The AIDS Drug Assistance Program
Overview

Ryan White HIV/AIDS Part B Program
Administrative Reverse Site Visit Meeting
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HAB DSHAP Vision and Mission

• Vision: Optimal HIV AIDS prevention, care and treatment for all.

• Mission: To provide leadership and support to States/Territories for developing and ensuring access to quality HIV prevention, health care and support services.
AIDS Drug Assistance Program

Overview

• The AIDS Drug Assistance Program (ADAP) is a component of the Ryan White Part B program that provides access to HIV/AIDS medications and medications to prevent the serious deterioration of health resulting from HIV disease.
Ryan White Legislation ADAP Milestones

• Ryan White Legislation was signed into law on August 18, 1990
• 1990: AZT Demonstration Project incorporated into Title II of the Ryan White CARE Act.
• 1996: First reauthorization created the Federal ADAP earmark.
• 2000: Second reauthorization allowed insurance purchasing and flexibility for access, adherence and monitoring and created ADAP supplemental grants.
• 2006: Third reauthorization of the Ryan White Program created a new formula incorporating living HIV/AIDS cases in the state award, minimum formulary requirements, and ADAP supplemental set aside & eligibility.
• 2009: Currently reauthorized for four years as the Ryan White HIV/AIDS Treatment Extension Act (Ryan White HIV/AIDS Program
ADAPs— National Overview

• Each of the 59 States and Territories are provided funding for ADAP.

• There is a wide variation in program characteristics due to individual State administration of each ADAP and HIV/AIDS prevalence in each State.

• Differences most pronounced in areas of funding, eligibility criteria, formulary size, and cost-saving strategies.
FY 2014 Ryan White HIV/AIDS Appropriations

Total $2.319 Billion

- Part A 28%
- Part B 18%
- Part B ADAP 39%
- Part C 9%
- Part D 3%
- AETC 1%
- Dental 1%
- SPNS 1%

(dollars in millions)
ADAP Funding (FY14)

- Part B (X07)
- ADAP Base: $781,976,828
- ADAP Supplemental: $41,352,275
- ADAP Emergency Relief Funding (X09)
- $72,611,510 (from ADAP Base)
- Other sources of ADAP Funding: State match, medication rebates, state general revenue funds, Part A/B contributions
ADAP Funding Distribution

- 95% of the ADAP Base is distributed by formula, based on the number of living HIV/AIDS cases in the state in the most recent calendar year.
- 5% of the ADAP Base is set-aside for the ADAP Supplemental grant, which is distributed based on need:
  - FPL eligibility standards = or <200%
  - Reduction in formulary
  - Initiation of waiting list
  - Unanticipated increase in eligible PLWH
- There are 27 ADAP Supplemental grantees in FY14.
ADAP Services

• ADAPs provide access to medications by either:
  • purchasing medications; or
  • providing assistance with health insurance premiums, co-pays and deductibles (See HAB Policies 07-05, 13-01, 13-04, 13-05, 13-06, 14-01)
ADAP Services, continued

• Through the ADAP Flexibility Policy (HAB Policy 07-03), ADAP funds may also be used to assist with:
  • adherence support
  • monitoring of drug treatment
  • enhanced access to services
ADAP’s Impact: ADAP Data Report

Preliminary Data

• @1 in 4 PLWH receiving ARVs in USA use ADAP services.
• 256,657 PLWH served through ADAP in CY 2014.
• 168,684 ADAP clients received medications
• 75,635 ADAP clients received insurance assistance (including medications co-pays and deductibles)
ADAP-Related Sections of the RWHAP Legislation

• Section 2616. [300ff–26] Provision of Treatments

(a) IN GENERAL.—A State shall use a portion of the amounts provided under a grant awarded under section 2611 to establish a program under section 2612(b)(3)(B) to provide therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.
ADAP-Related Sections of the RWHAP Legislation

2616. [300ff–26] (f)(1)

• (f) USE OF HEALTH INSURANCE AND PLANS.—IN GENERAL.—In carrying out subsection (a), a State may expend a grant under section 2611 to provide the therapeutics described in such subsection by paying on behalf of individuals with HIV/AIDS the costs of purchasing or maintaining health insurance or plans whose coverage includes a full range of such therapeutics and appropriate primary care services.
ADAP-Related Sections of the RWHAP Legislation

2616. [300ff–26] (f)(2)

• (2) LIMITATION.—The authority established in paragraph (1) applies only to the extent that, for the fiscal year involved, the costs of the health insurance or plans to be purchased or maintained under such paragraph do not exceed the costs of otherwise providing therapeutics described in subsection (a).

Also see HAB Policies 07-05, 13-01, 13-04, 13-05, 13-06, 14-01
2616. [300ff–26](b)

- (b) ELIGIBLE INDIVIDUAL.—To be eligible to receive assistance from a State under this section an individual shall—

  (1) have a medical diagnosis of HIV/AIDS; and
  (2) be a low-income individual, as defined by the State.

Payer of Last Resort requirement is in Section 2617(b)(7)(F)
ADAP Eligibility

• All clients must be HIV+
• Other Eligibility Criteria are determined by each State or Territory
• In collaboration with an ADAP Advisory Body or respective State Legislature or other Health Department stakeholders
• Eligibility criteria include proof of HIV/AIDS status, financial/income eligibility, residency, and uninsured or underinsured status
ADAP Eligibility Criteria

- **Financial eligibility:**
  - Income limit (as percentage of Federal Poverty Level); may also include asset limit.

- **Medical eligibility:**
  - Diagnosis of HIV infection

- **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 Recertification

- ADAPs are required to recertify the clients’ eligibility at least every six months (per NGA since 2005) and at least once a year (whether defined as a 12-month period or calendar year).

- If a RWHAP State Part B grantee has developed a multi-tiered and continuous residency, insurance, and income verification review process, that state verification process may satisfy the RWHAP recertification requirement.
  - The RWHAP Part B verification processes and supporting documentation must be consistently applied to each individual and available for review either in hard copy or electronically.
  - HAB will consider requests to approve these review processes as the RWHAP six month recertification process on a case-by-case basis and will document approval as appropriate in the Electronic Handbook.
  - See HAB Policy Clarification Notice #13-02.

See HAB Policy Clarification Notice #13-02
ADAP-Related Sections of the RWHAP Legislation: Formulary

Section 2616. [300ff–26](e)

- (e) List of Classes of Core Antiretroviral Therapeutics—
  - For purposes of subsection (c)(1), the Secretary shall develop and maintain a list of classes of core antiretroviral therapeutics, which list shall be based on the therapeutics included in the guidelines of the Secretary known as the Clinical Practice Guidelines for Use of HIV/AIDS Drugs, relating to drugs needed to manage symptoms associated with HIV.

Public Health Service ARV Drug Classes

- FDA-approved antiretroviral drug classes currently available include: Entry and Fusion Inhibitor, Non-nucleoside Reverse Transcriptase Inhibitor, Nucleoside Reverse Transcriptase Inhibitor, and Protease Inhibitor.
ADAP Formulary

- ADAP Formulary must contain at least one medication from each class of PHS approved Antiretroviral classes
- Most States have an ADAP Advisory Body that provides guidance to the State on clinical, fiscal, and ADAP formulary recommendations
- Most State’s ADAP Advisory Body’s include physicians, PLWH, and other service providers.
ADAP-Related Sections of the RWHAP Legislation: ADAP Flexibility

Section 2616. [300ff–26] (c)(6)

(6) encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring.

Of the amount reserved by a State for a fiscal year for use under this section, the State may not use more than 5 percent to carry out services under paragraph (6), except that the percentage applicable with respect to such paragraph is 10 percent if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection (a).

Also see HAB Policy 07-03
ADAP Flexibility

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

• States may request to redirect up to 5% of their ADAP earmark under the Flexibility policy (10% in extraordinary circumstances) for expenditures that:
  • improve access to medications,
  • increase adherence to medication regimens, and
  • help clients monitor their progress in taking HIV-related medications
Affordable Care Act and ADAPs

• Key impacts of the ACA on ADAPs include:
  ▪ Creation of Pre-Existing Conditions Insurance Plans (PCIPs)
  ▪ ADAP expenditures counting towards Medicare Part D True Out of Pocket (TrOOP) Costs
  ▪ Medicaid Expansions
  ▪ Access to insurance for those with pre-existing conditions
  ▪ No annual or lifetime caps on expenditures
Revised Policy Clarification Notice (PCN) 13-05 on formulary equivalency

- On June 6th, HRSA released a revised PCN 13-05 that changes the formulary requirement be that it, at a minimum, includes at least one drug in each class of core antiretroviral therapeutics from the HHS Clinical Guidelines for the Treatment of HIV/AIDS as well as appropriate primary care services.

- Please note that the ADAP still needs to do a cost effectiveness analysis.
Revised Policy Clarification Notice (PCN) 13-06 on formulary equivalency

- Revised PCN 13-06 that clarifies that when RWHAP Part A planning bodies, Part B, Part C and Part D grantees provide funding for Medicaid premium and cost-sharing assistance for low-income individuals, the grantee must also assure that they are buying health insurance that, at a minimum, includes at least one drug in each class of core antiretroviral therapeutics.
New Policy Clarification Notice (PCN) 14-01 on reconciliation of advance premium tax credits

- On June 6th, HRSA released PCN 14-01, which clarifies HRSA policy regarding the use of Ryan White HIV/AIDS Program funds to purchase health insurance for clients in the Marketplace and the reconciliation of advance premium tax credits.

- RWHAP grantees and sub-grantees must vigorously pursue any excess premium tax credit a client receives from the IRS upon submission of the client’s tax return.
  - Collect excess premium tax credit attributed to individual client
CSM Final Rule for Exchange/Insurance Market Standards for 2015 and Beyond

• On May 16, the Department of Health and Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS), issued the final rule for Exchange/Insurance Market Standards for 2015 and Beyond

• The rule promotes affordability, transparency and takes the first step toward providing additional quality related tools for consumers shopping in the Health Insurance Marketplace
CMS Final Rule Highlight: Consumer Assistance

• “...in specific circumstances, certified application counselor (CAC) designated organizations can serve target populations without violating the broad non-discrimination requirement related to Exchange functions”

• RWHAP providers may offer CAC services exclusively to their client populations (e.g., enrollment assistance, post-enrollment assistance, outreach and education about getting covered), so long as they do not discriminate based on race, color, national origin, disability, age sex or other prohibited factors
CMS Final Rule Highlight: 24 hour expedited review of formulary requests

• Qualified Health Plans (QHPs) must have an expedited exceptions process for beneficiaries with exigent circumstances to seek a medication not covered under a plan
  • Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug
• QHPs must decide within 24 hours of receiving the request
• QHPs must provide coverage of any drug obtained through this expedited exceptions process for the duration of the exigency
ADAP Pricing and Purchasing
ADAP Costs

• The average cost per ADAP client is approximately $11,500/year
  ▪ Vary significantly by state depending on formulary and program costs
  ▪ Vary depending on ADAP’s adoption of cost saving’s strategies
The 340B Drug Discount Program is a U.S. federal government program created by the Veterans Health Care Act of 1992 (Section 602) that requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices.

The program is named for the section authorizing it in the Public Health Service Act (PHSA).
340B Eligible Entities

All RWHAP grantees are eligible entities under the 340B Program.

RWHAP sub-grantees are eligible entities under 340B if they are certified by OPA upon verification by the RWHAP grantee.

RWHAP grantees (and sub-grantees) can contract with pharmacies to provide 340B services to eligible clients. Contract pharmacies need to register with OPA.
340B Prime Vendor Program (PVP)

- 340B Covered Entities can choose to participate in the Prime Vendor Program:
  - Drug price negotiation services
  - Multiple wholesale distributor agreements
  - Favorable discounts on other pharmacy related products/service
  - 340B University – educational opportunity
  - No cost to participate

- More information is available at: [www.340bpvp.com](http://www.340bpvp.com) and ApexusAnswers@340bpvp.com
ADAP Drug Purchasing

AIDS Drug Assistance Programs (ADAPs) can either purchase medications directly from a wholesaler (“Direct Purchase”) or reimburse pharmacies for dispensing medications to ADAP clients (“Rebate Model”)—or both (“Dual”).
ADAP Drug Purchasing

ADAPs access the 340B pricing in the following ways:

• For “Direct Purchase”, the ADAP purchases the medications from a drug wholesaler at the 340B price.

• For “Rebate Model”, the ADAP reimburses the pharmacy at a negotiated rate, then invoices the manufacturer for the difference between the rate paid and the 340B price.

• For “Dual”, the ADAPs do a combination of the above.
ADAP Drug Purchasing

- As was mentioned earlier, ADAPs can also choose to pay for insurance premiums, deductibles, co-payments and co-insurance, as long as the insurance assistance program is cost-effective.

- ADAPs receive rebates on medications for which they made a co-payment or deductible payment.
ADAP Drug Purchasing

• In addition to the 340B price reduction, ADAPs have negotiated deeper discounts on antiretroviral therapies (ARV) through the ADAP Crisis Task Force (ACTF).

• ACTF discounts received as rebates may be referred to as “supplemental rebates” or “voluntary rebates”.
ADAP-Related Sections of the RWHAP Legislation: Rebates

2616. [300ff–26](g)

(g) DRUG REBATE PROGRAM.—A State shall ensure that any drug rebates received on drugs purchased from funds provided pursuant to this section are applied to activities supported under this subpart, with priority given to activities described under this section.

2622. Timeframe for Obligation and Expenditure of Grant Funds

(d) Treatment of Drug Rebates
Rebates

• 340B and Supplemental Rebates that ADAPs receive are not considered program income.

• The RWHAP legislation requires that rebates must be put back into the RWHAP Part B program, with priority given to ADAP.
Drug Pricing

• 340B pricing can only be used for 340B eligible clients at 340B covered entities.

• Only one 340B covered entity can access 340B pricing for a pharmacy claim (no “double dipping”).
Need for Collaboration

• OPA is not prescriptive on who gets “first dibs” at the 340B pricing.

• ADAPs have the right to contract with (or not contract with) whichever pharmacies they choose.

• ADAPs can choose to mandate who gets 340B pricing in their pharmacy contracts.
340B Program Integrity

Areas of Focus

• Eligibility
• Duplicate Discount
• Diversion
• Group Purchasing Organization
340B Audits by HRSA

- All covered entity types considered for risk-based audit selection
  - Risk-based factors – length in program, number of outpatient facilities, number of contract pharmacies, complexity of program, volume of purchase
- Target audits – focus on specific allegation
- Conducted by HRSA regional staff
- Further information on the audit process is available at http://www.hrsa.gov/opa/programintegrity
ADAP Challenges

• Increased Demand for services in an environment of few new/declining resources:

  *ADAPs experienced 18% growth since 2010*

• Contributory Factors:
  • Economic downturn
  • Increased HIV testing
  • Push for earlier HIV treatment
  • More effective medications
  • Increased HIV prevalence
  • HIV is a chronic disease and PLWH are living with HIV longer and aging
Cost Containment

• Throughout their history, ADAPs have devised and implemented a variety of cost-containment strategies to maximize scarce resources.

• There are two categories of cost containment:
  • Cost Saving Strategies
  • Cost Cutting Strategies
Cost Containment: Cost Saving Strategies

- Measures taken to improve the cost-effectiveness of ADAP operations, which are required to achieve, improve, and/or maximize ADAP resources.
- Examples of “cost-saving” measures:
  - Improved systems and procedures for back billing Medicaid,
  - Improved client recertification processes,
  - Part B Program structural or operational changes
  - Expanding insurance assistance
  - Collection of 340B rebates for insurance co-pays, deductibles, co-insurance
  - CMS data-sharing agreements to allow ADAP expenditures to count towards TrOOP
  - Controlling ADAP administrative costs
Cost Containment: Cost Cutting Strategies

• Measures taken that restrict/reduce ADAP Services or enrollment. These activities are instituted out of necessity due to insufficient resources and/or to avoid starting a waiting list.

• Examples of “cost cutting” strategies include:
  • Lowering of financial eligibility (FPL)
  • Capping enrollment
  • Reducing benefits (formulary reductions with respect to antiretroviral medications and medications to treat opportunistic infections or complications of HIV disease)
  • Starting an ADAP Waiting List
ADAP Waitlist

- An ADAP waiting list is a mechanism used to limit access to the ADAP when funding is not available to provide medications to all eligible persons requesting enrollment in that State.

- The ADAP verifies overall eligibility for the program and places eligible individuals on a waiting list, as necessary, prioritized by a pre-determined criterion.
ADAP Waitlist

• The ADAP manages the waiting list to bring clients into the program as funding becomes available.

• ADAPs are expected to provide training, education and continual feedback to providers, consumers and case managers on how to access the Pharmaceutical Manufacturer's Patient Assistance Programs (PAP).
ADAP Reports

ADAP-related allocations and expenditures are reported to HAB through a variety of reports, including:

- ADAP Data Report (ADR)
- Regular Part B reports
- ERF-specific reports
ADAP Data Reporting
ADAP Data Report (ADR)

- 2013 ADR was submitted in June 2014
- All required grantees submitted the ADR
- There were numerous data issues
- Overall client numbers were similar to the AQR
- Approximately 250,000 unduplicated clients served
  - >75,000 receiving insurance assistance
  - >168,000 receiving medication assistance
• Completeness Issues:
  - Race: 7,358 unknown/missing
  - Poverty Level: 10,729 unknown
  - HIV Status: 13,886 unknown/Missing
  - Insurance Status: 16,673 missing

• Technical Assistance is available to ensure improvement of 2014 data submission.
ADAP Performance Measures

- HAB has developed recommended performance measures for ADAPs, including:
  - Percent of ADAP applications approved or denied for new ADAP enrollment within 14 days (two weeks) of ADAP receiving a complete application in the measurement year
  - Percentage of ADAP enrollees who are reviewed for continued ADAP eligibility two or more times in the measurement year
ADAP Performance Measures, continued

• Percentage of new anti-retroviral classes that are included in the ADAP formulary within 90 days of the date of inclusion of new anti-retroviral classes in the PHS Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents during the measurement year.

• Percent of identified inappropriate antiretroviral (ARV) regimen components prescriptions that are resolved by the ADAP program during the measurement year.
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/

• Technical Assistance
• Project Officer
TA Available through NASTAD – NASTAD has been funded by HRSA/HAB to provide TA to Ryan White Part B/ADAPs from July 2014 - June 2017

- Provide TA to ADAPs to implement an effective **ADAP financial forecasting model**
- Assist Part B/ADAPs in conducting **analysis and evaluation of health plans** and identifying barriers to access
- Provide TA to Part B/ADAPs to **leverage data to improve health outcomes** across the HIV Care Continuum (i.e., data to care), including building and enhancing comprehensive systems of care
- Assist Part B/ADAPs in implementing and participating in **integrated planning** processes
TA Available through NASTAD

- Provide TA to Part B/ADAPs to strengthen capacity to implement and administer insurance purchasing programs

- Assist Part B/ADAPs in implementing effective cost-containment strategies and preventing the use of waiting lists, including participating in the 340B program, CMS data sharing, and other data sharing

- Assist ADAPs in their efforts to “get the best price” and explore opportunities to negotiate or gain access to discounts on high utilization, non-HIV-specific drugs

- Provide on-going mentorship and peer-to-peer training and educational opportunities
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