Part B: AIDS Drug Assistance Program

HRSA's Ryan White HIV/AIDS Program

Program Fact Sheet | September 2023

The Health Resources and Services Administration's (HRSA) Ryan White HIV/AIDS Program (RWHAP) provides a comprehensive system of HIV primary medical care, medications, and essential support services for low-income people with HIV. Over half the people with diagnosed HIV in the United States—more than 576,000 people in 2021—receive services through RWHAP each year. First authorized in 1990, RWHAP funds grants to states, cities, counties, and local community-based organizations to provide care and treatment services to people with HIV to improve health outcomes and reduce HIV transmission. In 2021, 89.7 percent of RWHAP clients receiving HIV medical care were virally suppressed, which means they cannot sexually transmit HIV to their partners and can live longer and healthier lives. For more than three decades, RWHAP has worked to stop HIV stigma and reduce health disparities by caring for the whole person and addressing their social determinants of health.

HRSA Ryan White HIV/AIDS Program

The Health Resources and Services Administration's (HRSA) Ryan White HIV/AIDS Program (RWHAP) Part B provides grants to all states and U.S. territories to improve the quality, availability, and organization of HIV health care and support services. Under RWHAP Part B, the AIDS Drug Assistance Program (ADAP) provides U.S. Food and Drug Administration (FDA)–approved medications to low-income people with HIV who have limited or no health coverage from private insurance, Medicaid, or Medicare.

Grant recipients may also use ADAP funds to—

- Obtain health care coverage for eligible clients
- Provide services that improve access to, adherence to, and monitoring of drug treatments

In 2021, ADAP provided nearly 290,000 clients with HIV-related medications and/or access to medications through health care coverage assistance.

Recipients and Eligibility

Recipients are the chief elected officials of a state or territory who designate the state department of health or another state entity to implement and manage the RWHAP Part B grant. All 50 states, the District of Columbia, Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, and Federated States of Micronesia receive ADAP funding as a component of their Part B grant.

Client Eligibility

The state or territory decides client eligibility for ADAP based on the following criteria:

- **Residency:** State or territory determines how it defines residency, including for transient populations
- **Medical eligibility:** HIV diagnosis
- **Financial eligibility:** Usually determined as a percentage of the federal poverty level

ADAP Implementation

The RWHAP statute requires that each ADAP must cover at least one drug from each class of HIV antiretroviral medications on its ADAP formulary. ADAP funds may be used only to purchase FDA-approved medications. Within these requirements, each ADAP decides which medications to include on its formulary and how those medications will be distributed.

HRSA requires that ADAP eligibility criteria be applied consistently across the state or territory and expects that all formulary medications and ADAP-funded services are equitably and consistently available to all eligible enrolled people throughout the state or territory.

Funding Considerations

Part B base grants and ADAP base grants are determined using a formula based on reported living cases of HIV in the state or territory in the most recent calendar year for which data are available. Congress appropriated approximately $464.6 million for RWHAP Part B base in fiscal year (FY) 2023.

The ADAP base grants provide access to HIV-related medication through the purchase of medication and health care coverage. Congress appropriated approximately $900.3 million for Part B ADAP in FY 2023.

Five percent of ADAP appropriations is reserved for additional funding to states and territories that have a severe need for medication assistance. The states and territories that meet the eligibility criteria can choose to apply for this through ADAP supplemental funding.

ADAP Emergency Relief Funding is a competitive supplemental grant program intended for states and territories that can demonstrate the need for additional resources to prevent, reduce, or eliminate ADAP waiting lists, including through cost-containment measures.

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AIDS Drug Assistance Programs (ADAPs)

What are ADAPs?[1]

AIDS Drug Assistance Programs (ADAPs) provide HIV-related prescription drugs to low-income people with HIV/AIDS who have limited or no prescription drug coverage. With more than 250,000 enrollees in calendar year (CY) 2015, ADAPs reached approximately one third of people with HIV receiving care nationally, and provided HIV medications to half of all people with HIV on treatment in the U.S.[2,3]

ADAPs began serving clients in 1987, when Congress first appropriated funds to help states purchase the only approved antiretroviral (ARV) drug at that time, AZT.[4] In 1990, they were incorporated into the newly enacted Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, now known as the Ryan White Program.[5,6] Since Fiscal Year (FY) 1996, Congress has specifically earmarked funding for ADAPs through Part B of Ryan White, which is allocated by formula to states.[7] Ryan White has been reauthorized by Congress four times since first created and changes have been made to ADAPs over time. While the current authorization has lapsed, there is no sunset provision in the law. Therefore, ADAP, and the Ryan White Program more broadly, can continue to be funded through annual Congressional appropriations.

All states, Washington, D.C., and other U.S. territories receive federal ADAP earmark funding through Part B of Ryan White. In addition to the ADAP earmark, ADAPs receive state funding and contributions from additional sources, including other parts of Ryan White, but this support is highly variable and largely dependent on local decisions and resources. ADAPs are not entitlement programs – annual federal appropriations and, where available, other funding, determine how many clients ADAPs can serve and the level of services they can provide. Each state operates its own ADAP, including determining eligibility criteria and other program elements, such as formularies, resulting in significant variation across the country.
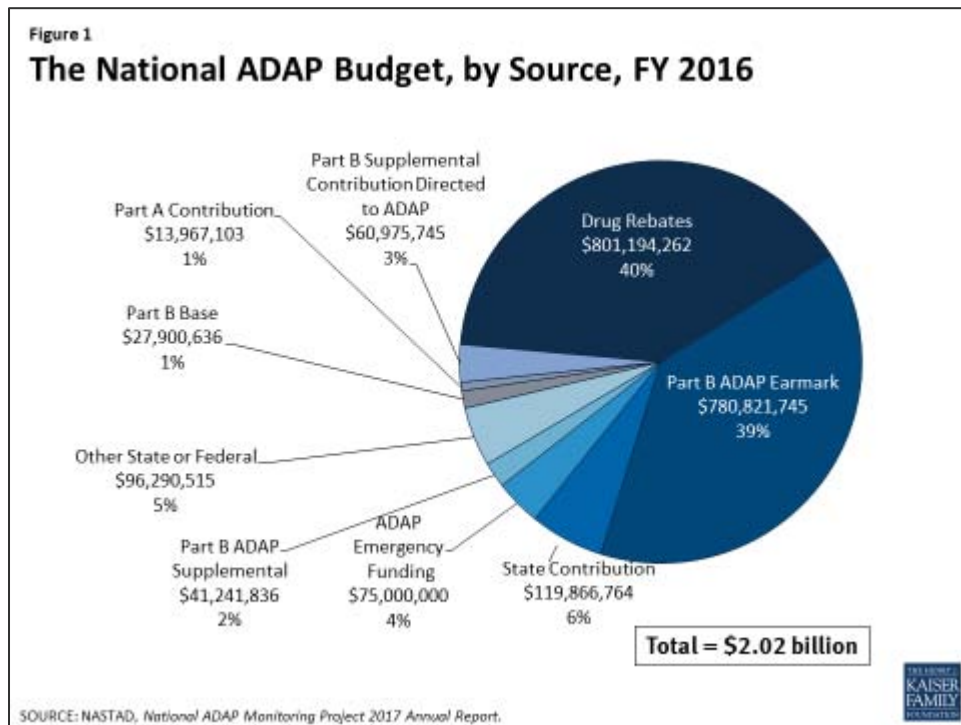
ADAP Budget

ADAP funding and budget composition is highly variable from year to year, and influenced by a broad range of factors. In recent years, the budget has also included transfers from other parts of Ryan White, as well as emergency funding to help alleviate ADAP waiting lists and unmet program needs.

- The national ADAP budget (including all funding sources) was $2.02 billion in FY 2016, lower than it was in FY 2015 ($2.24 billion).
- Through FY 2012, the federal ADAP earmark was the largest component of the budget.[8] It has declined as a share of the budget in recent years, and accounted for 39% of the FY 2016 budget, behind drug rebates.
- Drug rebates accounted for 40% of the overall ADAP budget in FY 2016, a drop from the previous year.
- State funding accounted for 6% of the budget.

- Other funding, including ADAP emergency funding; Part B ADAP supplemental awards; Part B supplemental contributions directed to ADAPs; transfers to ADAPs from state Part B base awards and from Part A; and other state/federal funding accounted for 16% of the overall ADAP budget.

- In FY 2016, 59 jurisdictions – all U.S. states, Washington, D.C., and other U.S. territories – received federal ADAP earmark funding. In addition: 38 ADAPs received drug rebates; 28 received state funds; 20 received other state/federal funding; 17 ADAPs received Part B base contributions; 15 states received Part B supplemental awards (not specific to ADAP) and, of those, 10 directed some of that supplemental funding to ADAP; 14 received emergency funds; 13 received direct Part B supplemental treatment funds;; and 6 received transfers of Part A funds.

- Among the states reporting data in both FY 2015 and FY 2016, 30 experienced net decreases in their budgets.

Figure 1

The National ADAP Budget, by Source, FY 2016

Part A Contribution $13,967,103 1%

Part B Supplemental Contribution Directed to ADAP $60,975,745 3%

Drug Rebates $801,194,262 40%

Part B Base $27,900,636 1%

Part B ADAP Earmark $780,821,745 39%

Other State or Federal $96,290,515 5%

Part B ADAP Supplemental $41,241,836 2%

ADAP Emergency Funding $75,000,000 4%

State Contribution $119,866,764 6%

Total = $2.02 billion

SOURCE: NASTAD, *National ADAP Monitoring Project 2017 Annual Report.*

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ADAP Formularies

ADAP formularies (the list of drugs covered) vary significantly across the country. In 2016:

- 6 states had an open formulary

- All offered all of the drugs identified in the **"recommended regimens"** in the nation's HIV treatment guidelines.[9]

- Of the 45 ARVs currently available (including multi-class combination products and generics), ADAP formularies covered between a low of 37 drugs in Arkansas to all 45 in 27 states.

- In addition to ARVs, many ADAPs provide access to drugs to treat opportunistic infections and HIV co-infection (e.g. treatment for hepatitis).

ADAP Expenditures and Prescriptions

In FY 2015:

- Drug expenditures totaled $1.315 billion, with an additional $310 million spent on insurance assistance (premiums and cost sharing).

- Annual per capita drug spending was $8,663 for drug purchases and co-payments and $2,720 for insurance purchasing and continuation.

ADAP Eligibility Criteria

The Ryan White Program requires all ADAP clients to be HIV-positive, low-income, and under- or uninsured, but no income level is specified under current law. Each ADAP determines its own eligibility criteria. As of January 1, 2015:

- All ADAPs have state residency requirements and many require proof of residency.

- Financial eligibility ranges from 200% FPL in 4 states to 500% FPL in 10 states.[10] In some cases, eligibility differs for the various program components within individual ADAPs (e.g., the insurance purchasing program vs. the direct medication program).

ADAP Clients

ADAP client enrollment and utilization have grown over time and are now at their highest levels to date. Client demographics vary by state and region, but nationally have remained fairly constant over time.

- 257,396 people were enrolled in ADAPs in CY 2015, ranging from 140 in Wyoming to more than 35,000 in California.

- Of CY 2015 clients enrolled, ADAPs provided medications only to 101,418 clients and insurance coverage (or insurance coverage and medications) to 124,099 clients.

Figure 2
Profile of ADAP Clients, CY 2015

NOTE: Percentages may not add to 100% due to rounding; Federal Poverty Level (FPL) was $11,770 for a household of one in 2015.
SOURCE: NASTAD, *National ADAP Monitoring 2017 Project Annual Report.*

- A majority of clients were people of color (69%) and most were male (78%).

- Three quarters (76%) had incomes at or below 200% of the Federal Poverty Level, (FPL), including over half (58%) with incomes at or below 138% FPL.

- Half of clients were between 45-64 years of age (50%), followed by those ages 25-44 (40%).

- Three quarters (77%) of all ADAP clients were virally suppressed (having a viral load of below 200 copies/ml), which is a higher share than for people with HIV nationwide (57% of those in care).[11] Viral suppression is higher among clients receiving insurance assistance (88% of whom are virally suppressed) compared to those receiving only medications from ADAPs (73% of whom are virally suppressed). Viral suppression is critical to achieving optimal individual health outcomes and research has shown there are also preventive benefits – when an individual with HIV is virally suppressed, the risk of sexual transmission is negligible.[12,13]
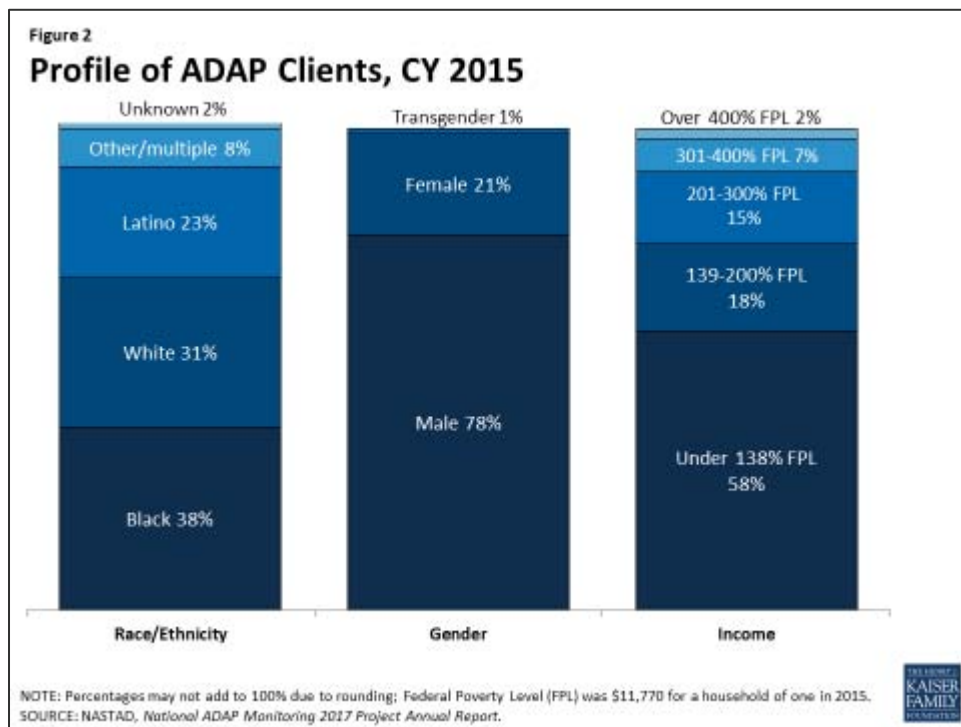
Cost-Containment Measures and Waiting Lists

ADAPs must balance client demand with available resources on an ongoing basis. Because of recent economic conditions, instituting cost-containment measures or management practices is common. In the past, waitlists were used as a primary cost-containment measure. Waitlists peaked in September 2011 when 9,298 individuals in 11 states were eligible for ADAPs yet unable to access medications. Currently, waitlists have been eliminated as a result of an influx of reprogrammed Ryan White funding and separate emergency funding between 2010 and 2013. In some cases, ADAPs received higher rebates from drug companies and individual ADAPs implemented stricter cost-containment measures such as capped enrollment and reduced eligibility and formularies. Few states currently have cost-containment measures (e.g., enrollment caps and waiting lists) in place, although as they were more common in the past when ADAPs faced budget crises, their use will be important to monitor their use moving forward.

Drug Purchasing Models

All ADAPs participate in the 340B program, enabling them to purchase drugs at or below the statutorily defined 340B ceiling price. ADAPs conduct drug purchasing through different mechanisms:

- 7 ADAPs centrally purchase and dispense medications through their own pharmacy or contract pharmacy (known as "direct purchase").

- 21 ADAPs pay retail pharmacies for drugs and subsequently bill manufacturers for the 340B rebate amount.

- 7 purchase through a "hybrid model," using an existing entity to purchase drugs and submitting rebate claims for any additional discount amount.

- 14 use a "dual model," purchasing medications through their own pharmacy or contract pharmacy and paying retail pharmacies for drugs, later filing for rebates.

Insurance Purchasing & Coordination

Clients have gained access to new coverage opportunities under the Affordable Care Act (ACA). In adjusting to the new health coverage landscape and in complying with Ryan White's payer of last resort requirement, ADAPs have intensified their efforts to coordinate with other health coverage entities, including private insurance marketplaces and Medicaid.[14] In many cases, providing insurance assistance is more cost effective for ADAPs (the average per capita cost of a client enrolled in insurance coverage is about one third of that of clients enrolled in direct drug programs) and doing so provides clients with robust coverage. ADAPs assisted with insurance coverage for 124,099 clients in 2015, at a cost of $310 million.

Only 3 ADAPs (ID, MS, SD) did not use funds for purchasing health insurance in 2015. The remaining states offer varying forms of insurance purchasing/coordination, including assisting with Medicare, employer-based coverage, and individual market coverage. While most ADAPs seek to leverage the opportunities provided by the ACA, not all ADAPs with insurance purchasing infrastructures use them to purchase qualified health plans in the health insurance marketplaces created by the law.

Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added an outpatient prescription drug benefit, Part D, to the Medicare program. As the payer of last resort, ADAPs must ensure that any Medicare Part D-eligible client is enrolled in Part D and that ADAP is not paying directly for prescription drug expenses. However, ADAPs can **help with clients' out**-of-pocket costs associated with Part D coverage. In CY2015, 13% of clients were served by Part D.

Under the ACA, as of January 1, 2011, payments made by ADAPs on behalf of a Medicare Part D beneficiary **count toward "TrOOP" (a beneficiary's true out**-of-pocket costs), allowing the client to pass through the "doughnut hole" **(or, coverage gap)** into catastrophic coverage.[15]

Looking Ahead

ADAPs continue to play a critical role in providing prescription drugs and a pathway to insurance coverage for low- and moderate-income people with HIV who would otherwise have limited access. In addition, ADAPs often serve as a bridge to other care and support services. As the number of people living with HIV has increased in the U.S., so too has the need for ADAPs. While ADAPs have faced challenging national and state fiscal conditions in the past, leading to the creation of waiting lists, emergency funding, increased rebates from manufacturers, and the implementation of the ACA have relieved much of this pressure. Looking ahead, as lawmakers continue to debate the future of the ACA, as well as federal spending more generally, it will be important to monitor the impacts of any policy changes on ADAPs and the clients they serve.

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[1] Except where noted, data included in this fact sheet are from the National Alliance of State and Territorial AIDS Directors (NASTAD), *National ADAP Monitoring Project 2017 Annual Report*. Not all states and U.S. jurisdictions reported data for each indicator. See the original report for a list of areas that did not report. See select state-level data at: http://www.kff.org/state-category/hivaids.

[2] Based on KFF analysis of data from CDC.

[3] KFF analysis of CDC and NASTAD ADAP Reporting Data. See ADAP Monitoring Report and https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6347a5.htm?s_cid=mm6347a5_w

[4] **The term "state" includes states, the** District of Columbia, and U.S. territories.

[5] Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, Pub. L. No. 101-381; Ryan White CARE Act Amendments of 1995, Pub. L. No. 104-146, SEC. 2616. [300ff-26].

[6] HRSA, HIV/AIDS Bureau.

[7] Five percent of the ADAP earmark is set-aside for the ADAP Supplemental Drug Treatment Grant.

[8] Not including the ADAP Supplemental Drug Treatment Grant set-aside.

[9] Department of Health and Human Services, Panel on Antiretroviral Guidelines for Adults and Adolescents (2013). Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents, July 14, 2016. Available at: http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/0/.

[10] The 2015 Federal Poverty Level (FPL) was $11,770 annually (slightly higher in Alaska and Hawaii) for a household of one.

[11] CDC. *Selected National HIV Prevention and Care Outcomes in the United States.* July 2016. https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-national-hiv-care-outcomes.pdf

[12] CDC. *Prevention Benefits of HIV Treatment*; updated January 2017.

[13] NIH. NIH Statement on World AIDS Day 2016; December 2016.

[14] The Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148.

[15] **The Medicare program includes a "coverage gap" or "doughnut hole" which, as mandated by the ACA, will gradually be phased out by 2020, when** beneficiaries will pay 25% of the cost of their drugs in the gap. Until then, recipients not receiving low-income subsidies (LIS) are liable for all prescription drug costs in the coverage gap. ADAP can assist with these expenses and ADAP spending can count towards the cli**ent's TrOOP until they** reach catastrophic coverage.