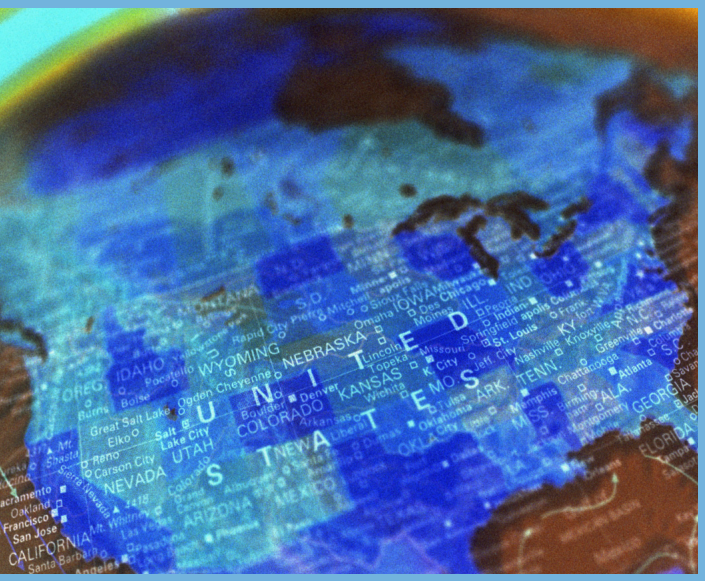

National ADAP Monitoring Project Annual Report

SUMMARY AND DETAILED FINDINGS

APRIL 2008

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NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

THE HENRY J. KAISER FAMILY FOUNDATION

Acknowledgements

The Henry J. Kaiser Family Foundation (Kaiser) and The National Alliance of State and Territorial AIDS Directors (NASTAD) would like to thank the state ADAP and AIDS program managers and staff for their time and effort in completing the National ADAP Survey which serves as the foundation for this report, and for providing ongoing updates to inform the National ADAP Monitoring Project.

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, Gilead Sciences, GlaxoSmithKline, 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.

National ADAP Monitoring Project
Annual Report

APRIL 2008

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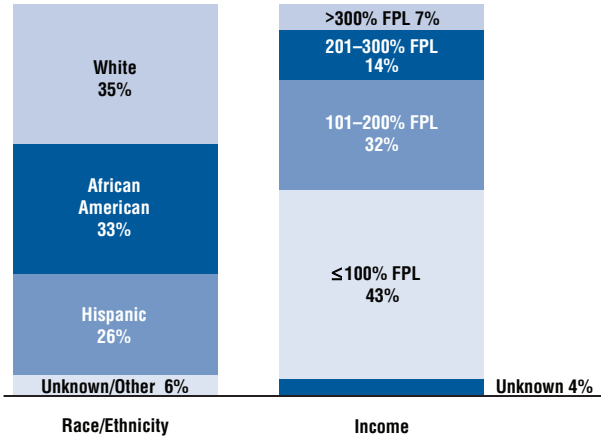
Summary and Highlights

The National ADAP Monitoring Project's *Annual Report* is based on a comprehensive survey of all AIDS Drug Assistance Programs (ADAPs), state-level[1] programs that provide prescription drug medications to low-income people with HIV/AIDS. The National ADAP Monitoring Project is a more than 10-year effort of the National Alliance of State and Territorial AIDS Directors (NASTAD) and the Henry J. 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. This report updates prior findings with data from fiscal year (FY) 2007 and June 2007 (unless otherwise noted) and discusses recent policy and programmatic changes that affect ADAPs. Key highlights from this year's report are as follows:

- **The national ADAP client caseload has grown over time.** With almost 146,000 enrollees in 2007—and 102,000 served in the month of June 2007 alone—it reached its highest level since the program began.

- As the **nation's prescription drug safety-net for people with HIV/AIDS**, ADAPs are designed to serve some of the most vulnerable people with HIV in the country. Most clients are low-income, with more than four in 10 having incomes at or below 100% of the Federal Poverty Level (FPL was $10,210 annually for a family of one in 2007), and uninsured (69%), and approximately two-thirds are people of color. Without ADAPs, many of these individuals would likely have limited or no access to medications and fall through the cracks in our larger health care system.

Profile of ADAP Clients, June 2007



Note: 53 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Marshall Islands, and Northern Mariana Islands did not report data. The Federal Poverty Level (FPL) was $10,210 (slightly higher in Alaska and Hawaii) for a household of one. Percentages may not total 100% due to rounding.

ADAP SNAPSHOT

- Number of ADAPs, FY 2007: 58
- Total ADAP Budget, FY 2007: $1.4 billion
- Federal ADAP Earmark Funds, FY 2007: $775 million
- Clients Enrolled, June 2007: 145,799
- Clients Served, June 2007: 101,987
- Drug Spending, June 2007: $100 million

- **ADAP clients primarily reflect the national epidemic, concentrated in states with the highest numbers of people living with HIV/AIDS**. Ten states accounted for two-thirds (67%) of total client enrollment in June 2007. Regionally, more than a third (37%) of clients enrolled lived in the South, 27% in the West, 25% in the Northeast, and 11% in the Midwest.[2]

- The **2006 reauthorization of the Ryan White Program**, the federal program under which ADAPs were established, changed the way in which federal funding is distributed to states for ADAPs. It also instituted new ADAP policies such as a minimum drug formulary requirement for antiretrovirals, the first such requirement in the program's history. While the implications of these recent changes are still being played out at the state level, they have introduced both new opportunities and new challenges for ADAPs. For example, the funding formula change has resulted in fluctuations in the amount of ADAP funding received by states between FY 2006 and FY 2007, and may continue to do so. Additionally, the new formulary requirement has served to expand access to medications in a few states but may pose resource challenges in others, particularly as newer, but usually more expensive, classes of antiretrovirals are introduced.

- **There is good news for ADAPs, as several recent factors have combined to ease past pressures**, although relief has not been felt equally across the country and its longevity is uncertain. For the first time since the Monitoring Project began tracking ADAPs, waiting lists were nearly eliminated in the most recent period. In addition, most ADAPs increased client

enrollment and added medications from two new drug classes almost immediately upon their approval, despite having a multi-month grace period for doing so. Among the factors contributing to the easing of past pressures for many states were:

– *President's ADAP Initiative (PAI)*: The PAI provided additional one-time funding[3] to 10 states with waiting lists, resulting in a drop in the number of people on waiting lists across the country (although not eliminating waiting lists completely; at the end of the PAI in 2006, more than 300 additional individuals were still on waiting lists in six states).
– *Medicare Part D*: Several ADAPs reported that the introduction of Medicare Part D in 2006 helped to ease constraints and/or provide a new avenue for prescription drugs for people with HIV. For example, many ADAPs have been able to reduce costs by transitioning from paying all prescription drug costs for Part D-eligible clients to covering their "wrap around" costs such as co-payments, monthly premiums, or costs when beneficiaries reach the "coverage gap" in their Part D plans.
– *Non-Federal Funding Sources*: Over time, non-federal funding sources—particularly state general revenue support and drug rebates—have become critical parts of the ADAP budget. States, although not required to do so, have generally acted to provide additional funding to ADAPs at key times, sometimes in response to state-level advocacy efforts. In addition, the easing of the economic downturn that hit states hard in the earlier part of the decade likely led to some states increasing their contributions to ADAP this year. Moreover, because of the uncertainty of ADAP funding from year to year, ADAPs have become increasingly sophisticated at seeking other sources of revenue, particularly pharmaceutical manufacturer drug rebates, which now appear to be a main factor allowing most ADAPs to continue to meet client demand and even expand access in some cases.
– *ADAP Supplemental Drug Treatment Grants*: Ryan White Reauthorization increased the amount of funding available for ADAP Supplemental Drug Treatment Grants, a set-aside of the federal ADAP earmark designed to provide additional funding to states with significant ADAP program limitations.

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 began as AZT Assistance Programs in the 1980s when federal assistance was initially provided to states for purchasing the first approved antiretroviral medication, were incorporated into the Ryan White Program when it was first enacted in 1990. The Ryan White Program was reauthorized in both 1996 and 2000, and was reauthorized for the third time in December 2006. Whereas all prior authorizations were for five-year periods, the recent authorization was for three years.

Each reauthorization of the Ryan White Program has brought changes and new developments for ADAPs, as well as for other parts of the Ryan White Program, reflecting both past experience and anticipated issues and challenges moving forward. The 1996 reauthorization created the federal ADAP earmark. The 2000 reauthorization created the ADAP Supplemental Drug Treatment 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, including:

Minimum ADAP Formulary: For the first time in the program's history, ADAPs are required to cover at least one medication from each of the approved 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 six classes subject to the requirement, but this provision will apply to any future classes of antiretroviral medications that are incorporated into the Guidelines). HRSA instituted the new provision into policy, effective July 1, 2007.

Earmark Formula: The formula used for distribution of federal ADAP earmark funding changed. Previously, estimated living AIDS cases were utilized in determining ADAP formula awards. The new formula has moved from estimated living AIDS cases to actual AIDS cases and also includes HIV cases. This change has resulted in some funding shifts for ADAP earmark awards although such shifts were limited by the hold harmless requirement which ensured each state received at least 95% of its FY 2006 award.

ADAP Supplemental: Several changes were made to the ADAP supplemental grant program. The set-aside increased from three to five percent of the ADAP earmark; eligibility requirements changed; and matching requirements can now be waived if certain requirements are met.

Beyond these ADAP-specific changes, reauthorization has brought changes to other parts of the Ryan White Program that continue to affect ADAPs, such as changes in the way overall state Part B funding is distributed across the country, which in turn affects the amount of funds states have available to provide to ADAPs. ◗

This resulted in the first increase in funds available through the ADAP Supplemental since FY 2003, and likely contributed to the easing of fiscal pressures in those states that received increases (13 states) or first-time (3 states) ADAP supplemental funding.

- **Despite these factors, there is a concern for the future.** ADAP funding levels and budget composition are highly variable from year to year, with revenue sources often being triggered as "levers" that rise and fall depending on the amount of federal funding available. Trend data indicate that when one ADAP revenue source decreases, others often increase to fill the gap. For example, as growth in federal ADAP earmark funding has slowed in recent years—even declining over the last year for the first time since it began—other funding sources, such as drug rebates, have been sought more actively. These "levers," however, are seldom permanent and usually unpredictable. The only two ADAP funding sources that increased over the last period were drug rebates and the ADAP Supplemental; all others decreased, including state funding, which has historically been a key driver of ADAP budget growth. Additionally, it is still not clear how the recent changes in the Ryan White Program will affect ADAPs over time; ADAP earmark funding, for instance, is still expected to shift state-by-state as hold harmless and other provisions in the law play out. Finally, there are recent signals of a new state-level economic downturn, with some states already reporting overall budget shortfalls for FY 2008 and/or expecting shortfalls for FY 2009[4]; these states include some of those with the largest ADAP caseloads, and it is unknown if or how ADAPs will be affected. Ultimately, the number of clients served by ADAPs will continue to be determined by the amount of funding the programs receive each year and may not correspond to the number of people who need prescription drugs or to the costs of medications.

The National ADAP Monitoring Project will continue to assess these issues, particularly the ongoing impact of Ryan White Reauthorization and the role of the larger state fiscal environment, over the next year and provide data on the critical role ADAPs play in providing low-income individuals with HIV access to needed medications.

A background and overview on ADAPs, followed by detailed findings on clients, drug expenditures, budgets, eligibility, and other key aspects of the program, are below. Charts and detailed tables with state-level data can be found in the full report and online.

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," [5,6] 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 146,000 enrollees, ADAPs reach about three in 10 people with HIV estimated to be receiving care nationally.[7] In the month of June 2007 alone, ADAPs provided medications to nearly 102,000 clients and insurance coverage for medications and other medical

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 10 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 living HIV and AIDS cases; new minimum formulary requirement; and changes in ADAP supplemental set-aside and eligibility.

2007: New minimum formulary requirement effective July 1; first CCR5 antagonist and integrase inhibitor approved by FDA. ◗

care to thousands more. 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 the Ryan White Program, 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… [5]

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 coverage of HIV treatments. Individuals are eligible for ADAP when they can demonstrate they are low income and have limited or no prescription drug coverage.

ADAPs began serving clients in 1987, when Congress first appropriated funds ($30 million over two years[8]) 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 called Part B) and became known as "AIDS Drug Assistance Programs," or ADAPs. The Ryan White Program is the

ALLOCATION OF FEDERAL FUNDING TO ADAPS & STATE MATCH REQUIREMENTS

Each year, Congress specifically earmarks federal funding for ADAPs through Ryan White Part B (funding for care grants to states). Prior to the most recent reauthorization of the Ryan White Program in 2006, the formula used to allocate these funds to state jurisdictions each year was based on their proportion of the nation's estimated living AIDS cases. The 2006 Reauthorization changed the formula by moving from estimated living AIDS cases to actual AIDS cases and by including HIV cases in the formula. AIDS case counts are determined by the Centers for Disease Control and Prevention (CDC) as reported by states. HIV case counts are now determined in one of two ways: (1) as certified by the 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, which then applies a five percent "duplication" penalty to the count. Once these counts are determined, a jurisdiction's proportion of living AIDS and HIV cases is applied to the funding available through the ADAP earmark to determine the award amount. In FY 2007, 58 jurisdictions were eligible for federal ADAP earmark funding, including all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, American Samoa, Federated States of Micronesia, Guam, Marshall Islands, and Northern Mariana Islands; Palau was eligible to receive funding but did not report any HIV/AIDS cases and therefore did not receive a funding award.

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 Part B 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 2006 Reauthorization increased the set-aside for ADAP Supplemental Drug Treatment Grants from three to five percent of the ADAP earmark and made changes to state eligibility criteria for these funds. Now, Supplemental grant eligibility is now based on current "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 (prior eligibility was based on "severe need" as defined by a January 2000 standard). Award amounts are based on the proportion of states' HIV and AIDS cases in those jurisdictions applying. In addition, while ADAPs eligible for supplemental awards are required to provide a $1 state match for every $4 of federal supplemental funds, the most recent reauthorization allows states to apply for a waiver of this requirement if they have met other Ryan White Part B matching requirements, if applicable. In FY 2007, 16 ADAPs received award funding (an additional 18 were eligible but did not apply).

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 2007 began on April 1, 2007 and ended on March 31, 2008. The Federal FY 2007 began on October 1, 2006 and ended on September 30, 2007. The State FY 2007, in most states, began July 1, 2007 and will end on June 30, 2008. ◗

nation's third largest source of federal funding for HIV care, after Medicaid and Medicare.[9]

Since FY 1996, Congress has specifically earmarked funding for ADAPs within Part B of the Ryan White Program, which is allocated by formula to states.[10] The ADAP earmark is the largest component of the overall ADAP budget, although available funds from it decreased slightly between FY 2006 and FY 2007 (by one percent) for the first time in its history.[11] Many ADAPs also receive funding from other sources, including state general revenue support,[12] funding from other parts of the Ryan White Program, and pharmaceutical manufacturers' drug rebates. These other 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 (DHHS) is the federal agency that administers the Ryan White Program, including ADAPs. In FY 2007, 58 jurisdictions received federal ADAP earmark funding, including all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, American Samoa, Federated States of Micronesia, Guam, Marshall Islands, and Northern Mariana Islands; Palau was eligible to receive funding but did not report any HIV/AIDS cases and therefore did not receive a funding award.

Each state administers its own ADAP and is given flexibility under the Ryan White Program to design many aspects of its program, including client eligibility guidelines, drug purchasing and distribution arrangements, and to some extent, drug formularies. There is no standard client income eligibility level required by law, although clients must be HIV-positive, low-income, and under- or uninsured. The reauthorization of the Ryan White Program in 2006 instituted a new "minimum drug list," to be determined by the Secretary of Health and Human Services, to ensure that antiretrovirals from the core antiretroviral drug classes are included on ADAP formularies. HRSA interpreted this requirement to mandate the inclusion of at least one antiretroviral from within each antiretroviral drug class, as specified by the DHHS guidelines on antiretroviral treatment, on all ADAP formularies, a requirement that went into effect on July 1, 2007. ADAPs still determine how many medications from within each antiretroviral class to offer, what, if any, non-antiretroviral 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 (co-payments 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,[13] 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. Trend data indicate that when one ADAP revenue source decreases, others appear to increase to fill the gap. However, these "levers" are seldom permanent and usually unpredictable.

Detailed Findings

The detailed findings below are based on a comprehensive survey sent to all 58 jurisdictions that received federal ADAP earmark funding in FY 2007; 53 responded (see Methodology). All data are from FY 2007 and June 2007, unless otherwise noted (supplemental data collection was conducted in select areas). For the first time, regional comparisons are provided where available.[2]

CLIENTS, DRUG EXPENDITURES, AND PRESCRIPTIONS

ADAP Clients

ADAP client enrollment and utilization were at their highest levels since the Monitoring Project began tracking ADAPs. Client demographics vary by state and region, but national ADAP client demographics have remained fairly constant over the course of the Monitoring Project with ADAPs primarily serving low-income, uninsured clients, most of whom are minorities.

- 145,799 clients were enrolled in ADAPs nationwide as of June 2007, representing a two percent increase over June 2006 (see Chart 1 and Table I). The number of clients enrolled ranged from a low of 57 in Alaska to a high of 28,723 in California. Client enrollment is an important measure of the aggregate number of clients who use ADAP services over time. More clients are typically enrolled in ADAPs than seek services in any given month; this difference comes as a result of changing clinical needs,

differing prescription lengths, and fluctuation in the availability of other resources to pay for medications. Some individuals cycle on and off ADAP throughout a year, particularly those with Medicaid or Medicare Part D coverage. Medicaid beneficiaries may face limits in their coverage in some states and/or are in the Medicaid spend-down process. Medicare Part D beneficiaries might not use ADAP until they reach the coverage gap (the time when Medicare Part D beneficiaries are responsible for all their drug costs), necessitating a return to ADAP.

- ADAPs provided medications to 101,987 clients across the country in June 2007, about 70% of those enrolled and a six percent increase over June 2006. ADAPs also paid for insurance coverage (premiums, co-payments, and/or deductibles) for 20,960 clients, some of whom may have also received medications (see Charts 2 and 39 and Tables I and XXI).

- Mirroring the national epidemic, most ADAP clients are concentrated in states with the highest numbers of people living with HIV/AIDS. For example, ten states accounted for two-thirds (67%) of total enrollment in June 2007; five states accounted for half (51%: California, New York, Texas, Florida, and Pennsylvania). The distribution is similar for clients served. Regionally, more than a third (37%) of clients enrolled lived in the South, 27% in the West, 25% in the Northeast, and 11% in the Midwest (again, breakdowns are similar by clients served).

- In June 2007, client demographics were as follows (see Charts 5–10 and Tables V–X):
  - Nationally, African Americans and Hispanics represented 59% (33% and 26%, respectively) of clients served. Asian/Native Hawaiian/Pacific Islanders and Alaskan Native/American Indians combined represented approximately two percent of the total ADAP population. Non-Hispanic whites comprised 35%. Regionally, the South has the highest percentage of African Americans among clients served (44% of clients served in the region); the West has the highest percentage of Hispanics (35% of clients served in the region) and the Midwest has the highest percentage of Non-Hispanic whites (50% of clients served in the region).
  - More than three-quarters (77%) of ADAP clients were men.
  - Half of clients (50%) were between the ages of 25 and 44, followed by those between the ages of 45 and 64 (43%).
  - Three-quarters (75%) were at or below 200% of the Federal Poverty Level (FPL), including more than four in ten (43%) who were at or below 100% FPL. In 2007, the FPL was $10,210 annually (slightly higher in Alaska and Hawaii) for a family of one. Regionally, 84% of clients in the South were low-income (200% or less of the FPL) compared to 67% in both the West and Northeast and 79% in the Midwest.
  - A majority of ADAP clients (69%) were uninsured, with few reporting any other source of insurance coverage—15% private, 12% Medicare, and/or two percent Medicaid; two percent were dual beneficiaries of both Medicaid and Medicare. For those with other sources of coverage, ADAP fills the gaps, such as paying client cost-sharing requirements (e.g., co-payments, deductibles, etc.) and/or providing additional medications for those clients who may be subject to monthly or annual prescription drug limits under other forms of coverage. Insurance coverage in June 2007 is similar to coverage reported for the same time period in the last two years, with the exception of Medicaid (six percent in June 2006 and 10% in June 2005).
  - More than half of ADAP clients (51%) had CD4 counts of 350 or below (at time of enrollment or at recertification), one potential indication of more advanced HIV disease. Higher CD4 counts may represent successful treatment or early intervention efforts. CD4 count information was available from 32 ADAPs and reflects clients enrolled in ADAPs over the last 12 months or the most recent 12 months for which data are available. In addition, ADAPs are required to recertify clients two times a year. As a result, these figures do not necessarily represent CD4 counts of new clients.

ADAP Drug Expenditures and Prescriptions

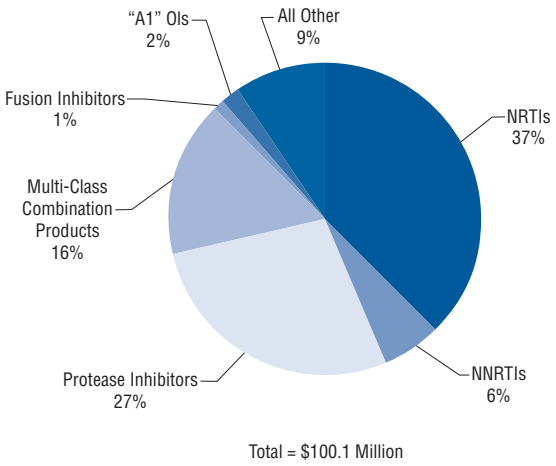
The distribution of drug expenditures and prescriptions varies across states and regions, likely reflecting differing formularies, drug prices, and prescribing patterns. Antiretrovirals, the standard of care for HIV, account for the majority of ADAP drug expenditures and prescriptions filled. (Note: data on drug expenditures and prescriptions are based on June 2007.)

- ADAP drug expenditures were $100,147,921 in June 2007, a five percent increase over June 2006, ranging from a low of $21,195 in Maine to a high of $22.3 million in California (see Chart 11 and Tables I and III). Ten states accounted for three-fourths (75%) of all drug spending; five states (California, New York, Texas, New Jersey, and Florida) accounted for over half (59%) of all drug spending.

- ADAPs spend most of their funding directly on medications with estimated annualized drug spending[14] reaching approximately $1.2 billion in 2007, or 84% of the national

ADAP budget. In addition to providing medications, 39 ADAPs spent $8.8 million on insurance purchasing/maintenance in June 2007, an increase of 63% over June 2006, and report that FY 2007 spending on insurance totaled $74.5 million (see Chart 39 and Table XXI).[15] Twelve ADAPs also reported spending $9.5 million on medication adherence, outreach, and monitoring activities.

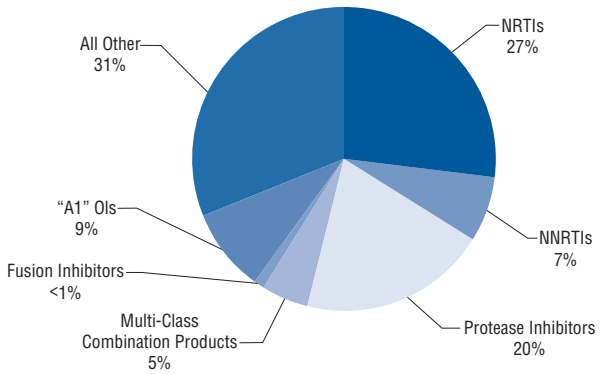
ADAP Drug Expenditures, by Drug Class, June 2007



Total = $100.1 Million

Note: 51 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Nevada, New Mexico, and Northern Mariana Islands did not report data. Percentages may not total 100% due to rounding. NRTIs = Nucleoside Reverse Transcriptase Inhibitors; NNRTIs = Non-Nucleoside Reverse Transcriptase Inhibitors; "A1" OIs = Drugs recommended ("A1") for the prevention and treatment of opportunistic infections (OIs). See Table III.

ADAP Prescriptions Filled, by Drug Class, June 2007



Total = 344,600 Prescriptions

Note: 52 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Nevada, and Northern Mariana Islands did not report data. Percentages may not total 100% due to rounding. NRTIs = Nucleoside Reverse Transcriptase Inhibitors; NNRTIs = Non-Nucleoside Reverse Transcriptase Inhibitors; "A1" OIs = Drugs recommended ("A1") for the prevention and treatment of opportunistic infections (OIs). See Table IV.

- Per capita drug expenditures were $982 in June 2007 (see Chart 13 and Table II), or an estimated $11,784 in annual per capita drug costs. Per capita expenditures in June 2007 ranged from a low of $116 in Oregon to $3,328 in Kansas (see Table II), again likely reflective of differing ADAP formularies, purchasing mechanisms, insurance programs, and/or prices paid by ADAPs across the country for drugs.

- ADAPs filled a total of 344,600 prescriptions in June 2007, ranging from a low of 70 in North Dakota to almost 76,000 in California (see Chart 16 and Table IV).

- Most ADAP drug spending is for antiretrovirals[16] (89% in June 2007). 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 (nearly 60%). The 29 "A1" drugs highly recommended for the prevention and treatment of HIV-related opportunistic infections (OIs),[17,18] accounted for two percent of expenditures and nine percent of prescriptions (see Charts 15 and 16 and Tables III and IV).

- The average expenditure per prescription was $291. It was significantly higher for antiretrovirals ($433) than non-antiretrovirals ($75 for "A1" OIs and $83 for all other drugs). Among antiretroviral drug classes, fusion inhibitors represented the highest expenditure per prescription ($1,323), followed by nucleoside reverse transcriptase inhibitors (NRTIs, $401), protease inhibitors ($391), and non-nucleoside reverse transcriptase inhibitors (NNRTIs, $281). Per prescription expenditures for multi-class combination products were $902 (see Chart 14).[19]

Trends in Clients and Drug Expenditures

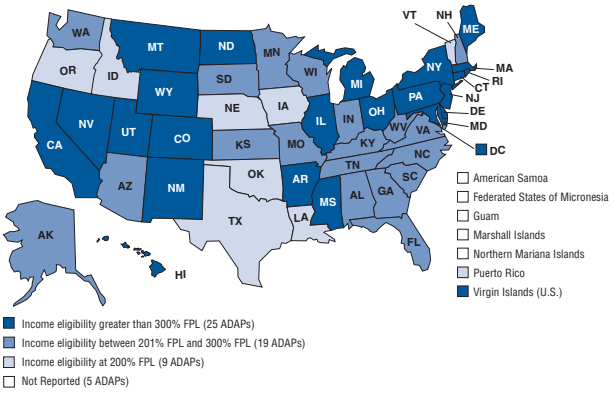
- Client enrollment has grown over time, reaching its highest level (145,799 in June 2007) since the program began, although the rate of growth has slowed in recent years (enrollment rose by two percent between June 2006 and June 2007).

- Client utilization (the number of clients receiving prescription medications) has grown significantly since 1996 (226% among the same 47 ADAPs reporting data in both periods), but at a decreasing rate in recent years and has generally lagged behind the rate of increase in drug expenditures (see Charts 3, 4, and 12). Client utilization overall increased by five percent between June 2006 and June 2007 (among the same 47 ADAPs). As expected, the one percent decrease in FY 2006 client utilization was a

temporary shift due to implementation of the Medicare Part D benefit. The move of Part D-eligible ADAP clients into the new benefit provided some ADAPs short-term client stability.

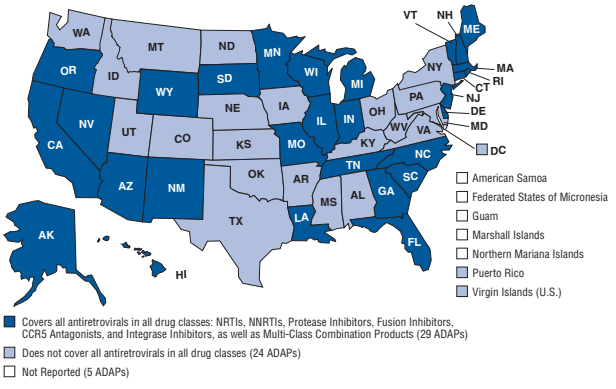
- Drug spending by ADAPs has increased more than six-fold (525%) since 1996, more than twice the rate of client growth over this same period (among the same 46 ADAPs reporting data in both periods). It too has continued to increase but at slower rates. Between June 2006 and June 2007, drug expenditures grew six percent (among the same 46 ADAPs). As observed with client utilization last year, there was a one-time decrease in drug expenditures (seven percent between June 2005 and June 2006), similarly attributable to the expected one-time move of Medicare-eligible ADAP clients into Part D, and/or the transition to ADAPs paying for client cost-sharing for Medicare Part D (versus direct drug expenditures).

ADAP Income Eligibility, December 31, 2007



Note: 53 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Marshall Islands, and Northern Mariana Islands did not report data. The 2007 Federal Poverty Level (FPL) was $10,210 (slightly higher in Alaska and Hawaii) for a household of one. See Table XI.

ADAP Formulary Coverage of Antiretroviral Drugs, December 31, 2007



Note: 53 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Marshall Islands, and Northern Mariana Islands did not report data. NRTIs = Nucleoside Reverse Transcriptase Inhibitors; NNRTIs = Non-Nucleoside Reverse Transcriptase Inhibitors. See Table XII.

ELIGIBILITY CRITERIA AND FORMULARIES

ADAP Eligibility Criteria

ADAP eligibility criteria are determined by each state, although clients are required by law to be HIV-positive, low-income, and must have insufficient or no insurance. There is no minimum income eligibility set by the federal government. Eligibility decisions reflect budget conditions within a state and the size of the population living with HIV/AIDS needing services. As a result of these factors, eligibility criteria vary by state, although some ADAPs set their eligibility criteria to be consistent with other health programs within their state (see Charts 17 and 18 and Table XI).

- All ADAPs require that individuals provide clinical documentation of HIV infection. Seven ADAPs reported additional clinical eligibility criteria (e.g., specific CD4 or viral load ranges).

- ADAP income eligibility in June 2007 ranged from 200% FPL in nine states to 500% FPL in six. Overall, 25 states set income eligibility at greater than 300% FPL, four more states than last year's report (Arkansas, Colorado, and Wyoming raised their income eligibility levels and New Mexico did not report data last year). Nineteen states were between 201% and 300% FPL. In addition to using income to determine eligibility, 18 ADAPs reported having asset limits in place in June 2007.

- All ADAPs require enrollees to be residents of the state in which they are seeking medications. Many ADAPs require documentation of residency and a few have specific residency requirements (e.g., must be a resident for 30 days).

ADAP Formularies

ADAP formularies (the list of drugs covered) vary significantly across the country. Until the most recent reauthorization of the Ryan White Program, there was no minimum requirement for ADAP formularies, although federal law specified that states use ADAP funds "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." Effective July 1, 2007, all ADAPs were required to include at least one drug from each antiretroviral drug class; ADAPs have a grace period[20] within which they must add a drug from a new class and at the time of this survey, the grace period was still in effect for two new antiretroviral classes (CCR5 antagonists and integrase inhibitors), for which the first medications were only approved in August and October, respectively. The minimum formulary requirement does not apply to multi-class combination products (not considered a unique class of drugs), drugs for preventing and treating opportunistic infections (OIs), hepatitis C treatments, or drugs for other HIV-related conditions (e.g., depression, hypertension, and diabetes) (see Charts 19–21 and Tables XII and XIII).

- As of December 2007, ADAP formularies ranged from 28 drugs covered in Louisiana to more than 460 in New York, as well as open formularies[21] in four states (Massachusetts, New Hampshire, New Jersey, and Oregon).

ADAP WAITING LISTS AND OTHER COST-CONTAINMENT MEASURES

Since the beginning of ADAP, states have struggled to meet client demand while facing growing prescription drug costs. As a result, many ADAPs have had to make difficult decisions between client access and services, sometimes leading to the implementation of waiting lists and other cost-containment measures.

In certain cases, states have capped program enrollment until more resources become available. When an enrollment cap is reached, the next individual 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 once the program can accommodate them.

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 health programs within their state, or through pharmaceutical 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 addition to waiting lists, states use a variety of other strategies to contain costs, some of which may affect client access and services. Occasionally, states must implement cost-containment measures multiple times over the course of a year, depending on their fiscal situation and client demand. States may also remove a measure when it is no longer needed. Cost-containment measures (other than waiting lists) used over time by ADAPs have included:

- Lowering financial eligibility criteria;
- Limiting and/or reducing ADAP formularies;
- Limiting access for a particular drug(s), including instituting a drug-specific waiting list;
- Instituting cost-sharing requirements for clients;
- Instituting monthly or annual limits on per capita expenditures.

It is important to note that some of these measures may be used by ADAPs to ensure efficient use of funds and support appropriate clinical management of patients on an ongoing basis, and therefore they may be considered standard program management policies.

Recent factors have combined to ease some of the pressure on ADAPs, including the President's ADAP Initiative (PAI), Medicare Part D, state-level funding contributions, pharmaceutical manufacturer drug rebates, and increased ADAP Supplemental Drug Treatment Grant funding. For the first time in the tracking of the program, waiting lists were nearly eliminated and some ADAPs removed existing cost-containment measures. However, this relief was not felt equally across the country and a small number of ADAPs needed to implement new program limitations to manage costs. ◗

- All ADAPs were in compliance with the new minimum formulary requirement which, at the time of data collection, applied to the four longer-standing antiretroviral drug classes—NRTIs, NNRTIs, protease inhibitors, and fusion inhibitors. In addition, although still within the grace period, most ADAPs had already added the new CCR5 antagonist (44 ADAPs) and integrase inhibitor (43 ADAPs) to their formularies.

- The majority of ADAPs (29) cover every approved antiretroviral in each of the six drug classes.

- All ADAPs also cover the one available multi-class combination product on their formulary.

- The minimum formulary requirement led South Dakota to add protease inhibitors and fusion inhibitors to its formulary for the first time and, although only required to add one protease inhibitor under the law, the state added all 10 approved medications in this class. Three additional states added fusion inhibitors (Alaska, Idaho, and North Dakota) as well.

- Thirty-nine ADAPs cover 15 or more of the 29 drugs highly recommended ("A1") for the prevention and treatment of opportunistic infections, including six that cover all 29 (Alabama, Alaska, Massachusetts, New Hampshire, New Jersey, and Oregon). Thirteen ADAPs cover less than 15 of these medications. One ADAP 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 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.

- Hepatitis A, B, and C infections are important considerations for people with HIV/AIDS, and ADAPs play an important role in the provision of treatment for the hepatitis C virus (HCV) and vaccines for hepatitis A and B viruses (see Chart 21 and Table XIII).
  - In June 2007, 22 ADAPs covered treatment for HCV on their formularies, down from 25 in 2006. HCV is classified as an HIV-related opportunistic infection, due to the relatively high co-infection rate of HIV and HCV.[18,22] Currently, no national funding infrastructure exists to provide treatment to those infected only with HCV, and state and local resources for such treatment vary greatly. Without HCV treatment programs, most of the burden for treating co-infected patients has fallen on ADAPs and other Ryan White programs. Across ADAPs, utilization of HCV treatment is low. The reason most commonly cited by ADAPs is that clients perceive the treatment to be too difficult. A secondary reason is the lack of client interest and the lack of providers to prescribe treatment.
  - 28 ADAPs cover hepatitis A and B vaccines, which are recommended for those at high risk for and living with HIV.[23]

WAITING LISTS AND OTHER COST-CONTAINMENT MEASURES/MANAGEMENT POLICIES

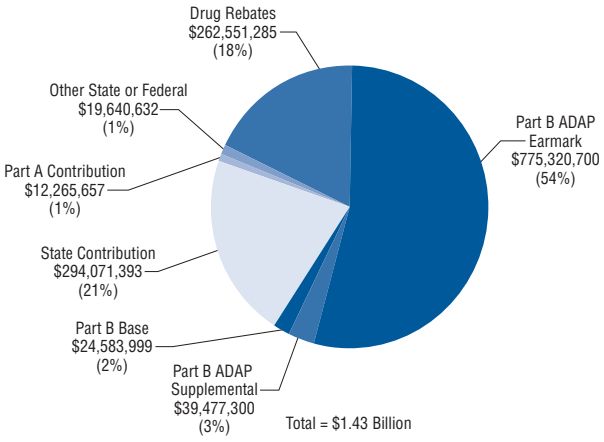
Waiting Lists

ADAP waiting lists have been documented since the Monitoring Project began tracking ADAPs in 1996, with detailed trend analysis beginning in 2002. At that time 1,108 individuals in seven ADAPs were on waiting lists for ADAP medications. Since then, a total of 20 different ADAPs have instituted a waiting list at some point with the largest number of clients on waiting lists reported at 1,629 in May 2004.

- In September 2007, and for the first time since tracking ADAPs, no ADAPs had client waiting lists. By March 2008, one state (Montana) had a waiting list in place (with three people on the waiting list), compared to four states with a combined total of 571 people on waiting lists in March 2007. This decrease was the result of several factors, including the President's ADAP Initiative (PAI), which provided short-term, targeted relief; increased state funding for ADAPs in some states and growing revenue from drug rebates; continued implementation of Medicare Part D; and, for those states with particular ADAP capacity limitations, increased ADAP supplemental funding. These factors contributed to the ability of states to move clients off waiting lists and into their programs (see Charts 22 and 23 and Table XIV).

- The size of waiting lists has fluctuated within and across states over time. The number of people on waiting lists reached its peak in mid-2004. Based on bi-monthly surveys conducted between July 2002 and March 2008 (37 surveys overall):
  - There was only one period (September 2007) when there were no ADAPs reporting waiting lists.
  - 20 ADAPs reported having a waiting list in place at some point over the entire period.
  - The highest number of states reporting a waiting list in any given period was 11.
  - 12 ADAPs had waiting lists in 10 or more of the survey periods.
  - The number of people on waiting lists ranged from a low of one to a high of 1,629 (the average was 653). The highest number of individuals on any one state's waiting list was 891 (North Carolina);

National ADAP Budget, by Source, FY 2007



Note: 53 ADAPs reported data. American Samoa, Federated States of Micronesia, Guam, Marshall Islands, and Northern Mariana Islands did not report FY 2007 data, but their federal ADAP earmark and supplemental awards were known and incorporated. The total FY 2007 budget includes federal, state, and drug rebate dollars. Cost recovery funds, with the exception of drug rebate dollars, are not included in the total budget. See Table XVI.

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 South Carolina (320). The lowest average was four in Guam and Wyoming.

- When states have had to use waiting lists, they generally report working with pharmaceutical assistance programs (PAPs) to help those on waiting lists access medications where possible. These programs, however, are not meant to be permanent sources of drug access and they require people to apply often, sometimes as frequently as every month, and to apply to each drug manufacturer separately.

Other Cost-Containment Measures and Management Policies

While waiting lists have always been the most visible representation of unmet need for ADAP services, there are other ways in which ADAPs have sought to control costs or manage resource constraints. These include reducing or limiting formularies, establishing enrollment caps on particular drugs, instituting patient cost-sharing on medications when it was previously not required, or limiting the number of prescriptions per month. As with the waiting list trend, fewer ADAPs reported instituting such measures and maintaining them through the end of FY 2007 compared with last year's report (three, not including the state with a waiting list, as of March 2008 compared to eight in the prior year), and seven ADAPs eliminated an existing cost-containment measure (see Chart 24). It is important to note that these measures are also used by ADAPs to ensure efficient use of funds and support appropriate clinical management of patients (see Chart 25 and Table XV).

ADAP BUDGET

The national ADAP budget reached $1.43 billion in FY 2007, an increase of three percent ($42 million) over FY 2006 (for purposes of determining the overall ADAP budget, federal, state, and drug rebate funds are aggregated). Since FY 1996, the budget has grown more than seven-fold. While the ADAP earmark continues to represent the largest share of the national ADAP budget, drug rebates have become the biggest driver of budget growth and only drug rebates and ADAP supplemental funding increased over the last period; all other funding sources declined (see Charts 26–36 and Tables XVI–XVIII):

- ADAP earmark funding,[11] specifically appropriated by Congress each year for ADAPs, has risen from one-quarter of the budget in FY 1996, the year it was created, to 54% in FY 2007. For the first time since the earmark was created, however, funding available from it decreased slightly (by one percent) between FY 2006 and FY 2007 (the ADAP supplemental, a legislated set-aside of the earmark, is accounted for separately below) (see Charts 29 and 31 and Tables XVI and XVIII).

- While ADAP Supplemental Drug Treatment Grants accounted for only three percent of the overall ADAP budget (as only 16 states received awards), they grew more than four-fold between FY 2006 and FY 2007 and were one of only two funding sources that increased over the period. They accounted for up to 18% of ADAP budgets in the states that received this funding. The overall supplemental amount is mandated by law to be five percent of the Congressionally appropriated ADAP earmark, an increase from three percent in the previous authorization period—this increased percentage, which resulted in increased supplemental grant funding for the first time, was by design, intended by Congress to help redistribute funds to ADAPs with more limited formularies, lower income eligibility thresholds, and those that had cost-containment measures in place. In addition, Ryan White Reauthorization changed the state matching requirement for the Supplemental Drug Treatment Grants, permitting a waiver of the requirement if other Part B matching requirements have been met (if applicable) and potentially providing

additional incentives for eligible states to seek funding (three new states received it in FY 2007) (see Charts 29 and 32 and Tables XVI and XVIII).

- Ryan White Part B base funding, formula-based funding allocated to states (other than that earmarked for ADAP) represented just two percent of the national ADAP budget in FY 2007; states are not required to allocate these funds to ADAPs. Part A funding represented one percent of the ADAP budget in FY 2007; these funds, which are allocated to metropolitan jurisdictions, are distributed by these jurisdictions based on locally-determined priorities and are not required to be allocated to ADAPs. Part B base and Part A funds were the only two funding sources in the national ADAP budget that were less in FY 2007 than in FY 1996 (see Charts 29, 33, and 34 and Tables XVI and XVIII). [Note: The 2006 Reauthorization created two tiers of Part A jurisdictions, eligible metropolitan areas (EMAs) and transitional grant areas (TGAs). To be eligible as an EMA, metropolitan areas must have a general population exceeding 500,000 and documentation of 2,000 or more actual AIDS cases reported in the previous five years. TGAs are those areas documenting 1,000–1,999 AIDS cases in the last five years. In FY 2007, there were 22 EMAs and 34 TGAs funded under Part A of the Ryan White Program (see Chart 41 and Table XXIII).]

- State funding (general revenue support) continued to account for the second largest share of the ADAP budget, although it decreased by four percent between FY 2006 and FY 2007, the first decrease since FY 1996. States are not required to provide funding to their ADAPs (except in limited cases), although many have historically done so either over a sustained period of time or at critical junctures to address gaps in funding. Such funding is, for the most part, dependent on individual state decisions and budgets; even where states are required to provide a match of federal Part B Ryan White base funds, they are not required to put this funding toward ADAP. In the case of the ADAP supplemental, where states are required to provide a state match (or apply for a waiver of this requirement if they have met their Part B match, if applicable), such funding represents a relatively small share ($35 million, or 11%, in FY 2007) of state funding for ADAPs (see Charts 29 and 35 and Tables XVI and XVIII).

- An increasingly critical component of the ADAP budget is drug rebates, which drove the overall budget growth between FY 2006 and FY 2007. Drug rebates have risen from six percent of the national ADAP budget in FY 1996 to 18% in FY 2007, growing more than 20-fold. While not all ADAPs obtain rebates, drug rebates accounted for about one-third or more of the ADAP budget in 11 states in FY 2007. 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 expenditures and prices (since rebates are based on a percentage of drug price). Drug rebates, however, are not available to some states due to their type of drug purchasing system and, while an important source of revenue for others, may be variable and unstable (some are based on negotiations determined with pharmaceutical manufacturers), may be subject to a lag, and could require intense labor on the part of ADAP staff to collect (see Charts 29 and 36 and Tables XVI and XVIII).

- ADAP budget composition varies by region. For example, ADAP earmark funding accounts for the largest share of the budget in the South (65%) followed by state contributions (19%) and drug rebates (three percent). In the Northeast, earmark funding accounts for 52% of the budget, with drug rebates representing 26% and state contributions 17%. ADAP budgets in the West are equally comprised of earmark funding, state contributions, and drug rebates, and in the Midwest, 63% of the ADAP budget is from earmark funding, 16% is from state contributions and 15% is from drug rebates. Nine ADAPs in the South received most (88%) of the ADAP supplemental funding available. Seven ADAPS in the Midwest and West received the remaining 12% of ADAP supplemental funding. No state in the Northeast received ADAP supplemental funding in FY 2007.

- By definition, all eligible jurisdictions (58 in FY 2007) receive federal ADAP earmark funding based on a formula of living HIV and AIDS cases, but, as noted above, 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. The breakdown of other sources of funding across the country was as follows (among 53 ADAPs reporting data) (see Chart 27 and Table XVI):
  - Part B ADAP Supplemental Treatment Grants: 16 ADAPs received funding (an additional 18 were also eligible but did not apply);
  - Part B Base Funds: 21 ADAPs received funding, 32 did not;
  - State General Revenue Support: 40 ADAPs received funding, 13 did not;
  - Part A Funds: 8 ADAPs received funding, 45 did not;
  - Other State/Federal Funds: 17 received funding, 36 did not;
  - Drug Rebates: 42 ADAPs received funding, 11 did not.

- Additionally, despite a three percent increase in the national ADAP budget across all ADAPs between FY

2006 and FY 2007, some ADAPs had decreases either in their overall budget or for specific funding streams. Some of these decreases were related to decreases in the overall federal funding allocation, federal funding distribution changes, and/or individual adjustments states made to their budgets (see Chart 28 and Tables XVII and XVIII):

- Overall Budget: 35 ADAPs had increases or level funding, 18 had decreases;
- Part B ADAP Earmark funding: 27 ADAPs had increases, 31 had decreases;
- Part B ADAP Supplemental Drug Treatment Grants: 16 had increases, seven had decreases;
- Part B Base Funds: 17 ADAPs had increases or level funding, 12 had decreases;
- State General Revenue Support: 26 ADAPs had increases or level funding, 16 had decreases;
- Part A Funds: five ADAPs had increases or level funding, nine had decreases;
- Drug Rebates: 31 ADAPs had increases or level funding, 13 had decreases.

- While not counted as an ADAP budget category (due to its high variability and significant delays including some that are multi-year), cost recovery, reimbursement from third party entities such as private insurers and Medicaid, for medications purchased through ADAP (other than drug rebates), represented $25.9 million in FY 2007. Private insurance recovery, in which an ADAP receives reimbursement from insurance providers, was the largest component (68%). Cost recovery from Medicaid represented 26% and other sources, including manufacturers' free product, represented six percent (see Chart 37 and Table XIX).

DRUG PURCHASING MODELS AND INSURANCE COVERAGE ARRANGEMENTS

Drug Purchasing Models

- The federal 340B Drug Discount Program, authorized under the Veterans Health Care Act of 1992, enables ADAPs to purchase drugs at or below the statutorily defined 340B ceiling price.[24] Participation in the program is not mandatory, yet all ADAPs participate (see Chart 38 and Table XX).
  - ADAPs may purchase drugs either at a lower negotiated price directly from wholesalers or through retail pharmacy networks and then apply to drug manufacturers for rebates. As of June 2007, 29 ADAPs reported purchasing directly; 24 reported purchasing through a pharmacy network and then seeking rebates.
  - Direct purchase ADAPs can also choose to participate in the HRSA Prime Vendor Program,[24] which was created to negotiate pharmaceutical pricing below the 340B price. The "prime vendor" is an entity that negotiates with manufacturers on behalf of a group of purchasers, in this case 340B-covered entities, to achieve sub-340B prices. Twelve of the 29 ADAPs that purchase directly from wholesalers participate in the HRSA Prime Vendor Program.
  - Although the District of Columbia participates in the 340B program, it purchases the majority of its drugs through the Department of Defense, allowing it to access the Federal Ceiling Price, a lower price only available to certain federal purchasers. Several other states that participate in the 340B program also have state laws regarding negotiation processes that result in lower prices.
  - NASTAD's ADAP Crisis Task Force 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.

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 drugs. The goal of the meetings was to obtain multi-year concessions on 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-antiretroviral 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 estimated 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, Michigan, 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 antiretroviral drugs for all payers) and other community partners. ◗

Insurance Purchasing/Maintenance Programs

- The Ryan White Program allows states to use ADAP 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.[25,26] States are increasingly using ADAP funds for this purpose. More ADAPs than ever before (40) reported purchasing or maintaining insurance in 2007, representing $74.5 million in expenditures in FY 2007. In June 2007, 20,960 ADAP clients were served by such arrangements—53% higher than in June 2006. June 2007 expenditures were 63% higher than in June 2006, although overall 2007 expenditures were 11% lower than in 2006 (see Chart 39 and Table XXI).

- These strategies appear to be cost effective—in June 2007, spending on insurance represented an estimated $422 per capita, less than half of per capita drug expenditures in that month ($982).

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. It is estimated that 12% of ADAP clients are also Medicare-eligible (representing about 17,000 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 encouraged to coordinate with Medicare prescription drug plans and, in accordance with state policy, pay for drug plan premiums, deductibles, coinsurance, and co-payments.[25] However, the MMA does not allow ADAP funds to be counted toward a beneficiary's True Out of Pocket expenses (TrOOP). This means ADAP enrollees whose income defines them as a standard Part D beneficiary (and, therefore, not eligible for low income assistance), must incur these costs themselves when in the coverage gap before they are eligible to receive catastrophic coverage under their Medicare drug plan.[27]

- To meet the federal requirements and maintain appropriate medication coverage for their clients, 30 ADAPs report having developed policies to coordinate with the Part D benefit (see Chart 40 and Table XXII). As of May 2007:
  - 20 ADAPs pay Part D premiums;
  - 25 ADAPs pay Part D deductibles;
  - 28 ADAPs pay Part D co-payments for ADAP clients eligible for Part D;
  - 26 ADAPs pay for all medications on their ADAP formularies when their Part D clients reach the coverage gap or "doughnut hole". This action meets the requirement of "payer of last resort" but also provides a safety net for continuing HIV treatment access for beneficiaries.

- In addition, 21 ADAPs report disenrolling Medicare Part D eligibles who qualify for the full low-income subsidy benefit under Part D (those dually eligible for Medicaid and Medicare and those with incomes less than 135% FPL). A subset of ADAPs also reports disenrolling Part D eligibles who only qualify for partial subsidies under Part D or no subsidy at all, in which case the ADAP tries to transition these clients from ADAP to their State Pharmacy Assistance Program (SPAP), if one is available, since SPAP contributions do count toward TrOOP.

Implementing the Part D benefit continues to be a complicated process for some ADAPs, depending on availability of Part D prescription drug plans in their state and their own program infrastructure and financial resources for coordinating with the benefit. However, the payer of last resort mandate requires that ADAPs do their due diligence to ensure all other payer sources for prescription drugs have been exhausted before an individual can be eligible for ADAP services.

CHARTS AND TABLES

Charts and tables for each major finding, with data provided by states, are included in the full report. State-level data from this report are provided on Kaiser's StateHealthFacts.org website: www.statehealthfacts.org/hiv.

REFERENCES AND NOTES

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

[2] U.S. Census Bureau, Geographic Terms and Definitions, Available at: http://www.census.gov/popest/geographic/ (accessed March 10, 2008).

[3] Between September 2004 and March 2006. See: The White House, "Extending and Improving the Lives of Those Living with HIV/AIDS," Fact Sheet, Available at: http://www.whitehouse.gov/news/releases/2004/06/20040623-1.html (accessed March 18, 2008).

[4] Center on Budget and Policy Priorities, http://www.cbpp.org/pubs/sfp.htm (accessed March 10, 2008).

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

[6] HRSA HIV/AIDS Bureau, http://hab.hrsa.gov/treatmentmodernization (accessed March 7, 2008).

[7] 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).

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 2007, 58 jurisdictions received earmark funding and all 58 were surveyed; 53 responded. American Samoa, Federated States of Micronesia, Guam, Marshall Islands, and Northern Mariana Islands did not respond; these jurisdictions represent less than one percent of estimated living HIV and 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 2007 and FY 2007, unless otherwise noted. Supplemental data collection is conducted in certain areas to obtain more current data, including: waiting lists, other cost-containment measures, 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. 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 one-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: http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2006supp_vol12no3/table1.htm.

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

[9] White House, Office of Management and Budget, February 2008.

[10] Up until the most recent reauthorization of Ryan White, three percent of the ADAP earmark was set-aside for the ADAP Supplemental Drug Treatment Grant, grants to states with severe need. As of FY 2007, this amount was increased to five percent. See box on "Allocation of Federal Funding to ADAPs & State Match Requirements".

[11] Congress earmarks a specific amount of Part B funds to ADAP each year. To adhere to other provisions of the Ryan White Program, however, the amount available to distribute to states may vary from that original earmark. Five percent of the ADAP earmark is removed to fund ADAP supplemental grants and remaining earmark funds may further fluctuate due to applicable hold harmless requirements. For example, in FY 2007, Congress appropriated $789.5 million to the ADAP earmark, of which $39.5 million was used for ADAP supplemental grants. In order to meet hold harmless requirements, HRSA then added approximately $25 million of Part B base funds to applicable state ADAP earmark awards.

[12] 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".

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

[14] This estimate is based on annualizing June 2007 drug expenditures. It is important to note that June 2007 expenditures may not be representative of monthly expenditures overall.

[15] There may be some duplication in the amount reported for drug expenditures and the amount reported for insurance purchasing/maintenance because some ADAPs are unable to disaggregate co-payments into these two categories.

[16] FDA, "Drugs Used in the Treatment of HIV Infection", Available at: http://www.fda.gov/oashi/aids/virals.html (accessed March 7, 2008).

[17] 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 7, 2008).

[18] CDC, "Treating Opportunistic Infections Among HIV-Infected Adults and Adolescents." *MMWR* 2004; 53(No. RR15):1-112. Available at: http://www.aidsinfo.nih.gov/ (accessed March 7, 2008).

[19] While multi-class combination products are not considered a unique class of drugs, the costs for these drugs were considered separately in this report (in the *2007 National ADAP Monitoring Project Annual Report* they were included in the NRTI class). The per prescription cost is difficult to compare, since the one approved multi-class combination product includes three different drugs (two NRTIs and one NNRTI), and can appear higher in cost than it actually is if compared to single class products.

[20] HRSA's HIV/AIDS Bureau requires that when a new drug comes to the market and is approved by the FDA, ADAPs do not have to add the drug to their formularies (to be compliant with the new minimum formulary requirement) until the DHHS "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents" have been revised to incorporate the drug. Once the revised guidelines are released, ADAPs have 90 days to officially add the new drug to their formularies.

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

[22] CDC, Frequently Asked Questions and Answers About Coinfection with HIV and Hepatitis C Virus. Available at http://www.cdc.gov/hiv/resources/qa/HIV-HCV_Coinfection.htm (accessed March 7, 2008).

[23] CDC, "Sexually Transmitted Diseases Treatment Guidelines, 2006," *MMWR*, Vol. 55, September 2006.

[24] HRSA, Pharmacy Services Support Center, "What is the 340B Program?" Available at: http://pssc.aphanet.org/about/whatisthe340b.htm (accessed March 7, 2008).

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

[26] 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.

[27] HRSA, HIV/AIDS Bureau, "Medicare Prescription Drug Benefit and CARE Act Grantees." Available at: http://www.hrsa.gov/medicare/hiv/about.htm (accessed March 7, 2008).

Matrix of Key ADAP Highlights

State/Territory	Financial Eligibility as % of FPL (GR = Gross Income; NET = Net Income), December 31, 2007	Total FY 2007 Budget*	FY 2007 State Contribution	FY 2007 State Contribution as % of Total Budget	June 2007 Clients Served	June 2007 Drug Expenditures	June 2007 Prescriptions Filled	June 2007 Per Capita Drug Expenditures
Alabama	250% GR	$16,973,461	$4,452,565	26%	981	$909,660	2,771	$927.28
Alaska	300% GR	$668,308	$29,326	4%	54	$40,244	174	$745.27
American Samoa	—	$1,979	—	—	—	—	—	—
Arizona	300% GR	$10,610,361	$1,000,000	9%	824	$890,306	4,518	$1,080.47
Arkansas	500% GR	$4,245,310	$0	0%	305	$729,460	839	$2,391.67
California	400% GR	$288,106,287	$90,565,000	31%	18,939	$22,285,233	75,869	$1,176.68
Colorado	400% GR	$14,407,880	$4,181,268	29%	921	$744,646	2,341	$808.52
Connecticut	400% NET	$15,876,996	$606,678	4%	1,351	$1,586,003	5,771	$1,173.95
Delaware	500% GR	$4,306,754	$0	0%	244	$85,350	911	$349.79
District of Columbia	400% GR	$14,429,241	$0	0%	740	$546,787	2,171	$738.90
Federated States of Micronesia	—	$4,947	—	—	—	—	—	—
Florida	300% NET	$97,649,008	$10,500,000	11%	8,640	$4,668,285	15,937	$540.31
Georgia	300% GR	$45,869,313	$14,003,984	31%	3,411	$2,889,590	10,021	$847.14
Guam	—	$91,084	—	—	—	—	—	—
Hawaii	400% GR	$2,570,088	$440,535	17%	205	$206,857	690	$1,009.06
Idaho	200% GR	$1,914,730	$779,300	41%	107	$349,320	479	$3,264.67
Illinois	400% GR	$36,878,149	$9,250,000	25%	3,042	$2,997,094	8,485	$985.24
Indiana	300% GR	$12,890,359	$0	0%	1,172	$261,946	6,451	$223.50
Iowa	200% GR	$2,272,594	$555,000	24%	225	$147,613	610	$656.06
Kansas	300% NET	$7,070,222	$2,500,000	35%	469	$1,560,997	1,114	$3,328.35
Kentucky	300% GR	$6,387,343	$250,000	4%	780	$417,622	2,563	$535.41
Louisiana	200% GR	$16,735,021	$0	0%	1,559	$1,291,580	3,722	$828.47
Maine	500% GR	$1,035,666	$60,000	6%	147	$21,195	230	$144.18
Marshall Islands	—	$2,968	—	—	—	—	—	—
Maryland	500% GR	$50,545,655	$0	0%	3,294	$2,625,968	8,686	$797.20
Massachusetts	488% GR	$20,150,935	$1,900,000	9%	2,833	$460,393	10,661	$162.51
Michigan	450% GR	$18,913,552	$0	0%	1,558	$1,621,669	7,082	$1,040.87
Minnesota	300% GR	$9,895,065	$1,100,000	11%	474	$544,582	1,661	$1,148.91
Mississippi	400% GR	$8,027,816	$750,000	9%	690	$730,056	2,380	$1,058.05
Missouri	300% GR	$17,929,783	$3,590,224	20%	1,062	$1,245,829	4,017	$1,173.10
Montana	330% GR	$740,954	$189,000	26%	66	$42,608	144	$645.58
Nebraska	200% GR	$2,234,366	$900,000	40%	236	$165,068	482	$699.44
Nevada	400% GR	$7,646,830	$1,777,000	23%	603	—	—	—
New Hampshire	300% GR	$2,907,001	$500,000	17%	136	$91,482	472	$672.66
New Jersey	500% GR	$71,515,052	$6,000,000	8%	4,241	$6,095,718	23,243	$1,437.33

Matrix of Key ADAP Highlights *(continued)*

State/Territory	Financial Eligibility as % of FPL (GR = Gross Income; NET = Net Income), December 31, 2007	Total FY 2007 Budget*	FY 2007 State Contribution	FY 2007 State Contribution as % of Total Budget	June 2007 Clients Served	June 2007 Drug Expenditures	June 2007 Prescriptions Filled	June 2007 Per Capita Drug Expenditures
New Mexico	400% GR	$2,243,691	$0	0%	58	—	155	—
New York	431% GR	$240,592,758	$45,000,000	19%	13,127	$19,628,372	54,853	$1,495.27
North Carolina	250% GR	$32,702,340	$9,620,856	29%	2,712	$2,695,867	8,137	$994.05
North Dakota	400% NET	$315,934	$0	0%	28	$24,314	70	$868.36
Northern Mariana Islands	—	$3,958	—	—	—	—	—	—
Ohio	500% GR	$17,366,314	$2,636,422	15%	1,681	$728,746	5,988	$433.52
Oklahoma	200% GR	$8,072,744	$1,615,000	20%	668	$467,532	1,716	$699.90
Oregon	200% GR	$10,631,947	$1,875,937	18%	1,493	$172,566	4,950	$115.58
Pennsylvania	350% GR	$59,390,779	$16,228,000	27%	3,259	$4,375,219	13,979	$1,342.50
Puerto Rico	200% GR	$37,860,798	$8,000,000	21%	3,413	$3,239,852	13,126	$949.27
Rhode Island	400% GR	$3,502,014	$0	0%	304	$177,248	488	$583.05
South Carolina	300% GR	$24,119,801	$4,500,000	19%	1,646	$1,109,251	3,346	$673.91
South Dakota	300% GR	$629,085	$0	0%	56	$43,674	113	$779.90
Tennessee	300% GR	$17,927,004	$5,200,000	29%	2,228	$1,053,258	3,164	$472.74
Texas	200% GR	$100,511,125	$33,649,329	33%	7,501	$6,439,495	17,916	$858.48
Utah	400% GR	$3,955,961	$184,427	5%	472	$215,123	699	$455.77
Vermont	200% NET	$827,212	$0	0%	127	$66,702	217	$525.21
Virgin Islands (U.S.)	400% NET	$957,874	$140,000	15%	87	$49,872	160	$573.24
Virginia**	300% GR	$23,908,487	$2,612,200	11%	1,535	$1,948,257	4,329	$1,269.22
Washington	300% GR	$18,875,980	$6,097,842	32%	1,354	$743,227	4,642	$548.91
West Virginia	250% GR	$2,124,271	$0	0%	161	$134,661	382	$836.40
Wisconsin	300% GR	$9,025,622	$464,000	5%	706	$523,765	1,509	$741.88
Wyoming	332% GR	$860,188	$367,500	43%	62	$57,756	166	$931.54
Total		**$1,427,910,966**	**$294,071,393**	**21%**	**101,987**	**$100,147,921**	**344,600**	**$981.97**

*The total FY 2007 budget includes federal, state, and drug rebate dollars. Cost recovery funds, with the exception of drug rebate dollars, are not included in the total budget.

**Virginia has an FPL of 333% in Northern Virginia and 300% FPL in all other parts of the state.

Note: The number of ADAPs reporting data for each category above varies. See Tables I, II, III, IV, XI, and XVI for additional detail. A dash (—) indicates no data available from the ADAP. A zero ($0) indicates a response of zero ($0) from the ADAP. The 2007 Federal Poverty Level (FPL) was $10,210 (slightly higher in Alaska and Hawaii) for a household of one.

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