

AIDS Drug Assistance Program 101

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Glenn Clark, MSW - ADAP Advisor

Kerry Hill, MSW - Project Officer

Division of State HIV/AIDS Programs (DSHAP)

HIV/AIDS Bureau (HAB)

Health Resources and Services Administration (HRSA)



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.



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 Part B of the Ryan White HIV/AIDS Program (RWHAP) legislation
- Provides 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: Additional ADAP Services

- **ADAP funds may also be used to purchase:**
 - Health insurance
 - Services that enhance access to, adherence to, and monitoring of antiretroviral
- **Recipients must ensure that purchasing health insurance is cost effective in the aggregate**
 - Assess and compare the aggregate cost of paying for the health insurance versus paying for the full cost for medications and other appropriate HIV outpatient/ambulatory health services



Overview: National ADAP Overview

- **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



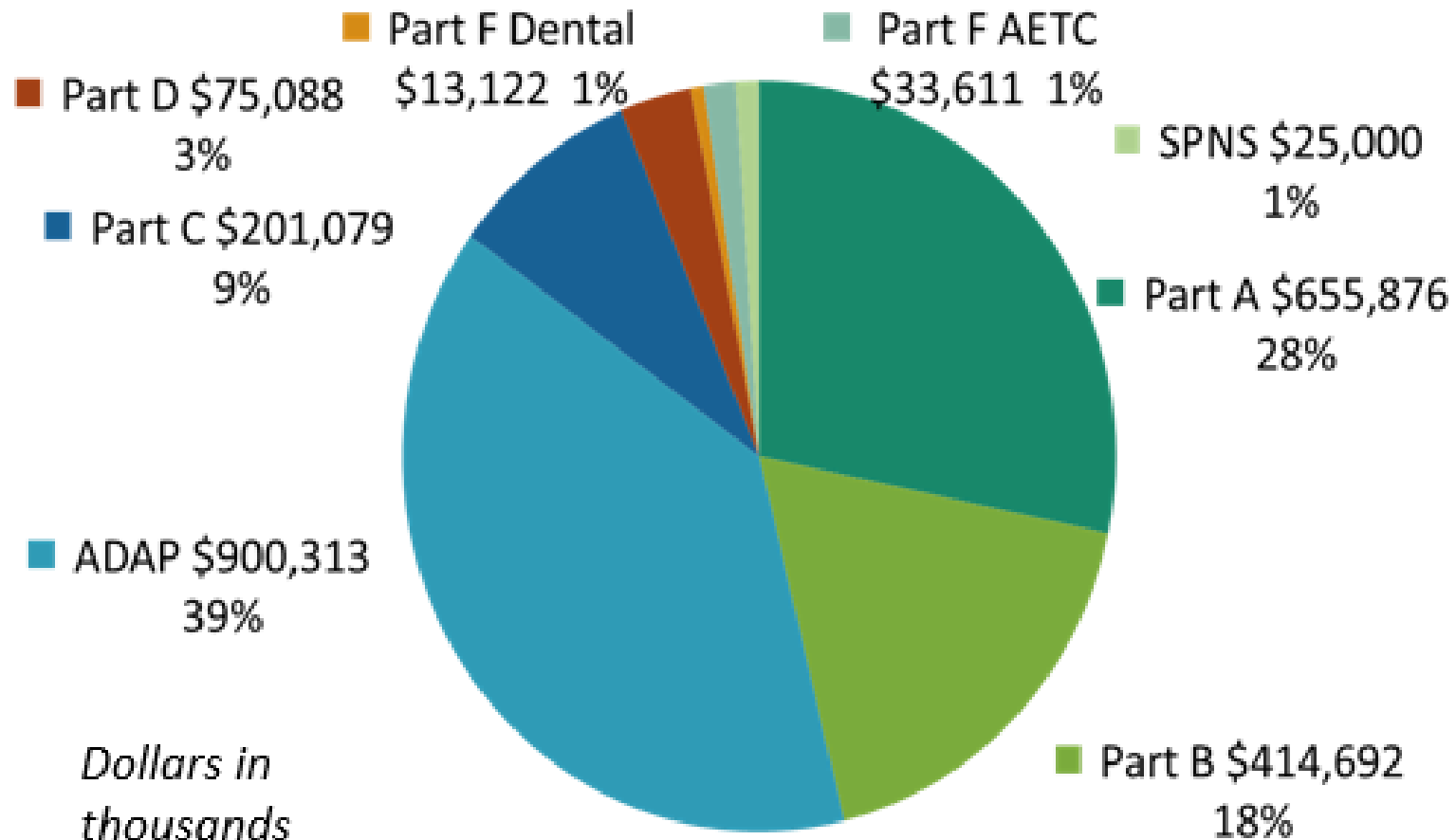
Overview: ADAP's Impact, 2015*

- **Approximately one in four people living with HIV (PLWH) receiving antiretroviral medications (ARV) in the U.S. use ADAP services**
- **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: Ryan White HIV/AIDS Program FY 2017 Full-Year Appropriation- \$2,318,781



Overview: ADAP-Specific Funding (FY 2017)

RWHAP Part B (X07)

- ADAP Base: \$808,868,040
- ADAP Supplemental: \$42,627,850

ADAP Emergency Relief Funding (X09)

- \$65,000,000 (from ADAP Base)

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



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% of their ADAP appropriations under the Flexibility policy (10% in extraordinary circumstances) to:

- improve access to medications
- increase adherence to medication regimens
- help clients monitor their progress in taking HIV-related medications

ADAPs must ensure that clients receive medication therapies consistent with current HHS HIV/AIDS treatment guidelines.

*Section 2616. [300ff-26] (c)(6)



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: CQM 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 outlined in PCN# 15-02 *Clinical Quality Management Policy Clarification Notice*
 - <https://hab.hrsa.gov/sites/default/files/hab/Global/clinicalqualitymanagementpcn.pdf>
 - <https://hab.hrsa.gov/sites/default/files/hab/Global/clinicalqualitymanagementfaq.pdf>



ADAP Operations: Eligibility Criteria

Eligibility Criteria 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
- **Uninsured or Underinsured:** Proof of no other insurance coverage or that the client's insurance coverage does not cover all their medication costs



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: Payer of Last Resort Requirement

- **RWHAP funds intended to fill gaps in care and serve as the payer of last resort**
- **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



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

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”
 - <https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters>



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).”
 - https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf
- **Most commonly generated by billing third party insurance for medications purchased at 340B pricing**
 - Program income would be 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) 13-05 Clarifications Regarding Use of Ryan White HIV/AIDS Program Funds for Premium and Cost-Sharing Assistance for Private Health Insurance

- “If resources are available, RWHAP recipients and subrecipients are strongly encouraged to use RWHAP funds for premium and cost-sharing assistance for these individuals when it is cost-effective, as appropriate.”

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, 13-04, 13-06

- <https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters>



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
- HRSA clarified in PCN 13-05 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.
- HRSA allows ADAPs to pay for Medicare Part D premiums, since they provide medication assistance



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)
- Can only provide cost-sharing for drugs that are on the ADAP formulary
- 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 13-05 clarifies that the ADAP must “assess and compare the aggregate cost of paying for the health insurance option versus paying for the full cost for medications”
- The required cost comparison is in the aggregate



Technical Assistance Resources

- **ADAP Manual**
 - <https://careacttarget.org/content/adap-manual>
- **HAB and TARGET Center Websites**
 - <http://hab.hrsa.gov/index.html>
 - <https://careacttarget.org/>
- **NASTAD**
 - <http://www.nastad.org/>
- **ADR-related Technical Assistance**
- **Project Officer and ADAP Advisor**



Questions and Answers



Agenda-Break

Break



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

Report Out and Discussion

Each group will report out



Evaluation Survey

- Please use the following link to complete a short evaluation of this session
- The link may also be found on your agenda

https://www.surveymonkey.com/r/ARSV2017_ADAP



Contact Information

Glenn Clark, MSW
ADAP Advisor
Email: glclark@hrsa.gov
Phone: 301-443-3692

Kerry Hill, MSW
Project Officer
Email: khill@hrsa.gov
Phone: 301-443-0583

Division of State HIV/AIDS Programs (DSHAP)
HIV/AIDS Bureau (HAB)
Health Resources and Services Administration (HRSA)
Web: hab.hrsa.gov
Twitter: twitter.com/HRSAgov
Facebook: facebook.com/HHS.HRSA

