

# National ADAP Monitoring Project Annual Report

SUMMARY AND DETAILED FINDINGS

APRIL 2007

## 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: Abbott Laboratories, Boehringer Ingelheim Pharmaceuticals, Gilead Sciences, GlaxoSmithKline, Pfizer, Roche, Solvay Pharmaceuticals and Tibotec Therapeutics. Outside of the National ADAP Monitoring and Technical Assistance Program, NASTAD 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 AND DETAILED FINDINGS

APRIL 2007

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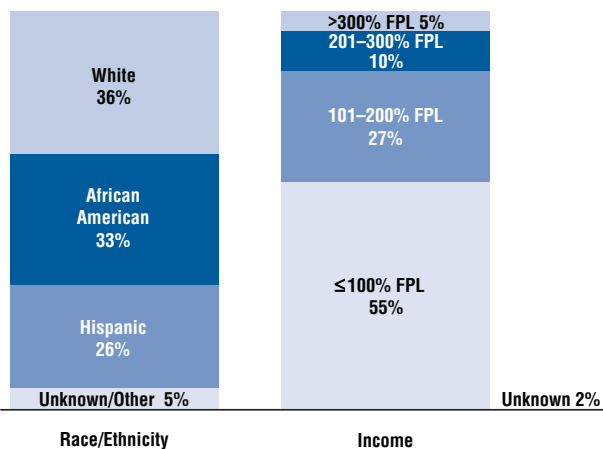
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# Summary & Highlights

The *National ADAP Monitoring Project* Annual Report is based on a comprehensive survey of all state and territorial AIDS Drug Assistance Programs (ADAPs), state-level<sup>1</sup> programs that provide prescription drug medications to low-income people with HIV/AIDS. 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 (Kaiser). Each year, the project documents new developments and challenges facing ADAPs, assesses key trends over time, and provides the latest available data on the status of these programs. Data in the current report are from FY 2006 and June 2006, unless otherwise noted. Key highlights from this year's report are as follows:

- ADAPs are the **nation's prescription drug safety-net for people with HIV/AIDS, serving primarily low-income, people of color who have limited or no access to needed medications.** Acting as payer of last resort, ADAPs provide HIV medications, the linchpin of HIV care today, to people with HIV/AIDS who would otherwise fall through the cracks in the larger U.S. health care system. With close to 142,000 enrollees, ADAPs reach approximately one-quarter of all people with HIV/AIDS in care. About two-thirds of those served are people of color, more than half have incomes at or below 100% of the Federal Poverty Level (FPL was \$9,800 annually for a family of one in 2006), and almost three-quarters are uninsured.

## Profile of ADAP Clients, June 2006



Note: Delaware, Guam, and New Mexico are not included in race/ethnicity and income data. The Federal Poverty Level (FPL) was \$9,800 for a single person in 2006. Percentages may not total 100% due to rounding.

## ADAP SNAPSHOT

- Number of ADAPs, FY 2006: 54
- Total ADAP Budget, FY 2006: \$1.4 billion
- Federal ADAP Earmark, FY 2006: \$789 million
- Clients Enrolled, June 2006: 141,856
- Spending on Prescription Drugs/Insurance, June 2006: \$101 million

- The ADAP safety-net, however, varies significantly across the country and, ultimately, **what one gets depends on where one lives.** For example, ADAP income eligibility in June 2006 ranged from 125% FPL in one state to 500% FPL or more in four. Formulary coverage varies from just a few medications in some states, including one state that does not cover any protease inhibitors and several that do not cover the one approved fusion inhibitor, to open formularies in others. This variation is the result of the way in which ADAPs, and the Ryan White Program overall, are structured—as discretionary grant programs, not entitlements, they are dependent on annual federal appropriations and funding from states and other sources where available, resources that are not necessarily tied to the number of people who need services and the cost of their care.
- ADAPs must therefore **delicately balance available program capacity with client demand.** To do so, ADAPs use the “levers” available to them, particularly through setting income and other eligibility criteria and determining the composition of their formularies. In some cases, this balancing act becomes one of difficult trade-offs between serving more people with less services and serving less people with more.
- **Waiting lists, while much fewer in number than in previous reports, do continue and after falling from their peak, may be showing signs of increase again.** Waiting lists reached their peak in mid-2004 but began to decline soon after, largely due to the introduction of the President’s ADAP Initiative, time-limited funds to address waiting lists, and to increases in state funding; some ADAPs also report that the new Medicare Part D prescription drug benefit helped to alleviate their waiting lists. Still, in March 2007, four states reported waiting lists, totaling 571 people, the highest number of people on waiting lists in more than 12 months.

- Importantly, **states have come to the fore as a major source of ADAP funding, and key driver of budget increases.** While not required to provide funding to their ADAPs (except in limited cases), state funding contributions to ADAPs increased more than any other budget component between FY 2005 and 2006, driving 60 percent of overall national ADAP budget growth. States have also been increasingly active in seeking drug rebates, another key source of funding used by programs.
- **One of the most significant developments to affect ADAPs was the implementation of the new Medicare Part D drug benefit.** Soon after implementation in January 2006, ADAPs began transferring some or all of their eligible clients to Part D, and/or moved from paying for medications in full to picking up ADAP client Part D cost-sharing expenses and were required to do so by May 15, 2006. For the first time in the history of tracking ADAPs,

the *National ADAP Monitoring Project* is reporting stabilization in the number of clients served between the June 2005 and June 2006 monthly snapshots and a decrease in drug expenditures. ADAPs report that client stabilization was due to the one-time transfer of some clients to Part D and is not expected to continue; in fact, client enrollment has continued to increase, as has the number of clients served by ADAPs through insurance purchasing and maintenance arrangements.

It is less clear what will happen with ADAP drug expenditures in the context of the new benefit. While it generally costs less for ADAPs to pay Medicare Part D cost-sharing than for medications directly, the timing of Part D implementation for ADAP clients (May 15, 2006) and this year's survey data (June 2006) mean that ADAPs had not yet experienced what may happen when those same clients reach Part D's coverage limit (the so-called "doughnut hole") due to the high cost of HIV medications, and must pay in full for their costs.

## Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a new outpatient prescription drug benefit known as Part D, effective January 1, 2006. Enrollment in Part D is voluntary, except for those who are dually eligible for Medicaid and Medicare. Part D provides prescription drug coverage up to an initial coverage limit (\$2,250 in 2006; \$2,400 in 2007), after which enrollees reach a coverage gap (the so-called "doughnut hole") where they must pay 100% of their drug costs until they reach a catastrophic coverage level (\$3,600 in 2006; \$3,850 in 2007). The costs that must be incurred by enrollees to reach the catastrophic level are called *True Out of Pocket Costs* (TrOOP). Low-income Part D enrollees are eligible for substantial premium and cost-sharing assistance.

Approximately 17,000 ADAP enrollees are estimated to be Medicare-eligible. As the payer of last resort, as specified in Ryan White legislation, ADAPs must ensure that all of their Medicare Part D-eligible clients enroll in a Medicare Part D drug plan (or at least ensure that they are not paying for any Medicare covered prescription drug service for Medicare eligible ADAP clients). At the same time, ADAPs are permitted, but not required, to coordinate with Medicare prescription drug plans and, in accordance with state policy, pay for all or part of an ADAP-eligible Medicare beneficiary's prescription drug premiums, deductibles, coinsurance, and/or co-payments. Any Part D payments made by an ADAP on behalf of its clients, however, are prohibited from being applied toward TrOOP. This means that ADAP-eligible

Medicare enrollees must incur these costs themselves before they reach catastrophic coverage levels under Part D, and may find themselves in the coverage gap. Since HIV-related medications are expensive and many ADAP-eligible Medicare clients are low-income, most ADAPs have developed policies to coordinate with Part D in order to help maintain appropriate medication coverage for their clients, including paying for their drug costs during the coverage gap. Some ADAPs report coordinating with their state's pharmacy assistance program (SPAP) to cover costs during the coverage gap, since SPAP payments do count towards TrOOP. However, this option is only available to a small number of states.

During 2006, the first year of Part D implementation, ADAPs were required to ensure that their Medicare eligible clients were enrolled in a Part D prescription drug plan by May 15 (or that the ADAP was no longer paying for any Medicare-eligible prescription drug service on their behalf). It is important to note that this deadline immediately preceded the time period represented by much of the data in this year's ADAP Monitoring Report. As noted in the report, the stabilization of client utilization in June 2006 compared to June 2005, and drop in drug expenditures between these two monthly snapshot periods, is due in large part to the one-time transfer of some Medicare-eligible ADAP clients to Part D. This trend in stable client utilization is not expected to continue for ADAPs, with growth again expected between FY 2006 and FY 2007. It is unclear what will happen with expenditures moving forward. ■

In some cases, these individuals may need to turn back to ADAP. Moreover, where ADAPs pick up their costs, as about half of states said they will do, the costs will not count towards a client's *True Out of Pocket Costs* (TrOOP), needed to reach Part D's catastrophic coverage levels and return to Medicare coverage. This could mean that ADAPs will continue to need to pay for their costs once again and for an indefinite period. Still, Part D has allowed some ADAPs to accommodate new clients who were not previously able to access the program, including one state that reported being able to eliminate its waiting list. The *National ADAP Monitoring Project* will continue to closely track the impact of Part D on ADAPs moving forward.

- Finally, the latest **reauthorization of the Ryan White program, particularly its new minimum ADAP formulary requirement, is likely to offer both new opportunities and challenges** to ADAPs and ADAP clients. The minimum ADAP formulary is the first in the program's history. As of July 1, 2007, ADAPs will be required to cover at least one medication from each approved antiretroviral drug class (currently there are four, but this provision will apply to any future classes of ARVs). As this report shows, this will require one state to add at least one protease inhibitor and six to add the only approved fusion inhibitor, currently one of the most expensive antiretrovirals available. In addition, it is very likely that medications in new classes of ARVs will be approved over the next couple

## Ryan White Reauthorization

The Ryan White CARE Act, now called "Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006," or the "Ryan White Program," is the single largest federal program designed specifically for people with HIV/AIDS. ADAPs, which saw their precursor in the 1980s when federal assistance was initially provided to states for purchasing the first approved antiretroviral medication, AZT, were incorporated into Ryan White when it was first enacted in 1990. Ryan White was reauthorized in both 1996 and 2000, and was just reauthorized for the third time in December 2006. Whereas all prior authorizations were for five-year periods, the recent authorization extends for three years.

Each reauthorization of Ryan White has brought changes and new developments for ADAPs, as well as for other parts of Ryan White, reflecting both past experience and anticipated issues and challenges moving forward. The 1996 reauthorization created the federal ADAP earmark. The 2000 reauthorization created the Supplemental Treatment Drug Grant Program, included a provision allowing ADAPs to use funds for insurance purchasing and maintenance, and increased their flexibility to provide other limited services (e.g., adherence support and outreach).

The 2006 reauthorization brought further changes to ADAPs, which will go into effect in the near future, including:

- **Minimum ADAP Formulary:** for the first time in the program's history, ADAPs will be required to cover at least one medication from each of the approved major antiretroviral drug classes, as indicated in the Department of Health and Human Services "Guidelines

for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents" (currently there are four classes, but this provision will apply to any future classes of ARV medications that are incorporated into the Guidelines). The new provision will go into effect on July 1, 2007.

- **Earmark Formula:** the formula used for distribution of federal ADAP earmark funding will change. Previously, estimated living AIDS cases were utilized in determining ADAP formula awards. The new formula will move from estimated living AIDS cases to actual AIDS cases and will also include HIV cases. This change will likely result in funding shifts for ADAP earmark awards, although they will be limited by the hold harmless requirement which will ensure each state receives at least 95% of its FY 2006 amount.
- **ADAP Supplemental:** several changes were made to the ADAP supplemental grant program. The set-aside will increase from three to five percent of the ADAP earmark; eligibility requirements will change; and matching requirements can now be waived if certain other requirements are met. At the time of this report, HRSA was still finalizing new supplemental award funding distribution guidelines based on changes made in the reauthorization, for FY 2007 and beyond (see box on "Allocation of Federal Funding to ADAPs & State Match Requirements" for more detail).

Beyond these ADAP-specific changes, reauthorization has brought changes to other parts of the Ryan White Program that may affect ADAPs, such as changes in the way overall state Title II funding will be distributed across the country, which in turn could affect the amount of funds states have available to provide to ADAPs. ▸

of years. It is unclear what the effects of this new requirement will be—it may serve to expand access to highly effective medications not previously available in some cases, while straining ADAP resources in others, which itself could result in access limitations to other components of the program. Reauthorization will also bring changes to the way in which funding is distributed to states through Ryan White, including to the federal ADAP earmark and ADAP Supplemental Drug Treatment Grants, and likely result in funding shifts in some places.

In addition to these overarching trends and findings concerning ADAPs, a background and overview on ADAPs are provided below, followed by detailed findings on clients, drug expenditures, budgets, eligibility, and other key aspects of the program. The full report contains charts and appendices with state-level data.

## Background and Overview of ADAPs

The AIDS Drug Assistance Program (ADAP) of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, now called “Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006,” or the “Ryan White Program,”<sup>2,3</sup> is 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. With almost 142,000 enrollees, ADAPs reach approximately one quarter of people with HIV/AIDS estimated to be receiving care nationally.<sup>4</sup> ADAPs provided medications to more than 96,000 clients and insurance coverage to thousands more in the month of June 2006 alone. 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.

The purpose of ADAPs, as stated in Ryan White legislation, 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 ...<sup>2</sup>

### 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 protease inhibitor approved by FDA, and the highly active antiretroviral therapy (HAART) era begins.

**1996:** First Reauthorization of CARE Act—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 program, using a set-aside of the federal ADAP earmark for states with “severe need.”

**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.

**2006:** Third Reauthorization of the CARE Act, now called, “Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006” or the “Ryan White Program.” Changes for ADAP include: new formula for determining state awards which incorporates HIV and AIDS cases; new minimum formulary requirement; and changes in ADAP supplemental set-aside and eligibility. ▶

ADAPs accomplish this 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. ADAPs began serving clients in 1987, when Congress first appropriated funds (\$30 million over two years)<sup>5</sup> 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 Program under Title II (grants to states, now known as “Part B”) and became known as “AIDS Drug Assistance Programs,” or ADAPs. The Ryan White Program is the nation’s third largest source of federal funding for HIV care, after Medicaid and Medicare.<sup>6</sup>

Since FY 1996, Congress has specifically earmarked funding within Title II of Ryan White for ADAPs, which is allocated by formula to states.<sup>7</sup> 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,<sup>8</sup> and from other parts of Ryan White, and programs may seek manufacturers' drug rebates, but these other 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 Ryan White Program. In FY 2006, 54 jurisdictions were eligible for federal ADAP earmark funding, including all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam; HRSA determined that some previously funded territories were not eligible for ADAP funding in FY 2006. The recent reauthorization of Ryan White specified that all territories will again be eligible for ADAP funding beginning in FY 2007.

Each state administers its own ADAP and is given flexibility under Ryan White to design many aspects of its program, including client eligibility, drug purchasing

### Allocation of Federal Funding to ADAPs & State Match Requirements

Each year, Congress specifically earmarks federal funding for ADAPs through Ryan White Title II (funding for care grants to states, now called Part B). To date, the formula used to allocate these funds to state jurisdictions each year has been based on their proportion of the nation's estimated living AIDS cases. The recent reauthorization of the Ryan White Program will change the formula by moving from estimated living AIDS cases to actual AIDS cases and by including HIV cases. HIV and AIDS case counts will be determined in one of two ways: (1) as certified by the Centers for Disease Control and Prevention (CDC) in states with "mature" HIV name reporting systems; or (2) as reported to the Health Resources and Services Administration (HRSA) by jurisdictions without mature HIV name reporting systems (in this case, a five percent duplication penalty will be applied to a jurisdiction's count). A jurisdiction's proportion of AIDS and HIV cases will be applied to the funding available through the ADAP earmark to determine the award amount. In FY 2006, 54 jurisdictions were eligible for federal ADAP earmark funding, including all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam; some previously funded territories were determined by HRSA not to be eligible for ADAP funding in FY 2006. Beginning in FY 2007, all territories will again be eligible for ADAP funding, as specified in the recent reauthorization of Ryan White.

States with one percent or more of reported AIDS cases during the most recent two-year period must match (with non-federal contributions) their overall 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 2000 reauthorization of Ryan White created a new "Supplemental Treatment Drug Grant Program" which awards grants, using a set-aside of the ADAP earmark (until the most recent reauthorization, this set-aside was three percent), to states with "severe need." To be eligible for supplemental awards, states were required to have at least one restriction in place as of January 1, 2000 related to ADAP income eligibility standards, formulary composition, or the number of eligible individuals at or below 200% of FPL to whom the state is unable to provide therapeutics. Award amounts were 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 was applied to the number of dollars available under the supplemental grant to determine each state's award amount. States applying for supplemental grants were required to 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). In FY 2006, 27 ADAPs were eligible for supplemental award funding and 20 applied for and met the matching requirements; the other eligible jurisdictions did not apply either because they could not meet the state match requirement or did not require supplemental funding. Beginning in FY 2007, the matching requirement can be waived if other Title II matching requirements are met, if applicable.

*(continued on next page)*

## Allocation of Federal Funding to ADAPs & State Match Requirements *(continued)*

In FY 2006, while a three percent set-aside of the ADAP earmark was the basis for ADAP supplemental grants, the “hold harmless” clause in Ryan White legislation required that adjustments be made in ADAP earmark awards so that each overall state Title II award was at least equal to the previous year. In order to accomplish this in FY 2006, funding from the set-aside was taken from the supplemental grant pool before awards were made to states. This meant that the total ADAP supplemental amount available for awards was less than three percent of the ADAP earmark. Beginning in FY 2007, the hold harmless requirement is not tied to the ADAP supplemental grant set-aside and so the entire supplemental amount should be available for distribution to eligible states.

The 2006 reauthorization of Ryan White made a number of changes to the ADAP supplemental grant program including: increasing the supplemental set-aside of the ADAP earmark from three to five percent each year; moving from eligibility based on “severe need” to eligibility based on “demonstrated need,” as measured by ADAP income eligibility criteria, formulary composition, the number of eligible individuals to whom a state is unable to provide medications, and an unanticipated

increase in eligible individuals with HIV/AIDS; elimination of the requirement that these factors had to be tied to January 1, 2000; adding a requirement that states must have less than two percent of unobligated Title II funds remaining from the previous grant year to be eligible for supplemental grants; and providing an option for the state matching requirement to be waived (see above). At the time of this report, HRSA was still finalizing new funding distribution guidelines for the supplemental grants based on changes made in the reauthorization, for FY 2007 and beyond.

It is important to note that the ADAP fiscal year differs from the federal and state fiscal year periods:

ADAP fiscal year: April 1–March 31  
Federal fiscal year: October 1–September 30  
State fiscal year (for most states): July 1–June 30

For example, the ADAP FY 2006 began on April 1, 2006 and ended on March 31, 2007. The Federal FY 2006 began on October 1, 2005 and ended on September 30, 2006. The State FY 2006, in most states, began July 1, 2006 and will end on June 30, 2007. ▀

and distribution arrangements, and to some extent, drug formularies. There is no client income eligibility level required, although clients must be HIV-positive, low-income, and under- or uninsured. Until the recent third reauthorization of Ryan White, no minimum drug formulary was required. The reauthorization added a new minimum formulary requirement for all ADAPs, effective July 1, 2007, to include, at a minimum, one medication from within each antiretroviral drug class (of which there are currently four). ADAPs will still be able to determine how many medications from within each ARV class are offered, what, if any, non-ARV medications are covered, and whether cost-sharing, quantity limits, or drug specific eligibility criteria are instituted.

Like all Ryan White programs, ADAPs serve as “payer of last resort”; that is, they provide prescription medications to, or pay for health insurance premiums or maintenance

(premiums, co-pays, and/or deductibles) 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,<sup>9</sup> 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. In addition, given that ADAPs are an integral component of the larger Ryan White system, the funding levels and capacity of other Ryan White components may also affect client access to ADAPs.



### *Trends in Clients and Drug Expenditures*

- Client enrollment has grown over time, reaching more than 141,000 in June 2006, a five percent increase over the prior period.
- Client utilization (the number of clients receiving prescription medications) has grown significantly since 1996 (203% among the 49 ADAPs reporting data in both periods), but growth has slowed considerably in recent years and has generally lagged behind the rate of increase in drug expenditures. For the first time since the *National ADAP Monitoring Project* began tracking ADAPs, however, client utilization remained relatively stable between June 2005 and June 2006 (a decrease of less than one percent) (see Chart 4). This relative stability between the two periods is attributable to the implementation of the Medicare Part D benefit and the one-time move of Medicare-eligible ADAP clients into Part D. This shift is not expected to continue, as some states are now able to accommodate additional clients, and not all states experienced it to the same degree—27 ADAPs reported decreases in clients served between the two periods; 21 reported increases (see Appendix I). In addition, the number of clients served by ADAPs through insurance purchasing/maintenance strategies continued to rise, increasing by 12% between June 2005 (12,311 clients) and June 2006 (13,744) and has almost doubled over a two-year period (see Chart 37).
- Drug spending by ADAPs has increased more than six-fold (508%) since 1996, more than twice the rate of client growth over this same period (in the same 49 states reporting data on clients). It too has continued to increase but at slower rates and, for the first time, was less in the current one-month snapshot compared to last year (a seven percent decrease among the 49 ADAPs reporting in both June 2005 and June 2006) (see Chart 11). ADAPs reported that this decrease is largely the result of the expected one-time move of Medicare-eligible ADAP clients into Part D, and/or the transition by ADAPs to paying for client cost-sharing for Medicare Part D (versus direct drug expenditures). In fact, drug expenditures likely decreased more than client numbers because many clients were maintained on ADAP while ADAPs shifted from paying full drug costs to Part D cost-sharing. As with clients, not all states experienced the same shift. Twenty-nine ADAPs had lower drug expenditures in June 2006 compared to June 2005; 20 had higher expenditures (see Appendix I). It is unclear what will happen with drug expenditures over time, and if such decreases will continue. While it generally costs less for ADAPs to pay Medicare Part D cost-sharing than for medications

directly, the timing of Part D implementation for ADAP clients (May 15, 2006) and this year's survey data (June 2006) means that ADAPs had not yet experienced what may happen when those same clients reach Part D's coverage limit (the so called "doughnut hole") due to the high cost of HIV medications, and must pay in full for their costs. In some cases, they may need to turn back to ADAP. Moreover, where ADAPs pick up these costs, as about half of states said they will do, the costs will not count towards a client's TrOOP, needed to reach Part D's catastrophic coverage levels and return to Medicare coverage (see box on "Medicare Part D"). This could mean that ADAPs will continue to need to pay for their costs once again. In addition, since the start of the new benefit, different plans have entered or left the Part D market and some plans have changed their benefit structure, factors which could also affect beneficiaries with HIV. This impact will need to be closely monitored.

- As with drug expenditures, the number of prescriptions filled between the monthly snapshots fell (by nine percent), but has generally been increasing over time (see Appendix I).

### **ELIGIBILITY CRITERIA AND FORMULARIES**

#### *ADAP Eligibility Criteria*

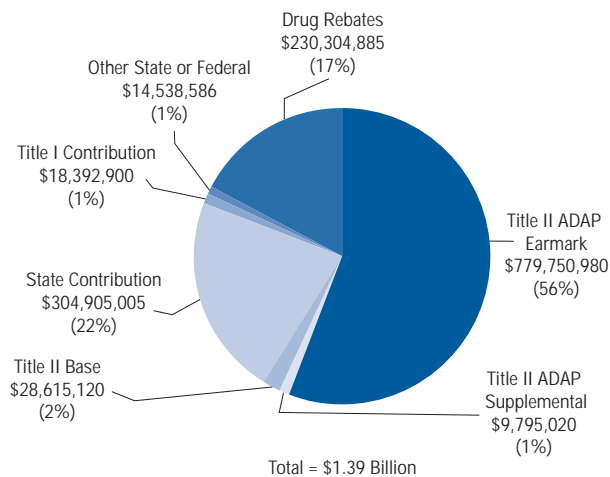
- All ADAPs require that individuals provide clinical documentation of HIV infection. Seven states reported additional clinical eligibility criteria (e.g., specific CD4 or viral load ranges), three more states than last year (see Appendix VIII).
- ADAP income eligibility in June 2006 ranged from 125% FPL in one state (North Carolina) to 500% FPL or more in four (Maryland, Massachusetts, New Jersey, and Ohio). Overall, 21 states set income eligibility at greater than 300% FPL, 19 between 201% and 300% FPL; 10 at 200% FPL and one at 125% FPL (see Chart 15). In November 2006, North Carolina raised its FPL from 125% to 200% FPL, representing the first time in the history of the project that no state currently has income eligibility below 200% FPL. In addition to income, 16 ADAPs reported having asset limits in place in June 2006.
- All ADAPs require enrollees to be residents of the state in which they are seeking medications. Some ADAPs require documentation of residency.







## National ADAP Budget, by Source, FY 2006



Note: 51 ADAPs reported data. Although Delaware, Guam, and New Mexico did not report, data on their Title II earmark and supplemental were available and included. American Samoa, the Marshall Islands, and the Northern Mariana Islands are not included because HRSA determined they were not eligible for ADAP funding in FY 2006. ADAP supplemental funds are only available for states meeting the required eligibility and matching funds.

put this funding toward ADAP. In the case of ADAP supplemental funding, states are required to provide a state match, but this generally represents a relatively small share (\$2.5 million, or less than one percent, in FY 2006) of state funding for ADAPs. States have also been increasingly active in seeking drug rebates, another key source of funding used by programs, and rebates were the second largest driver of budget growth over the last year.

- By definition, all eligible jurisdictions (54 in FY 2006) 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 2006, two ADAPs received only ADAP earmark funding. The breakdown of other sources of funding across the country was as follows (among 51 ADAPs reporting data) (see Chart 25 and Appendix XIII):
  - Title II ADAP Supplemental Treatment Grants: 20 ADAPs received funding, 34 did not;
  - Title II Base Funds: 21 ADAPs received funding, 30 did not
  - State General Revenue Support: 40 ADAPs received funding, 11 did not
  - Title I EMA Funds: 12 ADAPs received funding, 39 did not
  - Other State/Federal Funds: 14 received funding, 37 did not

- Drug Rebates: 39 ADAPs received funding, 12 did not.

- Additionally, despite a seven percent increase in the national ADAP budget across all ADAPs between FY 2005 and FY 2006, some ADAPs had decreases either in their overall budget or for specific funding streams (see Chart 26 and Appendices XIV and XV):

- Overall Budget: 34 ADAPs had increases or level funding, 20 had decreases
- Title II ADAP Earmark: 48 ADAPs had increases; 6 had decreases
- Title II ADAP Supplemental Treatment Grants: all 20 had decreases—See Chart 30 and box on “Allocation of Federal Funding to ADAPs & State Match Requirements”
- Title II Base Funds: 15 ADAPs had increases or level funding; 10 had decreases
- State General Revenue Support: 35 ADAPs had increases or level funding, 7 had decreases
- Title I EMA Funds: 5 ADAPs had increases or level funding, 8 had decreases
- Drug Rebates: 30 ADAPs had increases or level funding, 13 had decreases.

- State contributions to ADAPs ranged from 0%, in the 11 states that did not provide any state support, to 52% of the ADAP budget; Title II base funding ranged from 0% to 39%; Title I funding ranged from 0% to 34%; ADAP supplemental funding ranged from 0% to 5%; and drug rebates ranged from 0% to 43% of the ADAP budget (see Appendix XIII).

- The composition of the ADAP budget has shifted significantly over the past decade (see Chart 27):

- The ADAP earmark has risen from one quarter (26%) of the budget in FY 1996, the year it began, to its current share of 56%. The earmark amount has risen each year over this period as well.
- State general revenue support, while declining slightly as a proportion of the budget (from 25% in FY 1996 to 22% in FY 2006), has increased significantly in amount and has been the second largest source of funding over the entire period.
- Drug rebates rose from six to 17% 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 NASTAD’s ADAP Crisis Task Force in working to obtain rebates. Some drug rebates are dependent on negotiations by individual states

or state coalitions, 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 2006 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 as it was in earlier years. As noted above, the largest driver is now state funding, followed by drug rebates (see Charts 29–34 and Appendix XV).
  - The ADAP earmark increased by \$15.1 million, or two percent, over FY 2005, the smallest increase since the earmark began.
  - State funding increased by \$52.1 million, or 21%, over FY 2005.
  - Drug rebates increased by \$33.8 million, or 17%, reaching their highest level to date.
  - After declining for several years in a row, Title II base funds allocated by states to ADAPs rose for the second year in a row to \$28.6 million.
  - Contributions from Title I jurisdictions have fluctuated over time; they increased by \$0.5 million between FY 2005 and 2006.
  - ADAP supplemental funds of \$9.8 million in FY 2006, were their lowest since the program began. ADAP supplemental awards were provided to 20 states that met the federal eligibility criteria, applied for funding, and were able to meet the mandated matching requirement (27 were eligible). It is important to note that supplemental awards were reduced by 52% overall in FY 2006, in order to adjust the ADAP earmark awards in states that would otherwise have received an overall Title II award less than that of the previous year (per one of the hold harmless provisions of Ryan White that protects programs from this kind of overall decrease) (see box on “Allocation of Federal Funding to ADAPs & State Match Requirements”).
- While not included as a budget category because this source of revenue is highly variable and often subject to lengthy delays for states to obtain, cost recovery, that is, reimbursement from third party entities such as private insurers and Medicaid, for medications purchased through ADAP (other than drug rebates), represented \$31.4 million in FY 2006. Private insurance recovery was the largest component (64%) (see Chart 35 and Appendix XVI).

## DRUG PURCHASING MODELS AND INSURANCE COVERAGE ARRANGEMENTS

### *Drug Purchasing Models*

- The federal 340B program enables ADAPs to purchase drugs at or below the statutorily defined 340B ceiling price.<sup>17</sup> All ADAPs but one (the District of Columbia) participate (see Chart 36 and Appendix XVII).
  - ADAPs may purchase drugs either directly from wholesalers or through retail pharmacy networks and then apply to drug manufacturers for rebates. As of June 2006, 29 ADAPs reported purchasing directly; 25 reported purchasing through a pharmacy network and then seeking rebates.

### 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 at the time manufactured 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), price freezes, and free products to all ADAPs nationwide. During 2004, the Task Force expanded its negotiations to include companies that manufacture high-cost non-ARV drugs. Additional agreements have been obtained since then and previous agreements were extended and/or enhanced. Agreements are currently in place with 14 manufacturers. The Task Force estimates savings of \$145 million in FY 2006, and \$425 million since its formation. Current members of the Task Force include representatives from ADAPs in California, Florida, Ohio, New Jersey, New York, North Carolina, Texas, and Utah.

The Task Force also coordinates its efforts with the Fair Pricing Coalition (a coalition of organizations and individuals working with pharmaceutical companies regarding initial pricing of ARV drugs for all payers) and other community partners. ▶

- Direct purchase ADAPs can also choose to participate in the HRSA Prime Vendor Program,<sup>17</sup> which was created to negotiate pharmaceutical pricing below the 340B price. Seven of the 29 ADAPs that purchase directly from wholesalers participate in the HRSA Prime Vendor Program.
- NASTAD’s ADAP Crisis Task Force also negotiates directly with manufacturers for pharmaceutical pricing below the 340B price on behalf of both rebate and direct purchase ADAPs. When such agreements are reached, they are provided to all states (see box on “ADAP Crisis Task Force”).

**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.<sup>18,19</sup> States are increasingly using ADAP funds for this purpose. Most ADAPs (31, up from 29 last year) reported doing so in 2006, representing \$83.5 million in expenditures in FY 2006, an 11% increase over FY 2005. In June 2006, 13,744 ADAP clients were served by such arrangements—12% higher than in June 2005 (see Chart 37 and Appendix XVIII).
- These strategies appear to be cost effective—in June 2006, spending on insurance represented an estimated \$395 per capita, less than half of per capita drug expenditures in that month (\$991).

**Coordination with Medicare Part D**

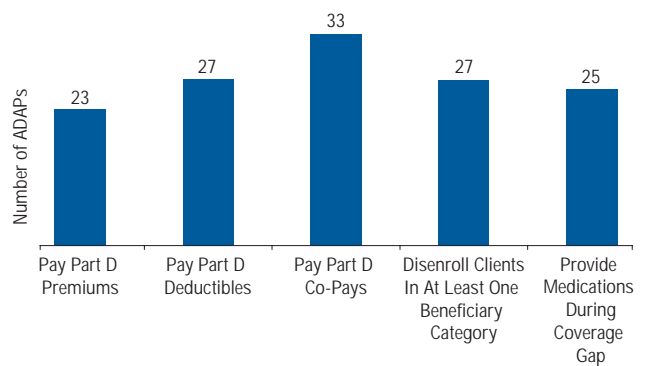
- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added a new outpatient prescription drug benefit, Part D, to the Medicare program effective January 1, 2006. An estimated 12% of ADAP clients are Medicare eligible (representing more than 11,500 of clients who used prescription drug services in June 2006, and more than 17,000 of all enrolled clients). A subset of these clients is dually eligible for Medicare and Medicaid.
- As the payer of last resort, ADAPs were required by HRSA to ensure that all Medicare Part D eligible clients enroll in a Medicare prescription drug plan by May 15, 2006 (or at least ensure that they are not paying for any Medicare covered prescription drug service for Medicare eligible ADAP clients). 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.<sup>18</sup> However, the MMA does not allow ADAP

funds to be counted toward TrOOP. This means ADAP enrollees must incur these costs themselves when in the coverage gap before they are eligible to receive catastrophic coverage under their Medicare drug plan.<sup>20</sup> 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 38 and Appendix XIX). As of November 2006:

- 23 pay Part D premiums
- 27 pay Part D deductibles
- 33 Part D co-payments for ADAP clients eligible for Part D
- 25 pay for all medications on their ADAP formularies when their Part D clients reach the coverage gap or “doughnut hole.”

In addition to these cost-sharing policies, 27 ADAPs reported that they have disenrolled some or all of their Medicare eligible clients from ADAP, particularly those dually eligible for Medicare and Medicaid, as these clients have guaranteed coverage through Part D. In some cases, states continue to provide cost-sharing where needed, and will cover medication costs in the coverage gap. Some ADAPs report coordinating with their state’s pharmacy assistance program (SPAP) to cover costs during the coverage gap, since SPAP payments do count towards TrOOP. However, this option is only available to a small number of states.

**ADAP Policies Related to Medicare Part D, as of November 2006**



Note: 48 ADAPs reported data.

**CONCLUSION**

The *National ADAP Monitoring Project* will continue to assess the multiple issues affecting ADAPs over the next year, tracking data on the critical role ADAPs play in providing low-income people with HIV access to needed medications. Particular issues to be monitored include:

the ongoing interaction between ADAPs and Medicare Part D; the impact of Ryan White reauthorization and its new ADAP minimum formulary requirement; and the status of ADAP waiting lists and other cost-containment measures over time.

Charts for each major finding and appendices, with data by state, are provided in the full report. Chart 1 provides key data by state across a range of indicators. State-level data from this report are also provided on Kaiser's State Health Facts website, [www.statehealthfacts.org/hiv](http://www.statehealthfacts.org/hiv), where they can be accessed and downloaded for free. Finally, a separate document is available that provides a listing of all drugs on ADAP formularies by state.

## Methodology

Since 1996, the *National ADAP Monitoring Project*, an initiative of the Kaiser Family Foundation (Kaiser) and the National Alliance of State and Territorial AIDS Directors (NASTAD), has surveyed all jurisdictions receiving federal ADAP earmark funding through Ryan White. In FY 2006, 54 jurisdictions received earmark funding and all 54 were surveyed; 51 responded. Delaware, Guam, and New Mexico did not respond; these jurisdictions represent less than one percent of estimated living AIDS cases.\*

The annual survey requests data and other program information for a one month period (June), the current fiscal year, and for other periods as specified. After the survey is distributed, NASTAD conducts extensive follow-up to ensure completion by as many ADAPs as possible. Data used in this report are from June 2006 and FY 2006, unless otherwise noted. Supplemental data collection is conducted in certain areas to obtain more current data, including for: waiting lists, other cost-containment measures; Medicare Part D coordination; and formulary composition.

All data reflect the status of ADAPs as reported by survey respondents; however, it is important to note that some program information may have changed between data collection and this report's release. In addition, 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. It is also important to note that data from a month snapshot may be subject to one-time only events or changes that could in turn appear to impact trends; these are noted where information is available. Data issues specific to a particular jurisdiction are provided on relevant charts and tables.

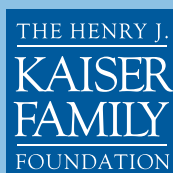
\*CDC, "Persons living with HIV/AIDS or AIDS, by geographic area and Ryan White CARE Act eligible metropolitan area of residence, December 2004", *HIV/AIDS Surveillance Supplemental Report 2006*; 12 (No. 1). Available at: [www.cdc.gov/HIV/topics/surveillance/resources/reports/2006supp\\_vol12no3/table1.htm](http://www.cdc.gov/HIV/topics/surveillance/resources/reports/2006supp_vol12no3/table1.htm). ▶

## REFERENCES

- 1 The term "state" is used in this report to include states, territories and associated jurisdictions.
- 2 Pub. L. 101-381; Pub. L. 104-146, SEC. 2616. [300ff-26].
- 3 HRSA HIV/AIDS Bureau.
- 4 Based on Kaiser Family Foundation analysis of data from the Centers for Disease Control and Prevention (CDC) and the Joint United Nations Programme on HIV/AIDS (UNAIDS).
- 5 HRSA, HIV/AIDS Bureau, Personal Communication, March 15, 2005.
- 6 White House, Office of Management and Budget, March 2007.
- 7 Up until the most recent reauthorization of Ryan White, three percent of the ADAP earmark was set-aside for the ADAP Supplemental Treatment Drug Grant, grants to states with severe need. As of FY 2007, this amount has been increased to five percent. See box on "Allocation of Federal Funding to ADAPs & State Match Requirements."
- 8 Some of these funds must be provided to ADAPs, due to state matching fund requirements for the ADAP supplemental. See box on "Allocation of Federal Funding to ADAPs & State Match Requirements."
- 9 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.
- 10 This estimate is based on annualizing June 2006 drug expenditures and combining the 12-month total with reported insurance spending for FY 2006. It is important to note that June 2006 expenditures may not be representative of monthly expenditures overall, especially in this year's report, due to the timing of Medicare Part D implementation. In fact, June 2006 drug expenditures may be lower than average, which would result in a lower than average annual estimate.
- 11 FDA, "Drugs Used in the Treatment of HIV Infection." Available at: <http://www.fda.gov/oashi/aids/virals.html> (accessed March 21, 2007).
- 12 CDC, "Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus," *MMWR* 2002; 51(No. RR08):1-46. Available at: <http://www.aidsinfo.nih.gov/> (accessed March 21, 2007).
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- 17 HRSA, Pharmacy Services Support Center, "What is the 340B Program?" Available at: <http://pssc.aphanet.org/about/whatisthe340b.htm> (accessed March 21, 2007).
- 18 HRSA, HIV/AIDS Bureau, Policy Notice 99-01, "The Use of the Ryan White CARE Act Title II ADAP Funds to Purchase Health Insurance."
- 19 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.
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