HRSA
Health Resources & Services Administration

Ryan White HIV/AIDS Program
AIDS Drug Assistance Program 101
Administrative Reverse Site Visit
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Vision: Healthy Communities, Healthy People

Learning Objectives

- Understand the federal requirements for RWHAP AIDS Drug Assistance Programs (ADAPs)
- Understand the impact of ADAPs nationally
- Understand the role of ADAPs within the RWHAP system of care, and EHE initiatives specifically

HIV/AIDS Bureau Vision and Mission

Vision

Optimal HIV/AIDS care and treatment for all to end the HIV epidemic in the U.S.

Mission

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.

Agenda

- Overview of ADAP Definition, Funding, and Impact
- ADAP Administrative Structure and Responsibilities
- ADAP Operations
- ADAP Medication Assistance
- ADAP Health Insurance Assistance
- Technical Assistance Resources

Overview

ADAP Definition (PCN 16-02)

- The AIDS Drug Assistance Program (ADAP) is a state-administered program authorized under RWHAP Part B to provide U.S. Food and Drug Administration (FDA)- approved medications to low-income clients living with HIV who have no coverage or limited health care coverage.
- HRSA RWHAP ADAP formularies must include at least one FDA-approved medicine in each drug class of core antiretroviral medicines from the U.S. Department of Health and Human Services' Clinical Guidelines for the Treatment of HIV.
- HRSA RWHAP ADAPs can also provide access to medications by using program funds to purchase health care coverage and through medication cost sharing for eligible clients.
- HRSA RWHAP ADAPs may use a limited amount of program funds for activities that enhance access to, adherence to, and monitoring of antiretroviral therapy with prior approval.

Overview

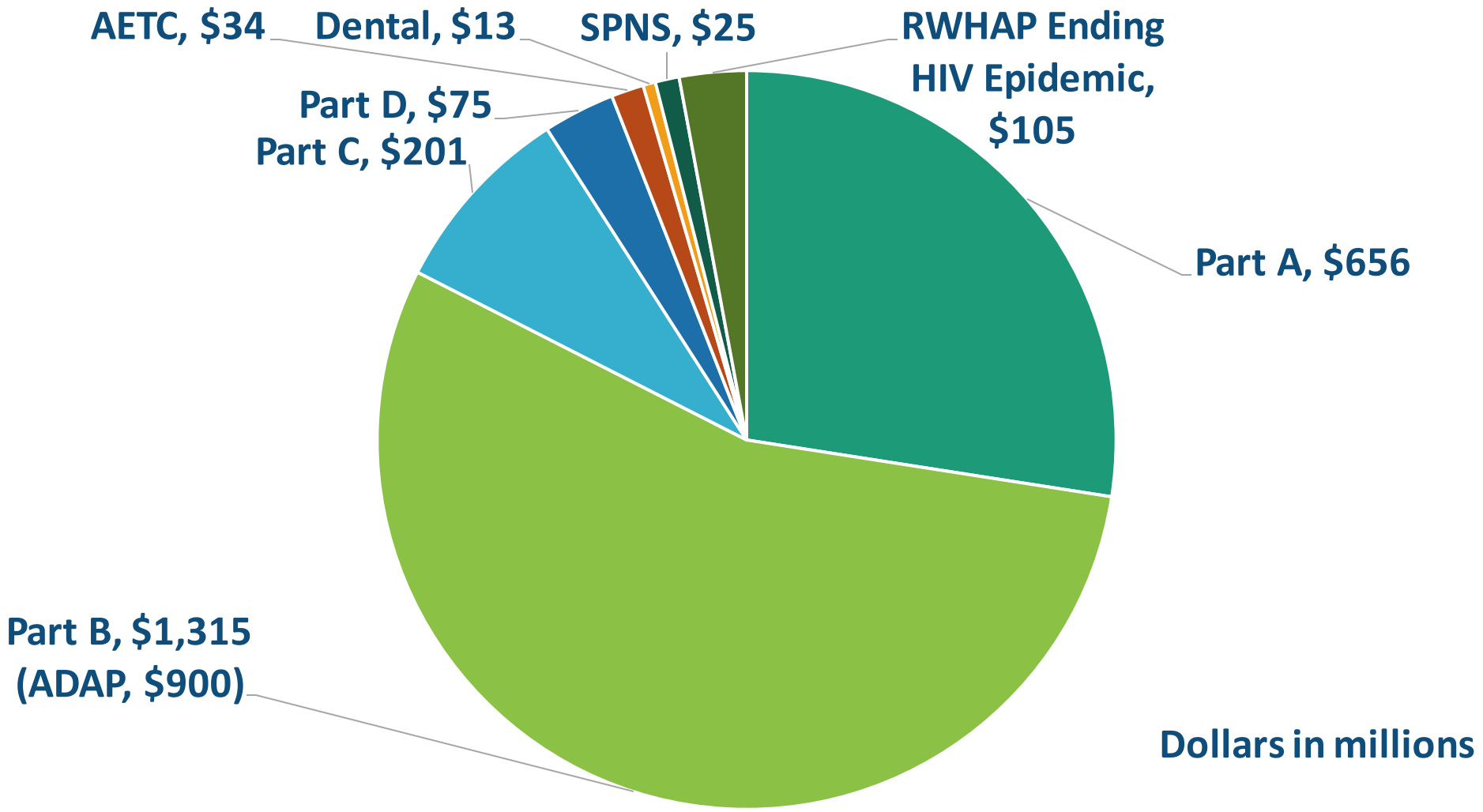
National ADAP Overview

- RWHAP Part B ADAP funds 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/territory'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

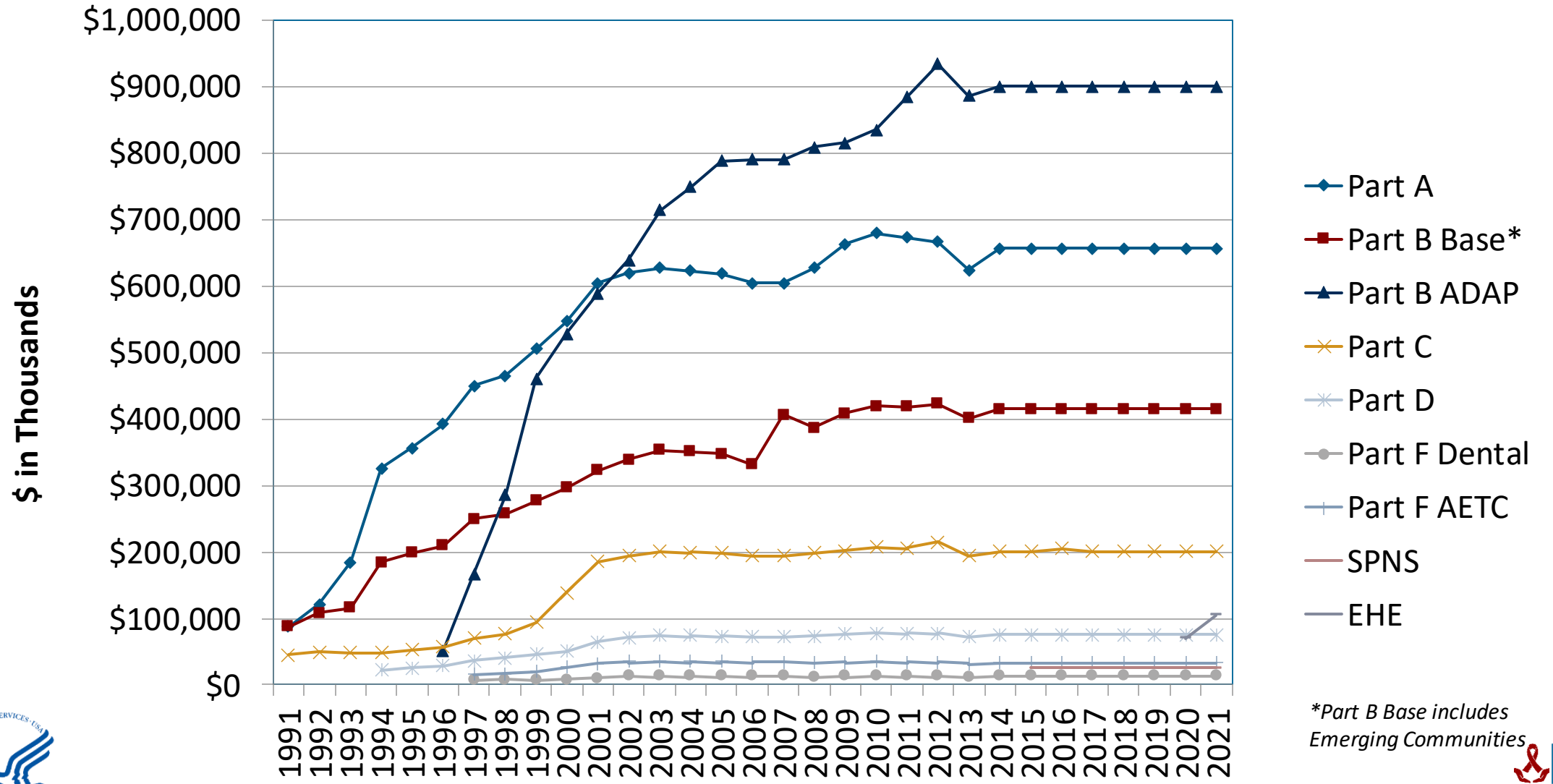
Overview

FY 2021 HRSA RWHAP Appropriations: ~$2.4 Billion



Budget History: Ryan White HIV/AIDS Program Appropriations

FY 1991 - FY 2021



*Part B Base includes Emerging Communities

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Overview

ADAP-Specific Funding and Expenditures

In FY 2021, budgets in the nation's ADAPs totaled over $2.1 billion*

- @ $1.387 billion for purchasing medications
- @ $635 million for health insurance assistance
  - $377 million for premiums and $258 million for medication co-pays and deductibles

Sources of funding for ADAP services*:

- RWHAP Part B/ADAP**: $955,403,889
- State funds: $106,369,425
- Drug rebates/program income: $884,066,643
- Other RWHAP Parts contributions: $8,478,077

*Source: NASTAD 2023 National RWHAP Part B ADAP Monitoring Project Report

**RWHAP ADAP here denotes all RWHAP Part B funds allocated to ADAP (ADAP Base, RWHAP Part B Base, ADAP Emergency Relief, RWHAP Part B Supplemental, ADAP Supplemental)

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Overview

ADAP-Specific Funding (FY 2023)

RWHAP Part B HIV Care Grant Program (X07)

- ADAP Base: $783,572,350
- ADAP Supplemental: $41,240,650

ADAP Emergency Relief Funding (X09)

- $75,000,000 (from ADAP Base)

Other sources of ADAP Funding: Drug rebates and program income, state general revenue funds, and RWHAP Part A and B contributions (including X07 and X08)

Overview

ADAP Funding Distribution

- 95% of the ADAP Base is distributed by formula, based on the number of reported living cases of HIV in the state or territory in the most recent calendar year for which data are available.
- 5% of the ADAP Base is set-aside for the ADAP Supplemental grant, which is distributed based on 'severe' need:
  - FPL eligibility standards = or < 200%
  - Reduction in Formulary
  - Initiation of Waiting List
  - Unanticipated increase in eligible people with HIV
- There are 7 ADAP Supplemental recipients in FY23.
- There are 17 ADAP Emergency Relief Funding recipients in FY23

Overview
ADAP's Impact

- ADAPs serve approximately one in four people with HIV in the U.S. that receive antiretroviral medications (ARV)
  - 289,289 people with HIV served through ADAPs in calendar year (CY) 2021
    - More than one-third (36.5%) of all ADAP clients have no health care coverage
    - 46.9% were at or below 100% FPL
  - 107,334 (45.5%) received only full-pay medication assistance
    - a decrease from 64.1% in 2014
  - 51,482 (21.8%) received only insurance assistance (for premiums and/or copays)
  - 78,866 (32.6%) received a combination of full-pay medication and insurance assistance

*Source: Health Resources and Services Administration. Ryan White HIV/AIDS Program ADAP Data Report, 2021

Overview

Source of ADAP Requirements

- RWHAP Legislation:
  - Section 2616. 300ff–26 PROVISION OF TREATMENTS
- HAB Guidance (available on https://ryanwhite.hrsa.gov/):
  - HRSA HAB 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 ('medication assistance')
  - Providing assistance with health insurance premiums, medication co-pays, and deductibles ('health insurance assistance')

- ADAP Flexibility Policy allows states/territories 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

- 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

Subaward Responsibilities

- RWHAP Part B recipients:
  - May choose to subaward 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 subaward
  - 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
- RWHAP legislation does not mandate an ADAP-specific Advisory Committee; however, most states/territories 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 are determined by each recipient. For ADAPs, eligibility is determined by each state/territory.
- As per PCN 21-02, RWHAP eligibility is based on:
  - HIV status:
    - A documented diagnosis of HIV
  - Low-income
    - The RWHAP recipient defines low-income
  - Residency
    - The RWHAP recipient defines its residency criteria

EHE only requires diagnosis of HIV infection

ADAP Operations

Eligibility Criteria—Federal Poverty Level (FPL)*

- For ADAPs, eligibility is determined by each state/territory. Here are the income caps for the ADAPs in 2021*:

% FPL	# States	# Clients in ADAP	% of Total ADAP Clients
200	2	36,693	12.68%
250	1	884	.31%
300	6	22,713	7.85%
400	17	79,886	27.62%
425	1	4,894	1.69%
500	25	134,507	46.51%
550	2	9,652	3.34%

*source 2021 ADAP Data Reports

ADAP Operations

Eligibility Determination (PCN 21-02)

- HRSA HAB expects all RWHAP recipients and subrecipients to establish, implement, and monitor policies and procedures to determine client eligibility based on each of the three factors outlined above, including documentation* requirements.

- RWHAP recipients and subrecipients are expected to develop protocols to facilitate the rapid delivery of RWHAP services, including the provision of antiretrovirals for those newly diagnosed or re-engaged in care**.

- If services are initiated prior to eligibility being established, RWHAP recipients and subrecipients must conduct a formal eligibility determination within a reasonable timeframe and reconcile (i.e., properly account for) any RWHAP funds to ensure that they are only used for allowable costs for eligible individuals.

ADAP Operations

Eligibility Confirmation (PCN 21-02)

- RWHAP recipients and subrecipients must conduct timely* eligibility confirmations, in accordance with their policies and procedures, to assess if the client's income and/or residency status has changed.
  - RWHAP recipients and subrecipients are permitted to accept a client's self-attestation of "no change" when confirming eligibility, although HRSA HAB does not recommend that recipients and subrecipients rely solely on client self-attestation indefinitely.
  - RWHAP recipients and subrecipients should not disenroll clients until a formal confirmation** has been made that the client is no longer eligible.

- RWHAP recipients and subrecipients should conduct periodic checks to identify any potential changes that may affect eligibility, and require clients to report any such changes.

- Recipients and subrecipients should use electronic data sources to collect and verify client eligibility information, when possible.

EHE does not require eligibility confirmation

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 (HHS)
  - 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
- 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:
  - ADAP clients expeditiously enroll 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 healthcare coverage

EHE requires compliance with POLR

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

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
- ADAP budgets included $1.387 billion for purchasing medications in FY21*
- 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

* Source: NASTAD 2023 National RWHAP Part B ADAP Monitoring Project Report

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Medication Assistance

340B Program

- 340B discounts required by the Veterans Health Care Act of 1992 (Section 602)
  - Requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices
- 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."

*EHE recipients/subrecipients are eligible for 340B pricing**

Medication Assistance

340B Program, Rebates and Program Income

- ADAPs have access to discounted drug prices through the 340B program
- Rebates are generated by ADAPs through the Pharmacy Network model.
  - ADAPs purchase medications through a retail pharmacy network at a price higher than the 340B price then submit rebate claims to drug manufacturers
  - Guiding document: PCN 15-04, "Utilization and Reporting of Pharmaceutical Rebates"
- Program income is generated by ADAPs through the Direct Purchase model.
  - ADAP bills third party insurance for medications it purchased at 340B pricing. Program income is the difference between the insurance reimbursement for 340B drugs and the cost of this medication
  - Guiding document: PCN 15-03, "Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income"

Health Insurance Assistance

- Health insurance assistance includes:
  - Payment of healthcare premiums
  - Medication cost-sharing (i.e., co-pays, deductibles, co-insurance)
    - Cannot pay for non-medication-related cost-sharing
- *ADAPs are encouraged, but not required, to assist clients with healthcare premiums and cost sharing**
- ADAP budgets included $635 million for health insurance assistance in FY21**
  - ($377 million for premiums and $258 million for medication co-pays and deductibles)

*PCN 18-01, "Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance"
** Source: NASTAD 2023 National RWHAP Part B ADAP Monitoring Project Report

Health Insurance Assistance, cont.

- HRSA encourages RWHAP recipients and subrecipients to assist clients with healthcare premiums and cost sharing in PCN 18-01, "Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance"
- Other PCNs related to ADAP, Medicaid, and private health insurance include 13-01 and 13-04

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

Health Insurance Assistance Requirements, cont.

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*

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

EHE and ADAPs

- HAB is funding EHE initiatives in 28 states
  - 8 states are funded directly (Alabama, Arkansas, Kentucky, Mississippi, Missouri, Oklahoma, South Carolina and Ohio*)
  - EMAs/TGAs receiving EHE funds are in 20 additional states/territories (Arizona, California, District of Columbia, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New York, North Carolina, Pennsylvania, Puerto Rico, Tennessee, Texas, Washington)
- Current ADAP FPL in funded jurisdictions:

ADAP FPL:	200%	300%	400%	500%
Directly funded States	0	1	3	4
States with funded EMAs/TGAs	1	3	6	10

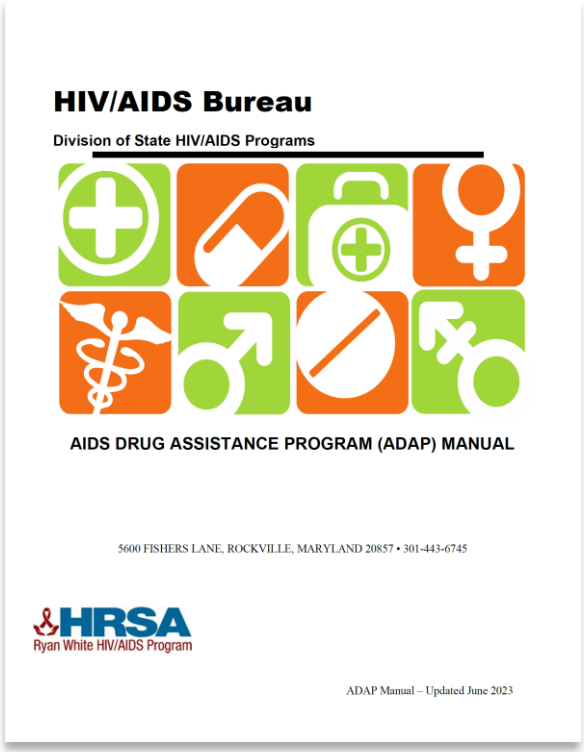
Overview of Potential Impact of EHE on ADAPs, continued

EHE may have impact on ADAPs in the following ways:

- Funding Challenges:
  - ADAPs in the 20 states containing EHE-funded EMAs/TGAs are not receiving any additional resources from HAB to cover additional clients added due to the EHE initiative. There is no plan to directly fund the ADAPs for these additional clients.
- Programmatic Challenges:
  - The directly-funded ADAPs and any of the 20 ADAPs that are not directly funded but who choose to accept EHE funding from the EMAs/TGAs will have to set up dual systems to track eligibility for EHE clients differently than that of their other clients, and to exclude EHE clients from recertification process.
- Systems Challenges:
  - ADAPs will need to adapt their data systems to be able to track EHE clients separately—for eligibility and recertification—and report them separately. This is particularly challenging in state systems.

Technical Assistance Resources

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



Background on ADAP Manual

The ADAP Manual serves as:

- An orientation 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 ensure access to HIV medications to persons in need;
- A reference document for ADAP staff on legislative and program requirements;
- A tool to guide ADAPs in managing fiscal and program components. Overseeing an ADAP is an ongoing endeavor of refining and reassessing operations to ensure and expand access to HIV medications and pursue cost-saving and cost-cutting strategies within the complex and evolving U.S. and state/territory-specific health care systems; and
- A source for information about where to obtain additional information and technical assistance (TA).

High Level Summary of Changes to 2023 ADAP Manual

The 2023 ADAP Manual includes the following key changes from the previous version (issued 2016):

- Incorporates requirements set forth in the Office of Management and Budget (OMB)'s release of the Uniform Administrative Requirements codified by HHS in 45 Code of Federal Regulations (CFR) part 75;
- Updates information to reflect HRSA HAB Policy Clarification Notices (PCNs) published since the last manual update in 2015;
- Updates language to provide clarification on ADAP-specific issues based on questions received by HRSA HAB since the last manual update.

Questions and Answers

Contact Information

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