

AIDS Drug Assistance Program 101

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HIV/AIDS Bureau (HAB)

Health Resources and Services Administration (HRSA)



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



HIV/AIDS Bureau Vision and Mission

Vision

Optimal HIV/AIDS care and treatment for all.

Mission

Provide leadership and resources to assure access to and retention in high quality, integrated care, and treatment services for vulnerable people living with HIV/AIDS and their families.



Ryan White HIV/AIDS Program

- Provides comprehensive system of HIV primary medical care, medications, and essential support services for low-income people living with HIV
 - More than half of people living with diagnosed 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
- 84.9% of Ryan White HIV/AIDS Program clients were virally suppressed in 2016, exceeding national average of 59.8%



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



Learning Objectives

- Understand the federal requirements for 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.

Overview: ADAP Definition

- State-administered program authorized under Ryan White HIV/AIDS Program (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



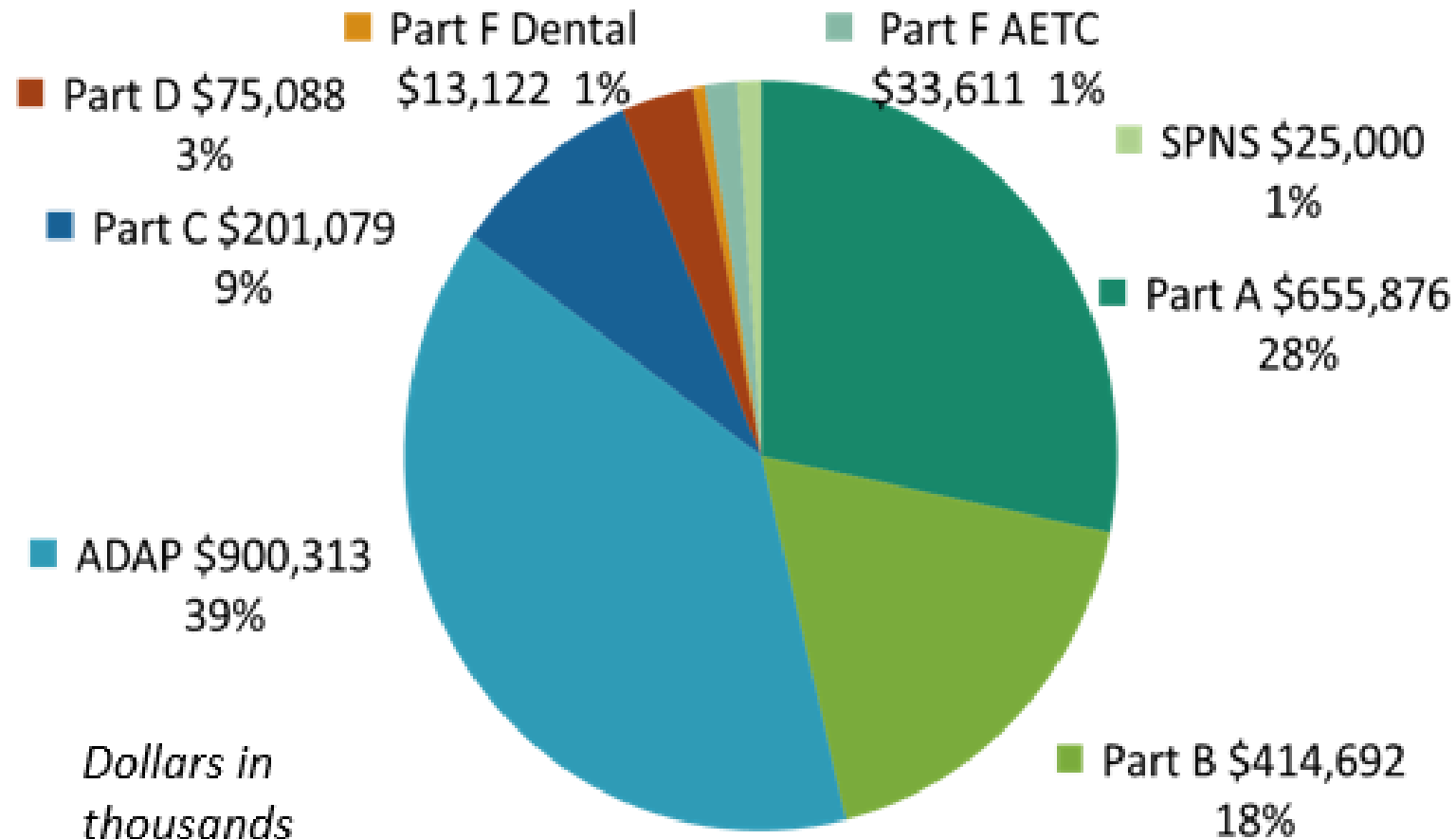
Overview: National ADAP Overview

- 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's Impact

- ADAPs serve approximately one in four people living with HIV (PLWH) in the U.S. that receive antiretroviral medications (ARV)
 - 260,920 PLWH served through ADAPs in calendar year (CY) 2015
 - 149,975 received full-pay medication assistance
 - 103,051 received insurance assistance for premiums and/or copays

*Source: Health Resources and Services Administration. Ryan White HIV/AIDS Program ADAP Data Report, 2015



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 5 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
 - for the specific purpose of increasing minority enrollment in ADAP
 - 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 Admin: 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 Admin: Sub-award Responsibilities

- RWHAP Part B recipients:
 - May choose to sub-award some, or in some cases, all of their ADAP operations
 - 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
 - Liable for improperly used RWHAP funds or delivered services



ADAP Admin: 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 Admin: 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
 - 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: Eligibility Restrictions

- Prohibition of Presumptive Eligibility
 - It is unallowable for an ADAP to provide services before a client has been determined to meet the ADAP's eligibility criteria (i.e., “presumptive eligibility”)
- Prohibition of Grace Periods
 - It is unallowable for a client to receive ADAP services after their six-month eligibility period has expired and before they recertify their eligibility



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 payer
 - Costs not covered by other public and private payers
- ADAPs must ensure:
 - Eligible individuals expeditiously enrolled in other programs for which they are eligible
 - ADAPs coordinate with other payers, 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 POLR

- “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 Payers
 - Recipients expected to work with other payers 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 2015, ADAPs spent \$1,407,438,015* purchasing medications for enrolled clients

* Source: Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2015



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 2015, ADAPs spent \$327,325,267 on health insurance assistance for enrolled clients*



* Source: Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2015



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 Part B and Part 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 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 payer (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 Website and TargetHIV
 - <https://hab.hrsa.gov/>
 - <https://targethiv.org/>
- NASTAD
 - <https://www.nastad.org/>
- Project Officer and ADAP Advisor



Q & A and Interaction

- What questions do you have about ADAP?
- How does ADAP work in your state/territory?
- Are there any issues in your state/territory regarding 340B pricing and ADAP?
- What feedback to you have for HRSA HAB about ADAP?



Contact Information

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