National ADAP Monitoring Project Annual Report

SUMMARY AND DETAILED FINDINGS

MARCH 2006

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NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

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Acknowledgements

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The National ADAP Monitoring Project is one component of NASTAD's National ADAP Monitoring and Technical Assistance Program which provides ongoing technical assistance to all state and territorial ADAPs. The program also serves as a resource center, providing timely information on the status of ADAPs, particularly those experiencing resource constraints or other challenges, to national coalitions and organizations, policy makers, and state and federal government agencies. NASTAD also receives support for the National ADAP Monitoring and Technical Assistance Program from the following companies: Boehringer Ingelheim Pharmaceuticals, Gilead Sciences, GlaxoSmithKline, Pfizer, Roche, and Tibotec Therapeutics. NASTAD also has a Training and Technical Assistance Cooperative Agreement with the Health Resources and Services Administration (HRSA), to provide technical assistance to ADAPs.

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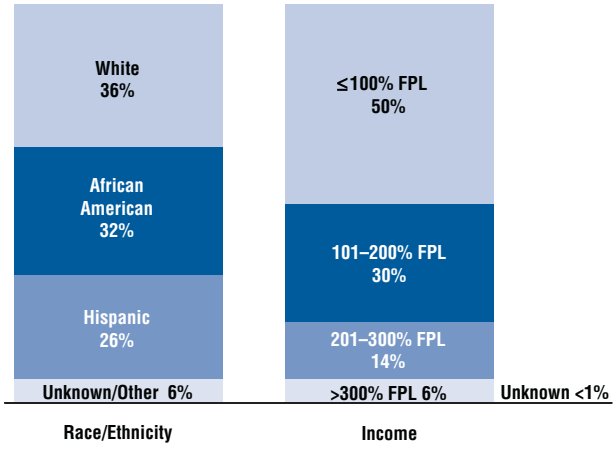
Summary & Highlights

The National ADAP Monitoring Project Annual Report is based on a comprehensive survey of all state and territorial AIDS Drug Assistance Programs (ADAPs). The ADAP Monitoring Project is a more than 10-year effort of the National Alliance of State and Territorial AIDS Directors (NASTAD) and the Kaiser Family Foundation. It documents new developments and challenges facing ADAPs each year, assesses key trends over time, and provides the latest available data on the status of these programs. The current report is being released on the cusp of two significant markers in the HIV/AIDS epidemic—the 25th year of the first case of AIDS in the United States and the 10th year since the advent of highly active antiretroviral therapy (HAART). Data in this report are primarily from FY 2005 and June 2005; more recent data are provided in select areas. Key highlights are as follows:

- ADAPs are the **nation's prescription drug safety-net for people with HIV/AIDS, serving primarily low-income, uninsured, people of color who have limited or no access to needed medications**. ADAPs act as the payer of last resort, the "net" which catches people as they fall through the cracks in the larger U.S. health care system. With more than 134,000 enrollees, and 96,404 clients served in June 2005 alone, ADAP reaches approximately one-quarter of all people with HIV/AIDS in care. Almost two-thirds of clients are people of color, half have incomes at or below 100% of the Federal Poverty Level (FPL was $9,570 for a family of one in 2005), and almost three quarters are uninsured.

Profile of ADAP Clients, June 2005



Notes: American Samoa, the Marshall Islands, New Mexico, and Rhode Island not included in race/ethnicity and income data; in addition, the District of Columbia, Idaho, Louisiana, the Northern Mariana Islands, and Puerto Rico were not included in income data. The Federal Poverty Level (FPL) was $9,570 for a single person in 2005. Percentages may not total 100% due to rounding.

ADAP SNAPSHOT

- Number of ADAPs: 57
- Total ADAP Budget, FY 2005: $1.3 billion
- Federal ADAP Earmark, FY 2005: $765 million
- Clients Served, June 2005: 96,404
- ADAP Drug Spending, June 2005: $102.6 million

- However, the capacity of the ADAP safety-net varies significantly by state and, ultimately, **what one gets depends on where one lives**. ADAP income eligibility ranges from a low of 100% FPL in one state to greater than 500% FPL in four. Formulary coverage also varies from just a few medications in some states, including one that does not cover any protease inhibitors, to open formularies in other states.
- The **need for HIV-related medications continues to outstrip their availability**, as evidenced by ADAP waiting lists and other cost containment measures including limited formularies and restrictive income eligibility criteria. As of February 2006, nine states had waiting lists in place, representing close to 800 people and several others had limited access in other ways. The "fixes" introduced thus far, while alleviating unmet need for some, have generally been time-limited; focused on one-time snapshots of the problem; and/or emergency measures undertaken by select states (e.g., The President's ADAP Initiative; supplemental state general revenue support). This is symptomatic of the fact that ADAPs are discretionary grant programs, not entitlements, and therefore dependent on annual federal appropriations and funding from states and other sources where available.
- Consequently, as currently configured with budget limitations, **ADAPs will continue to have to make difficult trade-off decisions between serving more people with less services or serving less people with more services**.
- **Waiting lists and other cost containment measures, may, therefore, be semi-permanent features of ADAPs**, amidst a growing population of people with HIV/AIDS in need of medications and rising drug costs. Indeed, waiting lists have been documented throughout the course of the National ADAP Monitoring Project

and have been present in some states for months if not years. Nationally, at least several hundred people with HIV/AIDS are waiting to obtain medications from ADAPs at any given point in time.

- **ADAPs are spending virtually all of their budgets on direct client services—medications and insurance coverage.** The national ADAP budget from all sources reached $1.3 billion in FY 2005, almost all of which supported direct client services. ADAPs have diversified their funding base to meet increasing client need over time, as key components of the budget have slowed in growth (e.g., the Title II earmark) or decreased/fluctuated over time (e.g., contributions from the Title II base). Twelve states experienced an overall decrease in their budgets while 43 had increases. ADAPs are increasingly relying on state general revenue support (39 states provided such support in FY 2005) and manufacturers' drug rebates (39 states). Once the smallest component of the national ADAP budget, drug rebates now represent the third largest share and, for the first time, were the largest driver of budget growth over the last fiscal period.

- **Drug rebates, however, require careful consideration as a major funding source for ADAPs**. Drug rebates fluctuate regularly and are not necessarily stable or predictable. Although never intended to fund these programs, some rebates are mandated by law and others are voluntary on the part of drug manufacturers. States must actively track and pursue rebates to receive them. Despite these factors, drug rebates represent an important example of collaboration with industry, in ways that have expanded access to medications over time.

- Two recent events—**Hurricane Katrina** and **Medicare Part D** implementation—provide critical insight into the role of ADAPs and offer lessons, and questions, for the future:

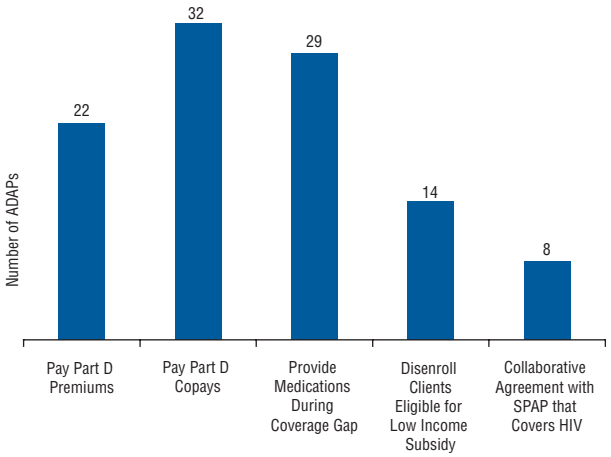
  – Hurricane Katrina threw into stark relief many of the structural challenges faced by all ADAPs but also their ability to serve as a life-line to those in need. An estimated 21,000 people with HIV/AIDS lived in the Hurricane affected counties prior to Katrina, many of whom evacuated. While those states most directly affected—Louisiana, Mississippi, and Texas—quickly jumped into action by reaching out to evacuees with HIV, they also faced such challenges as: how to account for varying eligibility criteria and formularies across states as displaced individuals relocated; the difficulty in transferring funds to follow people; and questions about the relative responsibilities of the federal and state governments in meeting client needs when they cross state lines.

  – Implementation of the new Medicare Part D drug benefit has also required quick action by ADAPs on a state-by-state basis in response to a new and evolving policy framework that is both complex and untested. For the estimated 17,000 ADAP enrollees who are also Medicare beneficiaries, most states have developed policies to coordinate with the new benefit and help transition clients between programs. How the new benefit unfolds over time for ADAPs and their clients, however, remains to be seen, and, as with other aspects of the AIDS Drug Assistance Program, will likely vary significantly by state. Key questions include:

    - How will clients fare in states where ADAPs are not able to pay for Part D co-pays or premiums, or to provide them with medications when they find themselves in the Part D coverage gap (the so called "doughnut hole") before they reach the new benefit's catastrophic coverage level?

    - What are the financial implications for ADAPs that do cover Part D drug co-pays and premiums and other expenses given that these, by law, cannot count towards Part D True Out of Pocket Costs (TrOOP)? Will Part D ease or exacerbate the budget pressure for some ADAPs?

ADAP Policies Related to Medicare Part D, as of November 2005



- Finally, what does all this mean for the current policy context? The Administration and Congress are actively considering the **third Reauthorization of the Ryan White CARE Act**, with a heavy focus on ADAPs. The Administration has released principles for Reauthorization and the President called for swift reauthorization in his State of the Union address; his FY 2007 budget request to Congress emphasized the need to eliminate ADAP waiting lists. A Congressional bill to reauthorize the CARE Act has already been introduced and others are in development.

The National ADAP Monitoring Report offers critical and timely data to this discussion, underscoring the increasingly important role played by ADAPs in serving people with HIV/AIDS throughout the U.S. as well as the many challenges these programs face. In particular, the report sheds important light on who ADAP clients are; the relationship between ADAP client utilization, drug spending, and funding; current capacity limitations; and key elements of program and access variation across the country.

Hurricane Katrina

Hurricane Katrina hit the Gulf Coast on August 29, 2005. More than 21,000 people with HIV/AIDS were estimated to be living in the disaster-affected counties of Alabama, Louisiana and Mississippi prior to Hurricane Katrina, and many were undoubtedly among those forced to take refuge elsewhere. As of the end of September 2005, ADAP and other CARE Act grantees in 27 States and the District of Columbia had already reported treating more than 1,500 evacuees with HIV/AIDS. NASTAD estimates that more than 420 Louisiana ADAP clients alone sought assistance in other states, primarily Texas, as a result of their evacuation.

Hurricane Katrina threw into stark relief many of the challenges already faced by ADAPs and their clients, particularly concerning differential access across the country and the lack of transferability of federal ADAP funding, provided via formula, across state lines. As such, it offers important lessons for Ryan White CARE Act Reauthorization. The disaster also demonstrated how ADAPs can quickly and innovatively adapt to emergency and changing circumstances to serve people with HIV in need.

Soon after the Hurricane hit, ADAPs in affected states quickly responded to identify displaced individuals with HIV/AIDS and facilitate their access to medications. The Louisiana ADAP staff, themselves forced to evacuate to Baton Rouge and beyond, immediately organized to try to locate their clients throughout the state and elsewhere. The Texas ADAP prepared to serve evacuees from New Orleans and other affected areas, and without guiding legislation, policies, or funding guarantees in place, decided to accept any evacuee with HIV into its ADAP. To facilitate this process, the Texas ADAP created a streamlined one-page application form and enrollment process. Nearly all ADAPs followed suit, rushing to accept evacuees into their programs despite program variations and even capacity challenges across states—for example, Alabama's ADAP had a large waiting list in place but accepted HIV positive evacuees from other states to avoid any potential interruption in their antiretroviral therapy.

HRSA worked with ADAPs to the extent possible within the constraints of the Ryan White CARE Act legislation, which does not allow for the transfer of federal funds across states to follow those who evacuated. Instead, states were encouraged by HRSA to waive their normal eligibility process and requirements for Ryan White CARE Act services as permissible under current state policy, even if client medical records were missing. To date, no supplemental federal funding has been provided to ADAPs serving evacuees with HIV, but HRSA has asked states to track the number of patients treated, their home location, services provided, and associated costs as the agency continues to work with the Department of Health and Human Services to assess additional funding options.

Finally, some pharmaceutical companies that manufacture antiretroviral medications agreed to partner with ADAPs on an emergency basis and provide in-kind replacement of medications dispensed to evacuees for the first 30–90 days following the disaster (the value of these contributions is estimated to be $150,000–$200,000). ◗

Sources:

KFF, *Fact Sheet: Assessing the Number of People with HIV/AIDS in Areas Affected by Hurricane Katrina*, September 2005; HRSA, Hurricane Relief and Recovery, Update October 3, 2005. Available at: www.hrsa.gov/katrina/updatehrsa1003.htm; KFF, *Report on The Experience of Hurricane Evacuees*, forthcoming 2006; KFF, *From the States: Beth Scalco, Louisiana AIDS Director.* Interview by Jackie Judd, 9/22/2005: www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=1522; Texas HIV Medication Program (THMP), News & Updates: www.tdh.state.tx.us/hivstd/meds/NEWS.htm.=

INTRODUCTION

This report of the National ADAP Monitoring Project, a more than ten-year initiative of the Kaiser Family Foundation and the National Alliance of State and Territorial AIDS Directors (NASTAD), provides the latest data on ADAPs across the country. It is based on a comprehensive survey of all 57 ADAPs; 53 responded (see Methodology). In addition to the main survey, supplemental data collection was conducted to provide more recent data in select areas. All data are from FY 2005 and June 2005, unless otherwise noted. Detailed findings are provided below, followed by accompanying charts and appendices. State-level data are provided in the appendices and on the Kaiser Family Foundation's State Health Facts website: www.statehealthfacts.org/hiv.

BACKGROUND AND OVERVIEW OF ADAPS

The AIDS Drug Assistance Program (ADAP) of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act[1] has become a critical source of prescription drugs for low-income people with HIV/AIDS in the United States who have limited or no prescription drug coverage. Reaching about one quarter of people with HIV/AIDS estimated to be receiving care nationally,[2] ADAPs provided medications to more than 96,000 clients and insurance coverage to thousands more in the month of June 2005 alone. ADAPs operate in 57 jurisdictions, including all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, three U.S. Pacific Territories (American Samoa, Guam and the Commonwealth of the Northern Mariana Islands) and one Associated Jurisdiction (the Republic of the Marshall Islands). In addition to helping to fill gaps in prescription drug coverage, ADAPs serve as a bridge between a broader array of healthcare and supportive services funded by Ryan White, Medicaid, Medicare, and private insurance. As the number of people living with HIV/AIDS in the U.S. has increased, largely due to advances in HIV treatment, and drug prices have continued to rise, the importance of ADAPs has grown over time. Today, there are more than one million people estimated to be living with HIV/AIDS in the United States.[3]

As stated in the Ryan White CARE Act, the purpose of ADAPs is to:

> …provide therapeutics to treat HIV disease or prevent the serious deterioration of health arising from HIV disease in eligible individuals, including measures for the prevention and treatment of opportunistic infections.[4]

ADAPs meet this purpose through two main activities: by providing FDA-approved HIV-related prescription drugs to people with HIV/AIDS and by paying for health insurance that includes HIV treatments. Eligible individuals are low-income individuals with HIV/AIDS who have limited or no prescription drug coverage. ADAPs began serving clients in 1987, when Congress first appropriated funds ($30 million over two years[5]) to help states purchase AZT, the only FDA-approved antiretroviral drug at that time. In 1990, these federally-funded, state administered "AZT Assistance Programs" were incorporated into the newly created Ryan White CARE Act under Title II (grants to states) and became known as "AIDS Drug Assistance Programs." The CARE Act has become the nation's third largest source of federal funding for HIV/AIDS care, after Medicaid and Medicare.[6]

Key Dates in the History of ADAPs

1987: First antiretroviral, (AZT an NRTI), approved by the FDA; Federal government provides grants to states to help them purchase AZT, marking beginning of federally-funded, state administered "AZT Assistance Programs."

1990: ADAPs incorporated into Title II of the newly created Ryan White CARE Act.

1995: First Reauthorization of CARE Act; first protease inhibitor approved by FDA, and the highly active antiretroviral therapy (HAART) era begins.

1996: Federal ADAP earmark created; first non-nucleoside reverse transcriptase inhibitor (NNRTI) approved by FDA.

2000: Second Reauthorization of CARE Act, changes for ADAPs include: allowance of insurance purchasing and maintenance, flexibility to provide other limited services (e.g., adherence support and outreach), and creation of ADAP supplemental grants.

2003: NASTAD's ADAP Crisis Task Force formed to negotiate with pharmaceutical companies on pricing of antiretroviral medications; first fusion inhibitor approved by FDA.

2004: President's ADAP Initiative (PAI) announced, allocating $20 million in one-time funding outside of the ADAP system to reduce ADAP waiting lists in ten states.

2005: CARE Act expired on September 30. CARE Act programs continue operating under current law while Congress considers the third Reauthorization. ◗

Since FY 1996, Congress has specifically earmarked funding for ADAPs within Title II of the CARE Act, which is allocated by formula to states.[7,8] The ADAP earmark has become the largest component of the overall ADAP budget. ADAPs may also receive funding from other sources, including state general revenue support,[9] funding from other parts of the CARE Act, and manufacturers' drug rebates, but these funding sources are highly variable and largely dependent on state and local policy decisions, differing ADAP program management strategies, and resource availability. The Health Resources and Services Administration (HRSA) of the Department of Health and Human Services is the federal agency that administers the CARE Act. Each state operates its own ADAP, and is given broad authority by the CARE Act to design its program, including determining client eligibility criteria, formularies, and other key program elements. Other than the broad stipulation above about the purpose of ADAPs, no minimum formulary is required under current law. Additionally, there is no client income eligibility level required, although clients must be HIV-positive, low-income, and under- or uninsured.

Allocation of Federal Funding to ADAPs & State Match Requirements

Each year, Congress specifically earmarks federal funding for ADAPs within the Ryan White CARE Act. The formula used to allocate federal earmark funding to states is based on their proportion of the nation's estimated living AIDS cases. Estimated living AIDS cases are determined by the Centers for Disease Control and Prevention (CDC) and provided to the Health Resources and Services Administration (HRSA). To determine estimated living AIDS cases, CDC applies annual survival weights to the most recent 10 years of reported AIDS cases.* A jurisdiction's proportion of estimated living AIDS cases is applied to the earmark to determine the award amount. In FY 2005, 57 jurisdictions received federal ADAP earmark funding.

States with one percent or more of reported AIDS cases during the most recent two-year period must match (with non-federal contributions) their Ryan White Title II award, which includes the ADAP earmark, according to an escalated matching rate (based on the number of years in which the state has met the one percent threshold). States are not required, however, to use all or even part of the state match for ADAP and the match may consist of in-kind or dollar contributions from the state.

The CARE Act Amendments of 2000 included a new Supplemental Treatment Drug Grant Program, which awards grants to states with "severe need." Three percent of federal ADAP earmark funding appropriated by Congress is set aside for ADAP supplemental awards. Award amounts are based on an eligible jurisdiction's proportion of estimated living AIDS cases among those states eligible for and applying to receive a supplemental grant. This proportion is applied to the number of dollars available under the supplemental grant to determine the award amount.

While a three percent set aside of the ADAP earmark is the basis for ADAP supplemental grants, the "hold harmless" clause in the ADAP supplemental grant legislation may require that adjustments be made in ADAP earmark awards so that each overall state Title II award is at least equal to the previous year. If this is required, those funds are taken from the three percent set aside for the ADAP supplemental before awards are made to states. In most recent years, the total ADAP supplemental amount distributed has been less than three percent due to this provision within the ADAP supplemental grant legislation.

States applying for supplemental grants must provide matching dollars in an amount equal to $1 for each $4 of federal funds provided in the grant, and the match must be put toward ADAP (in-kind contributions from the state such as office space, personnel, and other relevant expenses are allowable contributions to meet this required match). To be eligible for supplemental awards, states must have met one of the following criteria as of January 1, 2000:

- Financial eligibility at or below 200% of the Federal Poverty Level (FPL);
- Medical eligibility criteria in place (e.g., specific CD4 T-cell count or viral load);
- Limited formulary compositions for antiretrovirals; and/or
- Less than 10 medications on formulary to treat opportunistic infections.

In FY 2005, of the 27 ADAPs eligible for Supplemental Award funding, 20 applied; the other eligible jurisdictions did not apply either because they could not meet the state match requirement or did not require supplemental funding.

It is important to note that the ADAP fiscal year differs from the federal and state fiscal year periods. The ADAP fiscal year begins on April 1 and ends on March 31; the federal fiscal year begins on October 1 and ends on September 30; for most states, the state fiscal year begins on July 1 and ends on June 30. For example, the ADAP FY 2005 began on April 1, 2005 and will end on March 31, 2006. The Federal FY 2006 began on October 1, 2005 and will end on September 30, 2006. The State FY 2006, in most states, began July 1, 2005 and will end on June 30, 2006. ◗

*CDC, "AIDS cases by state and metropolitan area, provided for the Ryan White CARE Act", *HIV/AIDS Surveillance Supplemental Report* 2005. 11(No. 1). Available at: www.cdc.gov/hiv/STATS/HASRSuppVol11No1.pdf.

Like all Ryan White CARE Act programs, ADAPs serve as "payer of last resort;" that is, they provide prescription medications to, or pay for health insurance for, people with HIV/AIDS when no other funding source is available to do so. Demand for ADAPs depends on the size of the prescription drug "gap" that ADAPs must fill in their jurisdiction—larger gaps, such as in states that have less generous Medicaid programs, may strain ADAP resources further. But ADAPs are discretionary grant programs, not entitlements,[10] and their funding may not correspond to the number of people who need prescription drugs or to the costs of medications. Therefore, annual federal appropriations, and where provided, state funding and contributions from other sources, determine how many clients ADAPs can serve and the level of services they can provide. For the last several years, ADAPs have been the only part of the CARE Act to receive federal budget increases and these increases have helped ADAPs serve more clients.[6,11] Nonetheless, given that ADAPs are an integral component of the larger Ryan White system, it is unclear how level funding in other areas of the CARE Act may affect client access to ADAPs.

DETAILED FINDINGS

CLIENTS, DRUG EXPENDITURES, AND PRESCRIPTIONS

ADAP Clients

- In June 2005, 134,128 clients were enrolled in ADAPs nationwide, a slight increase over last year's enrollment (see Chart 2 and Appendix 1). More clients are typically enrolled in ADAPs than seek services in a given month, reflecting changing clinical needs, different prescription lengths, and fluctuation in the availability of other resources to pay for medications, with some individuals cycling on and off ADAP throughout a year. In June 2005, 72% of those enrolled received ADAP services.
- ADAPs provided medications to 96,404 clients across the country in June 2005, a three percent increase over the prior period (see Chart 3).
  - While most states experienced increases in clients served (33 ADAPs) between June 2004 and June 2005, 15 had decreases (see Appendix I).
  - In addition to providing medications, ADAPs also paid for insurance coverage (premiums, co-pays, and/or deductibles) for 12,311 clients (some of whom may have also received medications) (see Appendix XV).
- ADAP clients are predominantly low-income and uninsured. Most are people of color, and male, and many have indicators of advanced HIV disease (see Charts 5–9 and Appendices IV–VII). In June 2005:
  - African Americans and Hispanics represented 58% (32% and 26%, respectively) of clients. Asian/Pacific Islanders, and Alaskan Native/American Indians combined represented approximately two percent of the total ADAP population. White non-Hispanics comprised 36% of ADAP clients.
  - More than three-quarters (79%) of ADAP clients were men and the majority (54%) were between the ages of 25 and 44.
  - Eight in ten (80%) were at or below 200% of the Federal Poverty Level (FPL), including half (50%) at or below 100% FPL. In 2005, the FPL was $9,570 (slightly higher in Alaska and Hawaii) for a family of one.
  - A majority of ADAP clients (73%) were uninsured, with few reporting any other source of insurance coverage—18% private, 13% Medicare, and/or 10% Medicaid; three percent were dual beneficiaries of both Medicaid and Medicare.
  - Half of ADAP clients (49%) had CD4 counts of 350 or below at time of enrollment, an indication of advanced HIV disease.

ADAP Drug Expenditures and Prescriptions

- ADAP drug expenditures were $102,595,753 in June 2005, a six percent increase over the prior period (see Chart 10).
  - If annualized, this represents approximately $1.2 billion, or most (95%) of the FY 2005 national ADAP budget. When funds used by ADAPs for insurance purchasing/maintenance are included ($75.4 million in FY 2005) and all cost recovery accounted for, estimated annual ADAP spending for direct client services (medications and insurance coverage) would total almost the entire ADAP budget from all sources.
  - Thirty-two ADAPs had increases in their monthly drug expenditures; 17 had decreases (see Appendix I).
- ADAPs filled a total of 376,511 prescriptions in June 2005 (see Chart 13 and Appendix III). This represented a less than one percent increase over the prior period.
- Per capita drug expenditures were $1,064 in June 2005, an increase of four percent over last year ($1,024 in June 2004) (see Chart 12). This represents an estimated $12,768 in annual drug costs per client. Per capita expenditures in June 2005 ranged from a low of $240 in Ohio to $1,930 in Maine (see Chart 1).

- Most ADAP drug spending is for FDA-approved antiretrovirals[12] (89% in June 2005). While this is in part due to their high utilization, it is also related to their costs, as they represent a greater share of expenditures than prescriptions filled (63%). The 29 "A1" drugs highly recommended for the prevention and treatment of HIV-related opportunistic infections[13,14] accounted for three percent of expenditures and nine percent of prescriptions (see Chart 13 and Appendices II and III).
- The average expenditure per prescription was $272. It was significantly higher for ARVs ($382) than non-ARVs ($85). Among ARV drug classes, fusion inhibitors represented the highest expenditure per prescription ($1,412), followed by protease inhibitors ($430), nucleoside reverse transcriptase inhibitors ($372) and non-nucleoside reverse transcriptase inhibitors ($303). "A1" OI drugs were $84 per prescription filled in June 2005 (see Chart 14).

Trends in Client Utilization and Drug Expenditures

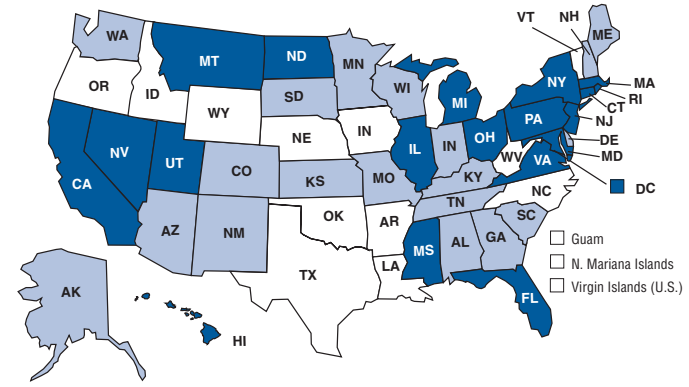
- Client utilization has grown significantly since 1996 (202% among the 47 ADAPs reporting data in both periods), but growth has slowed considerably in recent years and has never been as high as the rate of increase in drug expenditures. Between 2004 and 2005, client utilization increased by three percent (see Chart 4).
- Drug spending by ADAPs has increased more than six-fold (508%) since 1996, more than twice the rate of client growth (in the same 47 states reporting data on clients). It too has continued to increase but at slower rates; between June 2004 and June 2005, drug spending grew by six percent (see Chart 11).

ELIGIBILITY CRITERIA AND FORMULARIES

ADAP Eligibility Criteria

- All ADAPs require that individuals document their HIV status. Four reported additional clinical eligibility criteria (e.g., specific CD4 or viral load ranges), one more state than last year (see Chart 1).
- ADAP income eligibility ranges from a low of 100% FPL in the Northern Mariana Islands to 500% FPL or more in four states: Maryland, Massachusetts, New Jersey, and Ohio. Overall, 20 states set income eligibility at greater than 300% FPL; 19 are between 201% and 300% FPL; and 15 are at or below 200% FPL (see Chart 15).

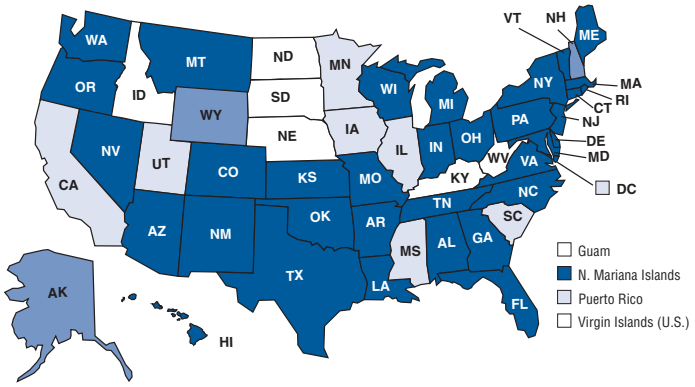
ADAP Income Eligibility by State, as of September 2005



Income eligibility greater than 300% FPL (20 ADAPs)
Income eligibility between 201% FPL and 300% FPL (19 ADAPs)
Income eligibility at 200% FPL or below (15 ADAPs)

Notes: The 2005 Federal Poverty Level (FPL) was $9,570 (slightly higher in Alaska and Hawaii) for a household of one. 54 ADAPs reported income eligibility criteria. American Samoa, the Marshall Islands, and Puerto Rico are not included.

ADAP Formulary Coverage of Approved Antiretroviral Drugs by State, as of September 2005



Covers all approved ARVs in all four drug classes, NRTIs, NNRTIs, PIs, and Fusion Inhibitor (35 ADAPs)
Covers all approved NRTIs, NNRTIs, PIs, but not approved Fusion Inhibitor (3 ADAPs)
Covers approved Fusion Inhibitor but not all approved NRTIs, NNRTIs, and PIs (9 ADAPs)
Does not cover approved Fusion Inhibitor or all approved drugs in other classes (8 ADAPs)

Notes: 55 ADAPs reported formulary data for ARV drugs. American Samoa and the Marshall Islands are not included.

ADAP Formularies

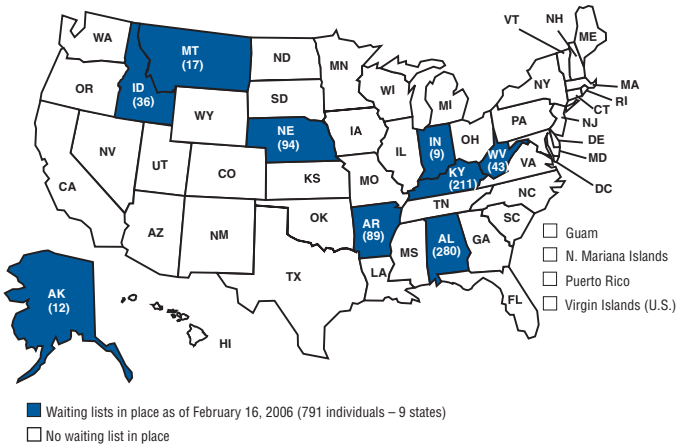
- ADAP formularies vary significantly across the country, ranging from 19 drugs covered in Guam to nearly 500 in New York and open formularies[15] in four jurisdictions—Massachusetts, New Hampshire,[16] New Jersey, and the Northern Mariana Islands (see Chart 1).
- While the majority of ADAPs (35) cover all 25 FDA-approved antiretrovirals on their formularies, 20 ADAPs do not, including one that does not provide any protease inhibitors (South Dakota). Forty-four ADAPs cover Fuzeon, the only approved fusion inhibitor for people with HIV/AIDS (see Charts 1, 16).
- Coverage of medications to prevent and treat opportunistic infections and other HIV-related conditions is also highly variable across the country (see Charts 1, 17):
  - Thirty-three ADAPs cover more than 15 of the 29 drugs highly recommended ("A1") for the prevention and treatment of opportunistic infections, including three that cover all 29 (Massachusetts, New Jersey, and the Northern Mariana Islands). Twenty-two ADAPs cover 15 or fewer of these medications, including one that does not include any medications for OIs or other HIV-related conditions on its formulary, and only covers antiretrovirals (Louisiana). It is important to note that ADAPs may cover slightly fewer than the full set of highly recommended OI medications because they cover equivalent medications, also highly recommended, on their formularies or have other state-level programs that can provide these medications.
  - Twenty-six ADAPs cover treatments for hepatitis C (HCV), a major co-morbidity for people with HIV, that is also considered to be an opportunistic infection[14,17] (see Chart 18).
  - Twenty-four ADAPs cover Hepatitis A and B vaccines, which are recommended for those at high risk for HIV and living with HIV[18] (see Chart 18).

WAITING LISTS AND OTHER COST CONTAINMENT MEASURES

Waiting Lists

- In February 2006, nine ADAPs had waiting lists in place, totaling 791 people. Waiting lists have been in place in some states for several months, if not years, and the size of waiting lists within and across states has fluctuated significantly over time (see Charts 19–21). Based on bi-monthly surveys conducted between July 2002 and February 2006 (26 surveys overall) (see Appendix VIII):

ADAPs with Waiting Lists, February 2006 (791 Individuals in 9 States)



Notes: 55 ADAPs reported waiting list data. American Samoa and the Marshall Islands are not included.

  - Eighteen states reported having a waiting list in place at some point over the period, including one (Alabama) that had a waiting list throughout.
  - The fewest number of states reporting a waiting list in any given period was six; the most was 11.
  - Twelve ADAPs had waiting lists in 10 or more of the survey periods.
  - The number of people on waiting lists ranged from a low of 435 to a high of 1,629 (the average was 804). The highest number of individuals on any one state's waiting list was 891 (North Carolina); the lowest was one (Alaska, Idaho, Montana, and West Virginia). North Carolina also had the highest average number of people on its waiting list over the period (337), followed by Alabama (200). The lowest average was four in Guam and in Wyoming, respectively.

President's ADAP Initiative

- The President's ADAP Initiative (PAI), announced June 2004, provided $20 million in one-time funds targeted to individuals on ADAP waiting lists in ten states (AK, AL, CO, ID, IA, KY, MT, NC, SD, and WV). Clients were first enrolled in October 2004, and the number of clients receiving medications through the PAI increased significantly through July 2005, when it reached its maximum of 1,487. It has since declined as states were required to transition PAI clients into their "traditional" ADAPs by the end of December 2005. Still, as of February 2006, four clients remained on the PAI who could not be absorbed into their state's ADAP

ADAP WAITING LISTS

Since the beginning of the AIDS Drug Assistance Program, many ADAPs have had to make difficult trade-off decisions between client access and services. In some cases, states have capped program enrollment until more resources become available. When enrollment is capped, the next individual eligible for ADAP who seeks services cannot get them through the ADAP. States that have enrollment caps have often turned to waiting lists in order to facilitate client access when the program can accommodate them. In February 2006, nine ADAPs had waiting lists, with a total of 791 individuals.

When an individual is on a waiting list, they may not have access to HIV-related medications. Or, they may have access through other mechanisms, but these are often unstable. Some individuals on waiting lists can get medications through other state pharmacy assistance programs, if their state has these programs, or through pharmaceutical manufacturer patient assistance programs (PAPs). PAPs, however, require people to apply often, sometimes as frequently as every month, and separate applications must be sent to the manufacturer of each medication needed. For someone on a multiple drug regimen, this process can be quite cumbersome and may not provide the full range of drugs necessary for optimal clinical outcomes.

To date, no state has eliminated current clients from its ADAP when faced with the need to implement a waiting list for new applicants. Nevertheless, states with waiting lists are faced with many challenges, such as: how to monitor those on waiting lists; how to help those on waiting lists access prescription drugs through other programs, if available; whether criteria should be developed to bring people off waiting lists into services or whether new clients should be accommodated on a first come, first serve basis; and what kinds of future decisions could be made to reduce or eliminate the need for waiting lists, while least compromising access for all clients?

In recognition of the challenges waiting lists pose to ADAPs, in June 2004, President Bush announced the one-time availability of $20 million for HIV-related drug therapies, targeted at 10 states with waiting lists at that time (see box on "President's ADAP Initiative"). This Initiative has served to alleviate the size of waiting lists in some states while in effect.

It is important to note that waiting lists are but one measure of unmet need for ADAP services. Some people who need ADAP services may not be counted on a waiting list. And, the level of services provided by ADAPs and the number of clients they serve vary across the country, so those receiving ADAP services in a state with a limited formulary may have unmet needs compared to others receiving services in a state with a more expansive formulary. ◗

ADAP COST CONTAINMENT MEASURES AND OTHER STRATEGIES FOR MANAGING COSTS

State ADAPs use a variety of strategies to contain costs. Some of these strategies may affect client access and services, whereas others may lead to a more efficient use of funding enabling ADAPs to serve more people. Occasionally states must implement cost containment measures (such as waiting lists) multiple times over the course of a year, depending on their fiscal situation and client demand. Cost containment measures used by ADAPs have included:

- Instituting waiting lists;
- Lowering financial eligibility criteria;
- Limiting and/or reducing ADAP formularies;
- Limiting access to one or more drugs, including instituting waiting lists for access to a particular drug;
- Instituting monthly or annual limits on per capita expenditures;
- Using drug purchasing strategies (discount programs, rebates, purchasing alliances and coalitions);
- Using ADAP dollars to pay for insurance coverage (premiums, co-payments, deductibles) instead of medications directly;
- Seeking cost recovery through drug rebates and third party billing; and
- Using non-ADAP Ryan White CARE Act and other funds (e.g., Title II Base, state funding) for ADAPs. ◗

PRESIDENT'S ADAP INITIATIVE (PAI)

On June 23, 2004, President Bush announced the one-time, immediate availability of $20 million to provide medications to individuals on ADAP waiting lists in 10 states with waiting lists as of June 21, 2004: Alabama, Alaska, Colorado, Idaho, Iowa, Kentucky, Montana, North Carolina, South Dakota, and West Virginia. Funding for 1,738 treatment slots (reflecting the number of individuals on waiting lists at that time) was made available through a reallocation of Department of Health and Human Services (DHHS) non-AIDS funding. It was provided to a pharmacy benefits manager (PBM) to directly serve individuals within the 10 states, rather than through the state-based ADAP system. Individuals were only allowed to obtain medications through the PAI that were included on their state's ADAP formulary as of June 21, 2004.

The Health Resources and Services Administration (HRSA), which coordinates the PAI, contracted with Bioscrip, Inc. (formerly Chronimed) to directly purchase and distribute medications to individuals on waiting lists in the 10 states. Eligible clients first began receiving medications in October 2004; by July 2005, the number of clients being served through the PAI reached its maximum of 1,487. The PAI initially expired on September 30, 2005; however, Bioscrip received a no-cost extension to continue serving PAI clients as long as funding remained available. Following a request by HRSA in September 2005, participating states began transitioning clients onto their ADAPs or into pharmaceutical patient assistance programs (PAPs) where available; by February 2006, only four individuals remained in the program. The PAI was scheduled to end in March 2006, as funding for the initiative was not renewed.

(see Chart 22 and Appendix IX). In addition, over the course of the Initiative, other states that were not originally eligible for the PAI have instituted waiting lists, and new individuals who were not eligible for the PAI have been added to ADAP waiting lists.

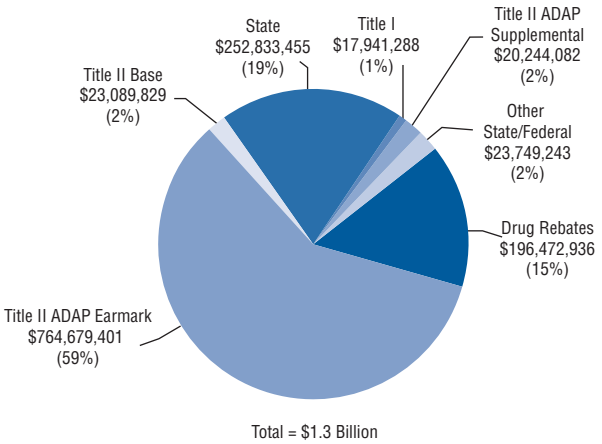
Other Cost Containment Measures

- In addition to waiting lists, some ADAPs have instituted other measures to contain costs (see Charts 23 and 24). As of February 2006, nine ADAPs had such measures in place including:
  - Four that had reduced the number of drugs on their formularies;
  - Three with waiting lists for Fuzeon, the only approved Fusion Inhibitor;
  - Two that further restricted eligibility to the program;
  - Two limiting annual per client expenditures;
  - One that has begun requiring clients to pay cost sharing (co-payments) in order to participate in the program;
  - One of these nine states also has a waiting list in place. Five of these states are in the U.S. South.
  - An additional nine ADAPs anticipate having to newly institute cost containment measures during ADAP FY 2006 (April 1, 2006–March 31, 2007).

ADAP BUDGET

- The national ADAP budget reached $1.3 billion in FY 2005, an increase of 10 percent over FY 2004. Since FY 1996, the budget has increased more than six-fold (see Charts 25, 29).
- The ADAP earmark represented the largest share of the ADAP budget (59%),[19] followed by state general revenue support (19%), and drug rebates (15%). Other sources of funding each represented two percent or less of the budget (see Chart 25).
- By definition, all eligible jurisdictions (57) receive federal ADAP earmark funding based on a formula, but not all ADAPs receive funding from other sources, which are often dependent on individual state and local planning, policy, and/or legislative decisions, as well as resource availability. In FY 2005, four ADAPs

National ADAP Budget, by Source, FY 2005



Notes: 53 ADAPs reported all National ADAP Budget data. National ADAP Budget includes FY 2005 federal Title II ADAP earmark and Title II ADAP supplemental only for American Samoa, the Marshall Islands, New Mexico, and Rhode Island.

received only ADAP earmark funding (see Chart 26). The breakdown of other sources of funding across the country was as follows (see Appendix X):

- – Title II ADAP Supplemental Treatment Grants: 20 ADAPs received funding, 37 did not;
- – Title II Base Funds: 19 ADAPs received funding, 34 did not;
- – Title I EMA Funds: 12 ADAPs received funding, 41 did not;
- – State General Revenue Support: 39 ADAPs received funding, 14 did not;
- – Other State/Federal Funds: 13 received funding, 40 did not;
- – Drug Rebates: 39 ADAPs received funding, 14 did not.

- Additionally, despite a 10 percent increase in the national ADAP budget across all ADAPs between FY 2004 and FY 2005, some ADAPs had decreases either in their overall budget or for specific funding streams (see Chart 27):
  - – Overall Budget: 43 ADAPs had increases or level funding, 12 had decreases;
  - – Title II ADAP Earmark: 54 ADAPs had increases; 3 had decreases;
  - – Title II ADAP Supplemental Treatment Grants: 3 ADAPs had increases; 17 had decreases;
  - – Title II Base Funds: 10 ADAPs had increases or level funding; 10 had decreases;
  - – Title I EMA Funds: 9 ADAPs had increases or level funding, 4 had decreases;
  - – State General Revenue Support: 32 ADAPs had increases or level funding, 12 had decreases;
  - – Drug Rebates: 31 ADAPs had increases or level funding, 12 had decreases.
- The composition of the budget has shifted significantly since the introduction of the federal ADAP earmark in FY 1996 (see Chart 28):
  - – The ADAP earmark has risen from one quarter (26%) of the budget in FY 1996, the year it began, to its current share of 59%.
  - – State general revenue support decreased from 25% in FY 1996 to 19% in FY 2005 as a share of the overall budget, but has increased significantly in amount and has been the second largest source of funding over the entire period. Such state support is, for the most part, dependent on individual state decisions and budgets.
  - – Drug rebates rose from six percent to 15% of the budget. The rise of drug rebates as a source of revenue is an important development that is in part due to the need for states to seek additional funding as client demand continues, and to the growing sophistication of states and the ADAP Crisis Task Force in working to obtain rebates. Some drug rebates are dependent on negotiations by individual states or state coalitions, most of which include the ADAP Crisis Task Force, and rebate increases are in part a function of rising drug prices (since rebates are based on a percentage of drug price).
  - – Title II base funding and funding from Title I EMAs each represent much smaller proportions of the budget today than they did in FY 1996, and were also the only two funding sources in the national ADAP budget that were less in FY 2005 than in FY 1996.
- Although the ADAP earmark continues to increase, its growth has slowed over time and it is no longer the largest driver of national ADAP budget growth. Rebates were the largest driver of budget growth between FY 2004 and FY 2005, as measured by dollar increase,

ADAP CRISIS TASK FORCE

The ADAP Crisis Task Force was formed by a group of state AIDS Directors and ADAP Coordinators in December 2002 to address resource constraints within ADAPs. NASTAD serves as the convening organization for the Task Force, which originally consisted of 10 representatives of the largest ADAP programs. Beginning in March 2003, the Task Force met with the eight companies that manufacture antiretroviral (ARV) drugs. The goal of the meetings was to obtain multi-year concessions on HIV/AIDS drug prices, to be provided to all ADAPs across the country. Agreements were reached with all eight manufacturers to provide supplemental rebates and discounts (in addition to mandated 340B rebates and discounts—see chart 25), price freezes, and free products to all ADAPs nationwide. The Task Force estimated savings of $65 million for ADAPs in 2003. During 2004, the Task Force expanded its negotiations to include companies that manufacture high-cost non-ARV drugs. Additional agreements were obtained during 2004 and 2005 and previous agreements were extended and/or enhanced. The Task Force estimated savings of approximately $90 million for ADAPs in 2004 and $145 million in 2005.

The Task Force also coordinates its efforts with the Fair Pricing Coalition (a coalition of organizations and individuals working with pharmaceutical companies regarding pricing of ARV drugs for all payers) and other community partners. Current members of the Task Force include representatives from ADAPs in California, Florida, Ohio, New Jersey, New York, North Carolina, Texas, and Utah. ◗

followed by state funding and then the earmark.

  - The ADAP earmark increased by $36.7 million, or five percent, over FY 2004 (see Chart 30).
  - State funding increased by $26.2 million, or 12%, over FY 2004 (see Chart 33).
  - Drug rebates increased by $50.3 million, or 34%, reaching their highest level to date (see Chart 34).
  - After declining for several years in a row, Title II base funds allocated by states to ADAPs rose slightly over FY 2004, to $23.1 million (see Chart 31).
  - Contributions from Title I jurisdictions have fluctuated over time, and decreased by $3.1 million between FY 2004 and 2005 (see Chart 32)

- State contributions to ADAPs ranged from 0%, in the 12 states that did not provide any state support, to 50% of the ADAP budget in one state; Title II base funding ranged from 0% to 40%; Title I funding ranged from 0% to 47%%; ADAP supplemental funding ranged from 0% to 9%; and drug rebates ranged from 0% to 39% (see Appendix X).

- Cost recovery, reimbursement from other entities for medications purchased through the ADAP (other than drug rebates), represented $26.9 million in FY 2005 (see Chart 35). [Note—this category is not included in the National ADAP Budget].

DRUG PURCHASING MODELS AND INSURANCE COVERAGE

Drug Purchasing Models

- The federal 340B program enables ADAPs to purchase drugs at or below the statutorily defined 340B ceiling price.[20] All but three ADAPs participate (see Chart 36 and Appendix XIV).

  - ADAPs may purchase drugs either directly from wholesalers or through retail pharmacy networks and then apply to drug manufacturers for rebates. As of June 2005, 30 ADAPs reported purchasing directly; 24 reported purchasing through a pharmacy network and then seeking rebates.
  - Direct purchase ADAPs can choose to participate in the HRSA Prime Vendor Program,[20] which was created to negotiate pharmaceutical pricing below the 340B price. Seven of the 30 ADAPs that purchase directly participate in the Prime Vendor Program. One antiretroviral is currently on the prime vendor list.
  - While the prime vendor is only available to ADAPs that purchase directly, the ADAP Crisis Task Force has worked with all ADAPs (direct purchasers and pharmacy network ADAPs) to achieve below 340B pricing for all antiretrovirals.

Insurance Purchasing/Maintenance Programs

- The Ryan White CARE Act allows states to use ADAP earmark dollars to purchase health insurance and pay insurance premiums, co-payments, and/or deductibles for individuals eligible for ADAP, provided the insurance has comparable formulary benefits to that of the ADAP.[21,22] States are increasingly using ADAP funds for this purpose. Most ADAPs (29, up from 26 last year) reported doing so in 2005, representing $75.4 million, or nearly double the amount spent in FY 2004. In June 2005, 12,311 ADAP clients were served by such arrangements, significantly higher than in June 2004 (see Charts 37–38 and Appendix XV).

- These strategies appear to be cost effective—in June 2005, spending on insurance represented an estimated $513 per capita, about half of per capita drug expenditures in that month ($1,064). In addition to ADAPs, other CARE Act (Title I, Title II base) or state programs may also purchase and maintain insurance coverage for eligible individuals.

Coordination with Medicare Part D

- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added a new outpatient prescription drug benefit, Part D, to the Medicare program effective January 1, 2006. An estimated 17,000 ADAP enrollees are Medicare eligible (13% of ADAP clients in June 2005 were Medicare beneficiaries). A subset of these clients is dually eligible for Medicare and Medicaid (see Appendix VI).

- As the payer of last resort, ADAPs are required by HRSA to ensure that all Medicare Part D eligible clients enroll in a Medicare prescription drug plan (2006 enrollment is to be completed by May 15, 2006). ADAPs are permitted to coordinate with Medicare prescription drug plans and, in accordance with state policy, pay for drug plan premiums, deductibles, coinsurance, and co-payments.[23] However, the MMA prohibits ADAP funds (whether federal or state) from being applied toward a beneficiary's True Out of Pocket Costs (TrOOP). This means that ADAP enrollees must incur these costs themselves (costs incurred by a State Pharmacy Assistance Program on their behalf and co-pays waived by a pharmacy will count towards TrOOP) when in the coverage gap before they are eligible to receive catastrophic coverage under their Medicare drug plan.[24] To meet these federal requirements and maintain appropriate medication coverage for their clients, most ADAPs have developed policies to coordinate with the Part D benefit (see Chart 39 and Appendix XVI). As of November 2005:

- Thirty-two ADAPs report that they will pay Part D co-payments for their Part D eligible ADAP clients (these payments will not count toward TrOOP);
- Twenty-two will pay Part D premiums (these payments will not count toward TrOOP);
- Twenty-nine will pay for all medications on their ADAP formularies when their Part D clients reach the coverage gap or "doughnut hole" (these payments will not count toward TrOOP);
- Fourteen ADAPs will disenroll clients if determined to be eligible for the Low Income Subsidy (LIS) available under Medicare Part D (some states are requiring clients to apply for the LIS to see if they are eligible);
- Eight ADAPs have collaborative agreements with their State Pharmacy Assistance Programs (SPAPs) to provide ADAP Medicare eligible clients with medications.

CONCLUSION

This report documents the ongoing role of ADAPs in providing medications to low-income individuals living with HIV/AIDS in the United States. It also offers insight into the ways in which ADAPs adapt to policy and other changes over time, as well as the challenges they face. Looking forward, perhaps the most significant change that stands to affect ADAPs is the Reauthorization of the Ryan White CARE Act. Some of the critical questions concerning ADAPs in Reauthorization include:

- What is the best way to address waiting lists? Are time-limited and/or geographically targeted efforts enough to alleviate unmet need? Should such efforts be channeled through the existing ADAP structure or parallel to it, as the PAI has done? Should HRSA have the authority to use un-obligated CARE Act funds for ADAPs with waiting lists? Does a heavy focus on ADAP waiting lists run the risk of missing other ways in which access varies across the country, such as limited formularies and restrictive income eligibility criteria?
- Should funding from other parts of the CARE Act be "tapped" for ADAPs? What would that mean for the larger CARE Act-supported infrastructure and system? If ADAPs represent one "leg" in the Ryan White program chair, will shoring up the ADAP leg more so than others cause an imbalance that could affect the very clients who need to find their way to ADAP? Conversely, will trimming other legs of the chair (e.g., Title I, Title II) also affect clients' abilities to access ADAP? Or does bolstering access to medications through ADAP ultimately produce the largest benefit to clients?
- Should the ADAP Supplemental Treatment Grant Program (which channels three percent of ADAP earmark funding to areas with severe need and requires a state match to receive such funds) be changed or strengthened to meet the ongoing problem of ADAP waiting lists and other program limitations? Can this be done without harming programs that may not face the same fiscal challenges? Should states with severe need continue to be required to provide a state match to receive supplemental funding or does this hinder their ability to access these funds?
- Should a standard drug formulary be mandated, at least for FDA-approved antiretroviral therapy and highly recommended medications for the prevention and treatment of opportunistic infections? Would such a standard set a floor that would be difficult for some states to meet without limiting their programs in other ways? Could a standard be designed to enable ADAPs to quickly add newly approved treatments even if they are more expensive?
- Are there better ways to help ADAPs assess whether or not they are getting the best prices for medications? Should other parts of the CARE Act that currently purchase medications for clients be required to coordinate purchasing with ADAPs?
- How can the lessons learned from the experience of Hurricane Katrina inform Reauthorization?

Beyond Reauthorization, ADAPs will continue to assess and adapt to Medicare Part D implementation. As medication providers, they represent an important nexus between the new benefit and a group of beneficiaries who face particularly complex and multiple prescription drug needs and as such offer a unique perspective on this new and important national policy. ADAPs will also continue to adapt to other system changes, particularly changes in Medicaid and in their state's fiscal condition.

In addition to ongoing tracking of ADAP client utilization, drug spending, budgets, and program characteristics over time, the National ADAP Monitoring Project will continue to monitor these issues and questions as they unfold.

Methodology

Since 1996, the National ADAP Monitoring Project, an initiative of the Kaiser Family Foundation (KFF) and the National Alliance of State and Territorial AIDS Directors (NASTAD), has surveyed all jurisdictions receiving federal ADAP earmark funding through the Ryan White CARE Act. In FY 2005, 57 jurisdictions received earmark funding and all 57 received the ADAP survey; 53 responded. American Samoa, The Marshall Islands, New Mexico, and Rhode Island did not respond; these jurisdictions represent less than one percent of estimated living AIDS cases.*

NASTAD distributes the survey to states on an annual basis. The survey requests data and other program information for a one month period (June), the fiscal year, and for other periods as specified. After the survey is sent out, NASTAD conducts extensive follow-up to ensure completion by as many ADAPs as possible. Due to differences in data collection and availability across ADAPs, some are not able to respond to all survey questions. Where trend data are presented, only states that provided data in relevant periods are included. In some cases, ADAPs have provided revised program data from prior years and these revised data are incorporated where possible. Therefore, data from prior year reports may not be comparable for assessing trends.

Data used in this report are from June 2005 and FY 2005, unless otherwise noted. For example, NASTAD collects supplemental data on key issues, such as waiting lists, cost containment measures and Medicare Part D progress as part of its bi-monthly "ADAP Watch" survey. Every effort has been made to ensure that the annual report represents the current status of ADAPs as reported by survey respondents; however, some information may have changed between data collection and this report's release. Data issues specific to a particular jurisdiction are provided on relevant charts and tables. ◗

*CDC, "AIDS cases by state and metropolitan area, provided for the Ryan White CARE Act," *HIV/AIDS Surveillance Supplemental Report* 2005. 11(No. 1). Available at: www.cdc.gov/hiv/STATS/HASRSuppVol11No1.pdf.

REFERENCES

[1] Public Law No. 101-381.

[2] According to CDC, there were an estimated 1,039,000–1,185,000 people living with HIV/AIDS in the United States as of the end of 2003 (See, Glynn MK, Rhodes P, "Estimated HIV Prevalence in the United States at the End of 2003," 2005 National HIV Prevention Conference, June 2005). The CDC also estimates that approximately half of those living with HIV/AIDS, or 550,000, are in the care system (See, Fleming P, et al. Abstract #11, Oral Abstract Session 5, 9th Conference on Retroviruses and Opportunistic Infections 2002). ADAP client enrollment of 134,000 represents approximately 24% of the estimated number of people living with HIV/AIDS who are receiving care.

[3] Glynn MK, Rhodes P, "Estimated HIV Prevalence in the United States at the End of 2003," 2005 National HIV Prevention Conference, June 2005.

[4] Pub. L. 101-381; Pub. L. 104-146, SEC. 2616. [300ff-26]

[5] HRSA, HIV/AIDS Bureau, Personal Communication, March 15, 2005.

[6] Kaiser Family Foundation, *Fact Sheet: U.S. Federal Funding for HIV/AIDS: The FY 2007 Budget Request*, February 2006.

[7] The term "state" is used in this report to include states, territories and associated jurisdictions.

[8] Three percent of the ADAP earmark is set aside for the ADAP Supplemental Treatment Drug Grant, grants to states with severe need. See box on "Allocation of Federal Funding to ADAPs & State Match Requirements."

[9] Some of these funds must be provided to ADAPs, due to state matching fund requirements. See box on "Allocation of Federal Funding to ADAPs & State Match Requirements."

[10] Funding for entitlement programs, such as Medicaid and Medicare, generally changes (increases or decreases) based on the number of eligibles who enroll in these programs and the costs of providing them care.

[11] HRSA, HIV/AIDS Bureau, CARE Act Funding History. Available at: ftp://ftp.hrsa.gov/hab/fundinghis04.xls.

[12] FDA, "Drugs Used in the Treatment of HIV Infection," October 2005. Available at: www.fda.gov/oashi/aids/virals.html.

[13] CDC, "Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus." *MMWR* 2002; 51(No. RR08):1–46.

[14] CDC, "Treating Opportunistic Infections Among HIV-Infected Adults and Adolescents." *MMWR* 2004; 53(No. RR15):1-112.

[15] Providing any FDA-approved HIV-related prescription drug.

[16] New Hampshire has some restrictions to its open formulary.

[17] CDC, Frequently Asked Questions and Answers About Coinfection with HIV and Hepatitis C Virus. Available at www.cdc.gov/hiv/pubs/faq/HIV-HCV_Coinfection.pdf.

[18] CDC, "Sexually Transmitted Diseases Treatment Guidelines, 2002", *MMWR*, Vol. 51, No. RR-6, May 2002.

[19] Not including the ADAP supplemental, a three percent set aside of the total amount earmarked for ADAPs by Congress.

[20] HRSA, Pharmacy Services Support Center, "What is the 340B Program?" Available at: http://pssc.aphanet.org/about/whatisthe340b.htm.

[21] HRSA, HIV/AIDS Bureau, Policy Notice 99-01, "The Use of the Ryan White CARE Act Title II ADAP Funds to Purchase Health Insurance."

[22] HRSA, HIV/AIDS Bureau, DSS Program Policy Guidance No. 2, "Allowable Uses of Funds for Discretely Defined Categories of Services," Formerly Policy No. 97-02, First Issued: February 1, 1997, June 1, 2000.

[23] CMS, "Tip Sheet: People with Medicare and HIV/AIDS", August 2005. Available at: www.cms.hhs.gov/partnerships/downloads/AIDS.pdf.

[24] HRSA, HIV/AIDS Bureau, "Medicare Prescription Drug Benefit and CARE Act Grantees." Available at: www.hrsa.gov/medicare/HIV/about.htm.

FDA-APPROVED ANTIRETROVIRAL MEDICATIONS

GENERIC NAME	BRAND NAME
NRTIs	
abacavir	Ziagen
abacavir, zidovudine, and lamivudine	Trizivir
abacavir/ lamivudine	Epzicom
didanosine, ddI, dideoxyinosine	Videx
FTC, emtricitabine	Emtriva
lamivudine and zidovudine	Combivir
lamivudine, 3TC	Epivir
stavudine, d4T	Zerit
tenofovir disoproxil fumarate	Viread
tenofovir disoproxil/emtricitabine	Truvada
zalcitabine, ddC, dideoxycytidine	Hivid
zidovudine, AZT, azidothymidine, ZDV	Retrovir
NNRTIs	
delavirdine, DLV	Rescriptor
efavirenz	Sustiva
nevirapine, BI-RG-587	Viramune
Protease Inhibitors	
amprenavir	Agenerase
atazanavir sulfate	Reyataz
fosamprenavir Calcium	Lexiva
indinavir, IDV, MK-639	Crixivan
lopinavir and ritonavir	Kaletra
nelfinavir mesylate, NFV	Viracept
ritonavir, ABT-538	Norvir
saquinavir	Fortovase*
saquinavir mesylate, SQV	Invirase
tipranavir	Aptivus
Fusion Inhibitors	
enfuvirtide, T-20	Fuzeon

Sources: DHHS, "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents—October 2005": http://aidsinfo.nih.gov/Guidelines/GuidelineDetail.aspx?MenuItem=Guidelines&Search=Off&GuidelineID=7&ClassID=1; FDA, "Drugs Used in the Treatment of HIV Infection" www.fda.gov/oashi/aids/virals.html. *Discontinued on February 5, 2006: see www.rocheusa.com/newsroom/current/2006/pr2006020601.html

"A1" MEDICATIONS FOR THE PREVENTION & TREATMENT OF OPPORTUNISTIC INFECTIONS (HIGHLY RECOMMENDED)

GENERIC NAME	BRAND NAME	PREVENTION	TREATMENT
acyclovir	Zovirax	X	X
amphotericin B	Fungizone	X	X
azithromycin	Zithromax	X	
cidofovir	Vistide	X	X
clarithromycin	Biaxin	X	X
clindamycin			X
famciclovir	Famvir	X	X
fluconazole	Diflucan	X	X
flucytosine			X
fomivirsen	Vitravene	X	X
foscarnet	Foscavir	X	X
ganciclovir	Cytovene	X	X
Isoniazid (INH)	Lanizid, Nydrazid		X
itraconazole	Sporonox	X	X
leucovorin calcium	Wellcovorin	X	X
peginterferon alfa-2a	PEG-Intron		X
pentamidine	Nebupent		X
pentavalent antimony	—		X
prednisone	Deltasone, Liquid Pred, Metocorten, Orasone, Panasol, Prednicen-M, Sterapred		X
probenecid	—	X	
pyrazinamide (PZA)	—		X
pyrimethamine	Daraprim, Fansidar	X	X
ribavirin	Virazole, Rebetol, Copegus		X
rifabutin	Mycobutin		X
rifampin (RIF)	Rifadin, Rimactane		X
sulfadiazine (oral generic)	Microsulfon	X	X
trimethoprim- sulfamethoxazole (TMP/SMX)	Bactrim, Septra	X	X
valacyclovir	Valtrex		X
valganciclovir	Valcyte		X

*"A" = "should always be offered"; "1" = "evidence from at least one properly randomized, controlled trial"

Sources: CDC, "Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus." MMWR 2002; 51(No. RR08):1-46; CDC, "Treating Opportunistic Infections Among HIV-Infected Adults and Adolescents." MMWR 2004; 53(No. RR15):1-112.

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