



**MAXIMIZING ACCESS TO MEDICATIONS
THROUGH EFFICIENT USE OF
CARE ACT RESOURCES**



HEALTH RESOURCES

AND SERVICES

ADMINISTRATION

HIV/AIDS BUREAU

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**MAXIMIZING ACCESS TO MEDICATIONS THROUGH
EFFICIENT USE OF CARE ACT RESOURCES**

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INTRODUCTION

Since its initial passage in 1990, the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act has been critical in ensuring access to HIV care and treatment for hundreds of thousands of persons living with HIV/AIDS and their families. Today, the CARE Act remains a cornerstone of the Federal effort to fight HIV/AIDS and continues to provide a critical safety net for over 571,000 individuals affected by HIV/AIDS who are uninsured or underinsured each year.

With approximately 40,000 new HIV infections each year in the United States, but fewer AIDS deaths (as the result of remarkable new treatments), more people than ever are living with HIV/AIDS—more people who need the care and services funded by the CARE Act. Increasingly, these are historically underserved populations, including racial and ethnic minorities. Responding to these individuals and families, who depend on the CARE Act for essential health and support services, involves a number of challenges:

- + The ever-increasing cost of health care, particularly the cost of highly active antiretroviral therapy (HAART)
- + An increasing demand on the CARE Act as a primary source for long-term ambulatory and supportive care
- + Changes in the underlying health care financing system that surrounds CARE Act programs.

Each CARE Act reauthorization offers the U.S. Department of Health and Human Services an opportunity to assess how it can make the CARE Act even more effective at responding to changes in the epidemic and appropriately targeting resources. These policy studies attempt to improve our understanding of how the above challenges affect CARE Act programs and the people they serve.

The Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau is responsible for implementing the CARE Act. It is in partial fulfillment of this responsibility that the monograph *Maximizing Access to Medications Through Efficient Use of CARE Act Resources* is published. The goals for the monograph are to: expand on current knowledge; inform policy-related, administrative, and legislative decision-making; and provide technical assistance to CARE Act grantees and providers that will enhance the quality and reach of their programs.

This monograph addresses the fact that, given the demands on each CARE Act dollar, grantees must work even harder to ensure that every possible resource is appropriately directed to provide clients access to treatment, particularly medications. The monograph comprises four policy studies on issues related to the AIDS Drug Assistance Program (ADAP) Funded under Title II of the CARE Act:

- + Study 1: Factors Contributing to Variations in Per Capita State AIDS Drug Assistance Program Expenditures
- + Study 2: ADAP Supplemental Funds
- + Study 3: The Role of Title I-Funded AIDS Pharmacy Assistance Programs in Ensuring Access to HIV Therapeutics
- + Study 4: Issues Associated With Capped Enrollment and Waiting Lists.

Findings and recommendations from these studies will help inform HRSA's administrative procedures, technical assistance, and training activities; improve service delivery; and enhance intergovernmental relationships between Federal agencies and among Federal, State, and local jurisdictions. HRSA grantees are encouraged to read these reports and to incorporate findings and recommendations into their ongoing planning and program activities. HRSA welcomes feedback from readers on the usefulness of this monograph for their work.



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PURPOSE OF THE STUDIES

HRSA's HIV/AIDS Bureau (HAB) contracted with the George Washington University to conduct a series of studies regarding various aspects of HIV medications funding through the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, including the Title II-funded AIDS Drug Assistance Program and Title I-funded AIDS Pharmaceutical Assistance Programs. The goal of the studies was to inform HAB regarding (1) opportunities to promote more efficient use of scarce resources for HIV-related medications and (2) policy options that might ensure equitable access to life-saving therapies for low-income people living with HIV (PLWH). The three key issues addressed and the related study questions are shown in Table 1 on page 3. This report summarizes the methods, limitations, major findings, and recommendations of these studies. The contents of this report are solely the responsibility of the authors and do not necessarily represent the official views of HRSA.





STUDY 1

FACTORS CONTRIBUTING TO VARIATIONS IN PER CAPITA
STATE AIDS DRUG ASSISTANCE PROGRAM EXPENDITURES

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Background

State and territorial AIDS Drug Assistance Programs (ADAPs) (referred to in this report as State ADAPs) report substantial variability in resources for the purchase of HIV medications. Some State ADAPs have access not only to Title II ADAP earmark and base funds but also Title I and State and local government funds. Other State ADAPs are entirely funded by ADAP earmark and Title II funds. Some State ADAPs reportedly have been successful at maximizing their funds through effective cost-containment measures such as rebate and pricing agreements, retrospective billing to Medicaid, and health insurance purchasing. State ADAPs also vary in their eligibility criteria and benefits, as well as the extent to which they coordinate with Medicaid or other payers to ensure that the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is the payer of last resort (PLR).

As a result of the significant variability in State ADAP programmatic design, the per capita expenditures made by State ADAPs are likely to range widely. Issues of equity have been raised among policy makers, consumers, and advocates. The extent to which per capita expenditures actually vary is unclear, however, as is the influence of factors associated with that variability. Further analysis is required to obtain this information and to identify policy measures that might be adopted to ensure parity in per capita expenditures while ensuring continued contributions to ADAPs by State and local governments and other funders.

The goal of this project was to inform the HRSA HIV/AIDS Bureau (HAB) regarding the extent to which per capita State ADAP expenditures vary and the role of various factors in that variation (See Table 1). This study considered the following factors:

- + Source and amount of non-Federal ADAP funds
- + State ADAP eligibility requirements
- + State ADAP programmatic design, such as mechanisms used to purchase and distribute drugs
- + Covered ADAP benefits, such as the drug formulary
- + Coordination with other funders to ensure that CARE Act funds are used as the PLR
- + Drug payment levels and cost-containment strategies such as negotiated price reductions and rebate agreements
- + The external health insurance environment that may result in increased or decreased demand for ADAP enrollment.

Methodology

Data Sources

All data routinely gathered by the HAB ADAP staff for the period from Federal fiscal year (FY) 1999 through FY 2003 were reviewed, including the following data sources:

- + State Title II ADAP grant applications for FY 2001 through FY 2003 and ADAP-At-A-Glance tables that summarize the ADAP State Profiles submitted in the grant applications
- + ADAP Monthly Reports submitted by State ADAPs for January 2001 through June 2003
- + ADAP Quarterly Pricing Reports submitted by State ADAPs for March 2001 through June 2003
- + Calendar year (CY) 2002 ADAP reports submitted by State ADAPs in the CARE Act Data Reports (CADR)



Total ADAP expenditures, regardless of the funding source, were summed for each year to calculate the denominator. Sources of expenditures included Title II ADAP earmark funds, Title II base funds, Title I funds allocated to the State ADAP, State ADAP matching funds, other State revenue, other local funds, and other sources of funds. State ADAP per capita annual expenditures were used as the unit of analysis. State ADAP expenditure data included purchases made for the following five types of services:

1. Medications (including the price of individual medications and the dispensing fee)
2. Health insurance premiums
3. Health insurance deductibles
4. Health insurance co-payments
5. Flexibility policy expenditures for adherence and monitoring related to ADAP clients.

Per capita expenditures were calculated for each State ADAP for a 3-year period covering FY 2001, FY 2002, and FY 2003. State ADAP eligibility, coverage, cost-containment, Medicaid program coordination, and other relevant programmatic characteristics were appended to the per capita expenditure data for each State ADAP and fiscal year studied. Additional health insurance coverage data from the CPS were obtained for CY 2002, the most recent calendar year available. In the absence of trend data, individual State CY 2002 CPS data were used as a constant variable for CY 2001 and CY 2003.

Limitations

Computations of per capita expenditures did not include adjustments for inflation for the period in which this analysis was conducted. Inflation is likely to have some impact on the “real dollars” available to State ADAPs to purchase medications and health insurance premiums, deductibles, and co-payments. Because of the absence of State ADAP data regarding medication-specific and health insurance-related expenditures, it was not possible to identify medical market inflation data that closely mirrors the unique and varied benefit packages supported by the State ADAPs.

Pricing data submitted to HAB could not be used for this analysis. The pricing data apparently include medication purchases as well as co-payments and deductibles in the pricing data for pharmaceuticals purchased by individual ADAPs.

GWU staff encountered several challenges in assessing the factors associated with differences in per capita expenditures. Specific data issues that were identified and explored with HAB staff included the following:

- + Interviews with State ADAP staff indicated that they may interpret HAB data collection forms differently.
- + Per capita ADAP expenditure data available from HAB most directly measure medication purchasing and not the other services funded with ADAP dollars.
- + Some State ADAPs have not submitted all required forms, have not completed sections of some forms, or have submitted their “best guesses.” For example, 28 percent of State ADAPs did not submit total expenditure data in their CY 2002 ADAP CADRs. As a result, GWU staff could not use CADR data as part of this analysis.
- + Person-based expenditure data are not available to HAB for accurately computing the actual expenditures for the various types of services purchased. Despite substantial variability in the length of enrollment by clients in State ADAPs, the ADAPs do not report the data to HAB. Person-based data also are



Title II earmark funds represented 66.7 percent of total ADAP funds expended. Title II supplemental funds accounted for 2.1 percent; Title II base funds, 2.3 percent; Title I funds, 2.2 percent; ADAP State matching funds, 0.5 percent; other State funds, 15.5 percent; and other funds, 10.8 percent. City and county revenue made up most of these other funds. State ADAPs vary substantially in the array of funding streams used to support their programs. Of the 57 State ADAPs funded in FY 2003, 42 State ADAPs (73.7 percent) did not receive Title I funds; 18 State ADAPs (31.6 percent) received no State non-matching funds; and 26 State ADAPs (45.6 percent) received no other funds, such as city or county revenue. All State ADAPs received ADAP earmarked funds.

Other State funds, excluding revenue used for the ADAP match requirement of the CARE Act, were an important source of State ADAP support between FY 1999 and FY 2003. Nonmatching State funds fluctuated slightly between FY 2001 and FY 2003: 47.6 percent, 45.6 percent, and 46.4 percent (respectively) of non earmark State ADAP funds came from State revenue. Other funds, including city and county revenue, were also an important and growing source of State ADAP funds during this period. The percentage of State ADAP non earmark funds derived from other sources rose from 27.8 percent in FY 2001 to 28.0 percent in FY 2002 and to 32.4 percent in FY 2003.

Following the trends in enrollment, 10 State ADAP expenditures accounted for 72 percent of total expenditures. New York, California, and Florida alone accounted for 45 percent of State ADAP expenditures. On average, ADAP expenditures rose per State from \$13.4 million in FY 1999 to \$19.2 million in FY 2003. The average expenditures across State ADAPs, however, obscure the substantial range in actual expenditures among State ADAPs. In FY 2003, for example, total expenditures per State ADAP varied from \$91,319 to \$200.8 million, reflecting differences in the amounts and sources of funds that support those programs.

Analysis of the trends in average State ADAP expenditures indicated relatively steady growth in average expenditures by State ADAPs between FY 1999 and FY 2002, with the rate of increase in expenditures averaging 9.9 percent between FY 1999 and FY 2000, 10.2 percent between FY 2000 and FY 2001, and 14.8 percent between FY 2001 and FY 2002. The trend in increased growth in expenditures changed between FY 2002 and FY 2003, with the increase in expenditures dropping to 3.3 percent. In actual dollars, the average increase in State ADAP expenditures was \$1.3 million between FY 1999 and FY 2000, \$1.5 million between FY 2000 and FY 2001, \$2.4 million between FY 2001 and FY 2002, and \$616,792 in FY 2003. A slight but steady increase was observed in the average expenditures of State ADAPs between FY 1999 and 2003. These underlying numeric distributional characteristics of expenditures, along with expenditure patterns among some State ADAPs, resulted in the difference between average expenditures among State ADAPs over time being not statistically significant.

Per Capita Expenditures

Trends were identified in State ADAP per capita expenditures among State ADAPs. Annual total per capita expenditures varied greatly among State ADAPs during the period studied. In FY 2003, for example, total per capita expenditures per State ADAP varied from \$1,583 to \$23,304. This variability reflects differences in the size of the enrollments in State ADAPs as well as in the amount and sources of funds supporting those programs. The median per capita expenditures, less likely to be influenced by outlier data, rose from \$5,853 in FY 1999 to \$6,446 in FY 2000 and \$6,752 in FY 2001. Median per capita expenditures then decreased to \$6,604 in FY 2002 and rose again to \$7,099 in FY 2003.

Analysis of the trends in average State ADAP per capita expenditures indicated that average per capita expenditures by State ADAPs dropped 0.6 percent between FY 1999 and FY 2000 and then rose 1.5 percent



applications for Medicaid and ADAP enrollment (\$8,281) than among State ADAPs without dual applications (\$6,649). State ADAP per capita expenditures were higher among programs requiring proof of Medicaid application denial (\$7,758) than among State ADAPs without this requirement (\$6,411). A non-significant weak association was found between State ADAP per capita expenditures and joint ADAP and Medicaid administration at the State level; States with joint administration had lower average per capita expenditures (\$5,828) than State ADAPs without joint administration (\$7,188).

Statistical analysis also pointed to the importance of State ADAPs retroactively billing Medicaid for ADAP clients that are subsequently awarded retroactive Medicaid pharmaceutical coverage. State ADAP per capita expenditures were lower among programs with retroactive Medicaid billing (\$6,041) than among State ADAPs that did not have this billing process (\$7,808).

GWU staff explored the relationship between per capita State ADAP expenditures and receipt of Title I funds. In FY 2003, 12 States or territories (22 percent of State ADAPs) reported receiving Title I funds. In FY 2003, Title I funds received by State ADAPs ranged from \$57,425 to \$18 million and averaged \$426,924. The number of State ADAPs receiving Title I funds increased between FY 2002 and FY 2003, with 12 State ADAPs receiving Title I funds in FY 2003, compared with 8 State ADAPs in FY 2002. The average per capita amount was \$8,359 for States receiving Title I funds, compared with \$7,125 for States that did not receive Title I funds. This difference was not statistically significant, however.

Discussion

While conducting this study, State ADAPs continued to make rapid changes in their program designs and policies that were not reflected in the data available to GWU staff, including the following:

- + Setting further limits on income and assets
- + Adjusting the frequency of recertification (monthly, quarterly, biannually, or annually, as the formulary was changed)
- + Requiring Medicaid application or proof of denial
- + Establishing online interface with Medicaid to reduce dual enrollment
- + Increasing assessment of case management eligibility
- + Denying benefits to veterans
- + Establishing waiting lists and capped enrollment
- + Prioritizing applicants on the basis of clinical factors (pregnancy, CD4, or viral load)
- + Reducing the formulary to exclude drugs not directly related to HIV treatment
- + Establishing a monthly ceiling on the number of drugs paid for by the State ADAP
- + Setting limits on protease inhibitors (PIs) or opportunistic infection medications
- + Attempting to expand rebate agreements and reduced prices
- + Establishing co-payments for ADAP clients
- + Increasing the purchase of insurance premiums
- + Reorganizing distribution systems to reduce dispensing costs
- + Implementing retrospective Medicaid billing.





STUDY2

ADAP SUPPLEMENTAL FUNDS

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Background

The ADAP supplemental funds allocated in FY 2003 amounted to \$21 million, or 3 percent of the total amount allocated to the CARE Act ADAP earmark budget. ADAP supplemental funds are meant to assist the States that are most challenged in supporting their ADAP. Not all eligible State ADAPs, however, have accessed supplemental funds. ADAP supplemental funds target jurisdictions that met specific qualifications as of January 1, 2000. Only States that met at least one of the following criteria on that date are eligible to apply:

- + Financial eligibility restriction to less than or equal to 200 percent of Federal Poverty Level (FPL)
- + Medical eligibility restrictions
- + Limited formulary composition for antiretroviral drugs (ARVs)
- + Limited formulary compositions (fewer than 10 medications) for the treatment of opportunistic infections.

States are also required to match the Federal supplement award at a rate of one State dollar for every four Federal dollars. The CARE Act requires that States receiving ADAP supplemental funds maintain their current levels of effort in their ADAP funding. In FY 2003, 27 States and territories were eligible to apply for ADAP supplemental funds. Of those jurisdictions, 17 received ADAP supplemental funding: Alabama, Colorado, Georgia, Guam, Idaho, Kentucky, Louisiana, Nebraska, North Carolina, Oklahoma, Puerto Rico, South Carolina, Texas, Virgin Islands, Virginia, West Virginia, and Wisconsin. States that were eligible based on FY 2000 criteria but did not apply included Alaska, Arizona, Iowa, Maine, Montana, North Dakota, South Dakota, Tennessee, Utah, and Vermont.

HAB requested that GWU staff collect information about the following topics:

- + Why States are not availing themselves of ADAP supplemental funds
- + Whether different criteria might be established to determine need for ADAP supplemental funds
- + The likely impact of reducing the ADAP supplemental match requirement or modifying the eligibility criteria for ADAP supplemental funds.

Methodology

In a separate study sponsored by HAB, Positive Outcomes, Inc. (POI) staff interviewed ADAP coordinators in States that met the FY 2000 criteria for ADAP supplemental funds but did not request them. Under an agreement with HAB, POI provided interview notes to GWU staff to assist in this study. Additional information gathered by GWU staff included information gathered from HAB, the National Alliance of State and Territorial AIDS Directors, and the CARE Act legislation. The following information reflects a synthesis of those data.

Limitations

No limitations were identified in conducting this study. State ADAP staff was very cooperative with study staff.





STUDY 3

THE ROLE OF TITLE I-FUNDED AIDS PHARMACY ASSISTANCE
PROGRAMS IN ENSURING ACCESS TO HIV THERAPEUTICS

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Background

Many communities are encountering constrained public funding due to decreased tax revenue and increased expenditures for Medicaid and other entitlement programs. As a result, Medicaid and State-funded health insurance pools and pharmacy programs have reduced or eliminated benefits for medically needy adults, including people living with HIV (PLWH). At the same time, many State ADAPs have narrowed their eligibility criteria and decreased benefits to contain costs.

Changes in indigent care programs and the growing number of newly identified HIV-infected individuals have resulted in significant growth in the number of uninsured and underinsured PLWH in many communities. Concurrently, new HIV medications continue to be approved by the Food and Drug Administration (FDA), and new combinations of therapeutics are being introduced into HIV medical practice. These forces are likely to prompt either steady or increased demand for HIV medications in the near future.

These factors make the role of Title I-funded AIDS Pharmacy Assistance (APA) programs increasingly important in ensuring that HIV medications are accessible and affordable. In FY 2002 alone, Title I Eligible Metropolitan Areas (EMAs) allocated almost \$40 million to APAs. APA expenditures represented 6 percent of total Title I funds in FYs 1999 and 2000; 9 percent in FY 2001; and 6 percent in FY 2002. Despite the large financial outlays made by Title I APAs, little is known about their design. Moreover, it is unclear how APAs coordinate eligibility and benefits with State ADAPs, Medicaid, the Department of Veterans Affairs (VA), and other payers to ensure optimal use of public funds.

The goal of this study was to help HAB identify and maximize resources available to support HIV medication costs by

- + Gaining a better understanding of the role of APAs in ensuring access to HIV medications;
- + Identifying the distinction and overlap between APAs and ADAPs;
- + Evaluating the extent to which APAs coordinate benefits with ADAPs, Medicaid, and other payers; and
- + Assessing the extent to which APAs maximize their resources.

Methodology

GWU staff conducted a voluntary, email-based survey of Title I grantees that fund APAs. Before conducting the survey, an institutional review board (IRB) package was prepared and submitted to the GWU IRB for review. Approval was granted, and a copy of the survey and accompanying IRB materials were sent to the Title I grantees that HAB had identified as having an APA. The survey was in the field from February 2004 through March 2004, and a total of 21 Title I grantees with APAs were contacted. The Title I grantees received an initial email requesting that they complete the survey. Nonresponding grantees received several email reminders and one telephone reminder call. One Title I grantee (Denver) reported that it no longer operated an APA. Of the remaining 20 Title I grantees listed in Table 3, 17 (85 percent) responded. The three nonresponding APAs were located in moderate-size EMAs in California, Puerto Rico, and Texas.

Limitations

Three EMAs did not respond to the survey. It is unclear to what extent the characteristics of their APAs differ from APAs of responding EMAs. Several EMAs did not provide a copy of their formularies.



APA Covered Benefits

Among the 17 responding APAs, all purchase medications with Title I funds. Two of the 17 APAs also purchase insurance premiums, and 6 reported paying co-payments on behalf of clients. GWU asked Title I APAs to include a copy of their formulary with their completed survey form. Twelve APAs provided a copy of their current formulary. The submitted APA formularies vary substantially, and many APAs include HIV medications that are also covered by their State’s Medicaid program and ADAP. Additionally, the APAs tend to have formularies that are broader than their State ADAP to compensate for medications required to treat HIV and non-HIV-related conditions common among PLWH. In addition to prescribed medications, some APAs cover over-the-counter medications and medical supplies. APAs tended to report somewhat similar patterns of coverage of HIV antiretrovirals (ARVs). The number of ARVs covered by APAs ranged from 8 ARVs (Patterson, NJ) to 21 (Fort Lauderdale, FL); the modal number of ARVs covered was 20. Only 2 of the 12 APAs that submitted their formularies to GWU covered Fuzeon.

Relationship of APAs to ADAPs

The effective coordination of eligibility and coverage policies between APAs and ADAPs is important given the high number of APA clients that can also enroll in a State ADAP. While 88 percent of APAs allow their clients to enroll in a State ADAP, only 41 percent of the EMAs with APAs allocate funds to their State ADAPs. Two of the 17 APAs reported that their State ADAPs do not need Title I funds. Some APAs reported that their role is to provide benefits that wrap around those covered by the State ADAP. Almost all the APAs (94 percent) covered drugs not covered by ADAP. About one-third of APAs (35 percent) cover clients not eligible for ADAP, whereas almost one-quarter (23 percent) enroll ADAP-disenrolled clients. Despite the importance of coordination of benefits with ADAPs, only about one-third of APAs (35 percent) reported coordinating coverage of newly approved HIV drugs with their State ADAPs. Only 29 percent of APAs reported coordinating the benefits of individual clients.

Relationship of APAs to Medicaid

Reflecting the importance of coordinating APA eligibility with the Medicaid Program, almost three-quarters of APAs (71 percent) reported having access to electronic Medicaid eligibility records. It is unclear, however, how often those records are reviewed to identify newly enrolled or disenrolled Medicaid beneficiaries. Most APAs (82 percent) reported covering clients who are not Medicaid eligible, and more than one-half (59 percent) cover Medicaid beneficiaries. Reflecting the highly restrictive coverage of the Texas Medicaid Program, the APAs located in Texas reported enrolling Medicaid beneficiaries. As with State ADAPs, some APAs function as a wraparound for Medicaid benefits: almost one-third of APAs (29 percent) cover medications that are not on Medicaid’s formulary.

APA Cost-Containment Mechanisms

APAs reported using a variety of cost-containment strategies. As mentioned earlier, two APAs (12 percent) purchase health insurance premiums. About two-thirds of APAs (65 percent) have Section 340B direct purchase arrangements, whereas one APA (6 percent) participates in the 340B rebate program. Only three APAs (18 percent) reported having negotiated price reductions with manufacturers. It is unclear, however, how many of the drugs on these APAs’ formularies were purchased on a price-reduction basis. Only four APAs (23 percent) reported having negotiated dispensing fee or other price reductions from retail or mail-order pharmacies. Use of manufacturers’ patient assistance programs is uncommon among APAs: only six (35 percent) reported such referrals. Other cost-containment strategies that are used by APAs are likely to reduce access to HIV medications. Two APAs (12 percent) limit the number of clients that can enroll in the APA.





STUDY4

ISSUES ASSOCIATED WITH CAPPED ENROLLMENT
AND WAITING LISTS

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Background

Through the CARE Act, HRSA's HIV/AIDS Bureau (HAB) provides funding to States and U.S. territories to administer the AIDS Drug Assistance Program (ADAP). Over the past several years, ADAPs have experienced insufficient funds to support growing enrollment, increased expenditures, and lengthened enrollment periods. To deal with those difficulties, ADAPs have instituted a variety of cost-containment measures, including capped enrollment and waiting lists.

The purpose of this assessment was to identify ADAP policies and procedures developed by States to guide ADAP staff in implementing and operating capped enrollment programs, waiting lists, or both.

State ADAPs Participating in the Assessment

+ **State ADAPs with Waiting Lists or Capped Enrollment**

Alabama, Arkansas, Idaho, Iowa, Kentucky, Montana, North Carolina, Oklahoma, South Dakota, and West Virginia

+ **States Anticipating Waiting Lists and/or Capped Enrollment**

Massachusetts, Missouri, and New Mexico

+ **States with Capped Enrollment or Waiting Lists Not Participating in the Assessment**

Alaska and Colorado

Methodology

GWU researchers interviewed the ADAP administrators of 14 States. Eleven States reported using capped enrollment: Alabama had set its cap at 1,232; Arkansas, at 460; and Idaho, at 109. Kentucky had a rolling cap, as did Montana and North Carolina. South Dakota had set its cap at 70, and West Virginia at 200. Iowa, which had 210 clients, but needed to limit the program to 135 to 165 clients but had not officially set a cap. Indiana had set a cap of 1,250 but was just approaching the cap. Oklahoma had set a monetary cap of \$1,200 per client per month, but was just reaching that amount. Three additional States—Massachusetts, Missouri, and New Mexico—reported that they anticipated capping enrollments or instituting a waiting list in the near future.

Eight States reported having waiting lists. Alabama had 391 people on the waiting list at the time of the study. Idaho had 17; Iowa, 16; Kentucky, 18; Montana, 8; North Carolina, 774; South Dakota, 25; and West Virginia, 35. Arkansas reported having reached its cap of 460 and beginning a waiting list. Three applications had been received; if space was not available for those applicants, they would be the first three on the waiting list.

Alaska and Colorado reported having capped enrollment or a waiting list but did not participate in the interviews.



a governor's advisory council, regular meetings with State legislators, and health department administrators) to increase public awareness of the ADAP and its needs.

ADAPs reported consultations with various officials and groups regarding development and implementation of capped enrollment. These include community advisory boards; scientific, clinical, and medical advisory groups; community planning boards; health department directors and administrators; and program and financial staff.

ADAPs define capped enrollment differently; most ADAPs have established a “hard” cap—setting a maximum number of enrollees who can be permitted in the program. Others have created a “rolling” cap that adjusts to demand on a monthly basis.

“Capped enrollment” generally meant that an ADAP had determined a *set number of enrollees* that could participate in the program; several States reported having “rolling” caps, a *limit of enrollees in the program that changes throughout the year* based on available funding and program costs. For example, one ADAP caps annual enrollment at 200 clients. This number does not change throughout the year. Another ADAP has a rolling cap, currently set at 135, which changes as program staff evaluate program utilization from the past month and add clients as funding allows. For ADAPs with rolling caps, capped enrollment is based on available funding, so no set number is determined.

Eleven of the interviewed ADAPs reported capping the number of clients that are enrolled in the program. The cap ranged from 70 clients to 1,250 clients. Five ADAPs reported hard caps that had been exceeded. Four ADAPs reported rolling caps that were at capacity. One ADAP reported having set a hard cap but not having reached the number, and one ADAP reported its cap as a monetary cap of \$1,200 per client per month, which had been exceeded. (This ADAP had no cap on the number of clients.)

Given underlying variability in available resources and, thus, variability in eligibility requirements (Table 4), ADAPs cap enrollment at different levels. Because ADAPs are given flexibility in determining eligibility criteria (including income levels) for the program, an applicant at a certain income level might be wait-listed in one State and not in another.

ADAPs vary in the steps taken to contain costs prior to imposing capped enrollment. All ADAPs have considered a standard set of cost-containment measures (e.g., reduced formulary, change in eligibility rules, use of 340B pricing, use of ADAP Task Force negotiated prices, back-billing third-party payers, and imposition of client co-payments), but no standardized approach to cost-containment yet exists.

All ADAPs reported having used other budget control measures before implementing capped enrollment. Those measures include using a reduced formulary (3 States); changing the eligibility rules (2 States), using 340B pricing (7 States), using ADAP Task Force contracts (11 States), and back-billing Medicaid and other sources (3 States). Several ADAPs specifically mentioned ruling out several of these options, most commonly the reduced formulary, client copays, and lowering the income eligibility as a percentage of Federal Poverty Level (FPL). At least in some cases, the ADAP determined that the cost savings were insufficient to be worth the change in policy. For a full discussion of the policy opportunities in this area, see GWU's earlier report prepared under this Task Order, *The AIDS Drug Assistance Program: Assessing the Use and Distribution of Scarce Resources*, submitted to HAB in May 2004.



Table 4. ADAP Eligibility Requirements

| State | Federal Poverty Level % | Income | Household, Family, or Individual Income | Asset Limits | Require No Insurance | Medicaid Denial Letter, Application, or None |
|----------------|-----------------------------------|--------|---|--------------|----------------------|--|
| Alabama | 250 | Gross | H | N | Y | A |
| Alabama | 250 | Gross | H | N | Y | A |
| Arkansas | 300 | Gross | H | N | N | DL |
| Idaho | 200 | Gross | F | N | Y | A |
| Iowa | 200 | Gross | F | Y | N | A |
| Kentucky | 300 | Gross | H | N | N | DL |
| Montana | 330 | Net | F | N | N | DL |
| North Carolina | 125 | Net | F | N | N | A |
| South Dakota | 300 | Gross | H | N | N | A |
| West Virginia | 250 | Gross | F | N | N | DL |
| Indiana | 300 | Gross | H | N | N | DL |
| Oklahoma | 200 | Gross | F | N | N | DL |
| Massachusetts | \$50,000/yr and \$2,900/dependent | Gross | I | N | N | DL |
| Missouri | 300 | Gross | I | N | N | A |
| New Mexico | 300 | Gross | F | N | N | N |

Most ADAPs maintain waiting lists. ADAPs, even those not maintaining formal waiting lists, continue to receive and process new applications to determine program eligibility.

In all the ADAPs interviewed, case managers continue to take and forward applications for the program after the cap has been reached. Applications are sent to the ADAP staff where they are either held until a slot becomes available or the person is put on an official waiting list. Case managers trained to provide assistance to clients through other programs, primarily patient assistance programs established by the pharmaceutical companies. Case managers are updated regularly (usually monthly) on the status of clients on waiting lists. Clients are informed by letter regarding their status. All ADAPs provide this letter to clients. A copy of the letter is usually sent to the case manager. Information on the client (e.g., updating of address, current medical status) is maintained by the case managers at the organization level.

All ADAPs that maintain waiting lists determine client eligibility for the ADAP before placing them on the waiting list. The level of review of the applications varies for ADAP enrollment in general. For example, some States do not require proof of Medicaid denial or State residency, only statements to that effect. Variation also occurs in how frequently people on the waiting lists are recertified for eligibility in the program, though this generally follows the program's criteria for recertification.

Data collected vary from State to State. ADAPs reported using the following data to determine eligibility and add the applicant to the waiting list: FPL (12 States), residency requirement (12 States), Medicaid denial (7 States), no insurance (2 States), and asset limits (1 State). All ADAPs verify eligibility at the ADAP programmatic level after receiving the applications. Providing proof of residency, Medicaid denial, etc., varies. Some ADAPs require documentation, while others do not.

All ADAPs regularly review the status of current clients to determine whether a slot can be opened for someone on the waiting list.

Variability exists in how ADAPs make room for applicants to be moved from the waiting list. All ADAPs use recertification (meeting the criteria set by the ADAP to be eligible for the program) to open slots. Twelve ADAPs reported that they conduct recertification yearly, two ADAPs reported that they recertify every 6 months, and one ADAP reported recertifying every month. Eight ADAPs recertify applicants on the waiting list before they are placed on the program, unless they have been on the list less than 4 months (on average). Several ADAPs move clients off the program if they have not filled prescriptions in 90 days or more (unless documentation of a drug holiday is on file), and a few ADAPs remove applicants from the waiting list who move to a Title I EMA that covers medications.

Coordination between ADAPs and Medicaid programs varies. Some ADAPs have excellent working relationships, including online access to Medicaid eligibility verification systems; other ADAPs have essentially no working relationship with the Medicaid program, even with regard to eligibility determination.

ADAPs reported the following approaches to coordination with State Medicaid programs: access to online eligibility database (five States), access to phone eligibility database (five States), regular meetings with Medicaid staff (three States), and meetings at the case manager level (one State). Four ADAPs reported no coordination or contact. Some ADAPs reported a positive and highly interactive relationship with their Medicaid program, whereas others reported a poor, almost adversarial relationship with their Medicaid counterparts. Personal relationships provide the best hope for strong program coordination, but with strained Medicaid budgets, these relationships were not always helpful in coordinating programs.

No ADAP reported coordination between ADAP staff and the Social Security Administration (SSA) in determining SSI eligibility. Seven ADAPs reported this coordination as taking place at the case management level, although most reported that such coordination depends on personal relationships between case managers and SSA staff.

Clients on waiting lists receive varying levels of support in enrolling in pharmaceutical company patient assistance programs (APAs). Case managers have had a variety of levels of training and experience with this usually complex process, which requires different application forms for each pharmaceutical company.

All ADAPs reported having processes (although not written policies) for assisting clients in finding other sources of medications while on the waiting list. All reported that case managers are trained to assist clients in accessing APAs and are responsible for helping the client fill out the applications. Two ADAPs reported that clinics provide assistance in filling out applications for the programs. All reported that the APA application process is cumbersome because each pharmaceutical company has its own application process and most clients must apply to more than one company to cover their drug regimen.



Four ADAPs reported that they have written guidelines for their waiting list. Six ADAPs reported that they have no written guidelines, and four reported that they are in process of writing guidelines. These guidelines cover the process of managing the list, determining how applicants are placed on the list and removed from it, and providing assistance to applicants while they are on the list.

Eleven ADAPs reported relying on case managers to gather information about applicants being placed on the waiting list (completing the application and maintaining contact information). The case managers fill out the information and keep the client informed about movement of applicants on the list. Six ADAPs reported that ADAP staff also collect information on the applicants. No ADAPs reported that providers are involved in collecting information.

Criteria for moving applicants off waiting lists vary by ADAP. Some ADAPs use a strict “first come, first served” approach; others use a medical need approach (e.g., pregnant women, those with severely compromised immune systems) or a combination of the two. Most ADAPs move applicants from the waiting list to ADAP enrollment as slots become available, although at least one ADAP reported waits for enough slots to open up to move the entire waiting list at one time.

All ADAPs with waiting lists reported that they manage the waiting list at the ADAP programmatic level. Priority for placement on the list was reported as follows: first come, first served (nine States); medical need (six States); pregnant women (two States); those already on medications (two States) and, those that are non-EMA clients (two States). A few ADAPs list first come, first served as their priority, but actually bump clients with medical need to the top then prioritize by first come, first served.

Priority determination was developed in various ways: Program staff developed the guidelines; ADAP staff talked to each other to determine the best priority list; medical advisory boards were convened to determine the priority list; standing clinical care committees or ethics committees were used to determine the priority list; clinical advisory boards were used to set medical eligibility criteria for priority; and other methods were used. Most ADAPs did not include consumers in determining priority lists.

ADAPs reported simple policies and procedures for moving applicants off the waiting list. For example, when a space (or spaces) become available, the person (or group) of persons is moved off the list. However, some ADAPs wait until they have enough slots available to move *all* applicants off the waiting list at one time. Other ADAPs move applicants off the waiting list one at a time. Both clients and case managers are notified by letter.



- + *Work with ADAPs, consumer and community representatives, and ethicists to develop national recommendations for prioritizing waiting lists (e.g., date of application vs. medical criteria). When formal rationing occurs, the need for a national standard that is transparently arrived at is particularly strong, even if ADAPs ultimately adapt them to local needs.*

- + *Require ADAPs to have written policies regarding capped enrollment and waiting lists, including a transparent process for policy development that includes consumer representation. Consumer involvement in determining rationing strategies is an ethical obligation that is consistent with the underlying philosophy of the CARE Act. These policies should be reviewed by HAB staff on a routine basis to ensure that critical elements are in place to ensure sound fiscal stewardship of ADAP funds and optimized access to medications.*

¹ Institute of Medicine. *Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act*. Washington, DC: National Academy of Sciences; 2003.



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