAP
 - are only for the racial and ethnic minorities indicated in the legislation
- RWHAP Part B MAI funding may not be used to purchase medications or health insurance



ADAP Administration

Key Administrative Requirements

- ADAP Staffing
 - Must have sufficient staffing, whether employees or contractual, to provide ADAP services in compliance with legislative and programmatic requirements
- ADAP Policies and Procedures
 - Must have appropriate guidelines and controls in place to ensure compliance with legislative and programmatic requirements
- Financial Oversight and Monitoring
 - Must have appropriate financial systems and controls in place to ensure the appropriate use and reporting of Federal awards



ADAP Administration

Sub-award Responsibilities

- RWHAP Part B recipients:
 - May choose to sub-award some, or in some cases, all of their ADAP operations
 - Are responsible for ensuring that all legislative, programmatic, administrative, and fiscal requirements are met
 - Must oversee and monitor RWHAP funds, including those administered through sub-award
 - Are liable for improperly used RWHAP funds or delivered services



ADAP Administration

Planning Requirements

- Recipients must conduct planning to guide decisions about use of RWHAP Part B funds, including ADAP funds
- HRSA HAB strongly encourages RWHAP Part B programs to have advisory bodies
 - Provides recommendations on at least an annual basis on the use of RWHAP funds
 - RWHAP legislation does not mandate an ADAP-specific Advisory Committee; however, most States convene one as a best practice



ADAP Administration

Clinical Quality Management Requirements

- The RWHAP legislation requires that all RWHAP recipients have a clinical quality management (CQM) program
- ADAPs, as part of the overall RWHAP, must be included in the CQM program—either as an integrated component or a separate program
- The expectations of a RWHAP Part B recipient’s CQM program are outlined in [PCN# 15-02 Clinical Quality Management Policy Clarification Notice](#)



ADAP Operations

Eligibility Criteria

- Eligibility Criteria is determined by each state or territory but must include:
 - Financial eligibility: Income limit (as percentage of Federal Poverty Level)
 - Medical eligibility: Diagnosis of HIV infection
 - Required at initial enrollment only
 - Residency: Proof of current state residency



ADAP Operations

Certification/Recertification

- At the time of initial enrollment, and on an annual basis thereafter, an ADAP must complete an assessment of an individual's eligibility
- ADAPs must recertify client eligibility every six months
 - Must meet HRSA's minimum requirements for recertification
 - Self-attestation allowable
- ADAP certification and recertification processes allow clients access to medications in a timely manner



ADAP Operations

Formulary

- RWHAP funds may only be used to purchase medications approved by the FDA and the devices needed to administer them
 - Must include at least one drug from each class of HIV antiretroviral medications
 - Must be consistent with the most recent Adolescent and Adult HIV/AIDS Treatment Guidelines published by the Department of Health and Human Services (DHHS)
 - Must be equally and consistently available to all eligible enrolled individuals throughout the state/territory



ADAP Operations

Payor of Last Resort Requirement

- RWHAP funds intended to fill gaps in care and serve as the payor of last resort (POLR)
- RWHAP resources can only be used to pay for allowable costs when:
 - No other public or private payor
 - Costs not covered by other public and private payors
- ADAPs must ensure:
 - Eligible individuals expeditiously enrolled in other programs for which they are eligible
 - ADAPs coordinate with other payors, ensuring that ADAP is not paying for a cost that should be covered by the client's insurance coverage does not cover all their medication costs



ADAP Operations

Compliance with Payor of Last Resort

- “Vigorously Pursue” Health Care Coverage
 - Recipients and their contractors expected to vigorously pursue enrollment into health care coverage for which their clients may be eligible. Recipients and their contractors must ‘rigorously document’ efforts to enroll clients into other coverage.
- Coordination with Other Payors
 - Recipients expected to work with other payors and programs to provide clients with access to HIV medications and a continuum of care



ADAP Medication Assistance

- Medication Assistance is when the ADAP pays for the full cost of a medication for a client
 - Medication co-pays, deductibles, and co-insurance are considered Health Insurance Assistance, not Medication Assistance
- In CY 2017, ADAPs spent \$1,410,188,978* purchasing medications for enrolled clients

* Source: Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2017



ADAP Medication Assistance

Drug Purchasing

- ADAP Drug Purchasing Models
 - Direct Purchase: ADAP purchases medications directly from a wholesaler
 - Pharmacy Network/Rebate: ADAP reimburses retail pharmacies for dispensing medications to eligible clients
 - Hybrid/Dual: Combination of Direct and Pharmacy Network/Rebate Models



ADAP Medication Assistance

340B Program

- ADAPs have access to discounted drug prices through the 340B program
 - Requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices
- 340B discounts required by the Veterans Health Care Act of 1992 (Section 602)
- Per the 1996 HRSA /OPA Patient Definition Guidelines, ADAP clients categorically meet the 340B patient definition

“An individual registered in state-operated or funded ADAP that receives Ryan White funding is considered a patient of the ADAP if registered as eligible by the State program.”



ADAP Medication Assistance

Rebates

- HRSA 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 rebate claims to drug manufacturers
- Rebates achieve cost savings comparable to those received by directly purchasing medications at the 340B price
- [Policy Clarification Notice 15-04, “Utilization and Reporting of Pharmaceutical Rebates”](#)



ADAP Medication Assistance

Program Income

- [PCN 15-03 Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income](#) defines program income
 - “gross income earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance (or grant year) except as provided in 45 CFR § 75.307(f)”
- Most commonly generated by billing third party insurance for medications purchased at 340B pricing
 - Program income is the difference between the insurance reimbursement for 340B drugs and the cost of this medication



ADAP Health Insurance Assistance

- Health Insurance Assistance includes:
 - Payment of qualified premiums
 - Medication co-pays
 - Deductibles
 - Co-insurance

- In CY 2017, ADAPs spent \$469,080,687 on health insurance assistance for enrolled clients*



* Source: Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2017



ADAP Health Insurance Assistance, cont.

- [Policy Clarification Notice \(PCN\) 18-01 Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance](#) states, “RWHAP recipients and subrecipients should consider assisting individual clients by paying for premiums and/or cost sharing, if cost effective ”
- RWHAP recipients can provide health insurance assistance outside of ADAP through the “Health Insurance Premium and Cost-Sharing Assistance” service category
- Other PCNs related to ADAP, Medicaid, and private health insurance include 13-01 and 13-04



ADAP Health Insurance Assistance Requirements

- Premium Assistance: Minimum Coverage Standard
 - RWHAP legislation stipulates that an ADAP can only pay for health insurance that includes both primary care services and HIV treatments
 - PCN 18-01 clarified that RWHAP recipients, including ADAPs, can pay for Medicare Parts B and C premiums if they are also paying for a Medicare Part D premium
 - HRSA allows ADAPs to pay for Medicare Part D premiums alone, since it provides medication assistance
 - HRSA clarified in PCN 18-01 that the health coverage purchased must include “at least one drug in each class of core antiretroviral therapeutics from the HHS Clinical Guidelines for the Treatment of HIV/AIDS” (i.e., the minimum formulary requirement for ADAPs)
 - ADAPs cannot pay for a health insurance premium that does not include a pharmacy benefit
 - For example, an ADAP cannot pay for a stand-alone dental or vision insurance policy



ADAP Health Insurance Assistance Requirements, cont.

- Medication Cost-Sharing

- Can choose to use resources to pay for medication cost-sharing (deductibles, co-payments and/or co-insurance costs) for clients who have another payor (e.g., health insurance, Medicare D, Medicaid)
- Cannot pay for non-medication-related cost-sharing (e.g. medical visit deductibles, co-payments and/or co-insurance)
- Reported as an ADAP Health Insurance Assistance service, not as an ADAP Medication service

ADAP Health Insurance Assistance

Cost-Effectiveness

- Cost-Effectiveness Assessment

- RWHAP legislation states that ADAP can purchase insurance if, “for the fiscal year involved, the costs of the health insurance or plans to be purchased or maintained...do not exceed the costs of otherwise providing therapeutics.”
- PCN 18-01 clarifies that the “ADAP must determine the cost of paying for the health care coverage is cost-effective in the aggregate *versus paying for the full cost for medications*”
- The required cost comparison is in *the aggregate*

Technical Assistance Resources

- ADAP Manual
 - <https://targethiv.org/library/adap-manual>
- HAB and TargetHIV Websites
 - <https://hab.hrsa.gov/>
 - <https://targethiv.org/>
- NASTAD
 - <https://www.nastad.org/>
- Project Officer and ADAP Advisor



Questions and Answers



Small Group Break-out Instructions

Break into small groups

Each group needs to pick a note-taker and someone to report out

Each group should answer the three scenarios in the handouts

- Allot 15 minutes to discuss each scenario

Each group will report out to the larger group



Contact Information

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