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HIV/AIDS DRUGS

Funding Implications of New Combination Therapies for Federal and State Programs



**Health, Education, and
Human Services Division**

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The Honorable Arlen Specter
Chairman
The Honorable Tom Harkin
Ranking Minority Member
Subcommittee on Labor, Health and Human
Services, and Education
Committee on Appropriations
United States Senate

Recent estimates of the prevalence of HIV infection in the United States range from 650,000 to 900,000 people.¹ Almost 240,000 of these individuals are living with AIDS, the end stage of HIV and the leading cause of death among 25- to 44-year-olds.² Since 1996, there have been major breakthroughs in the fight against HIV and AIDS. New drug therapies, such as combining protease inhibitors (which inhibit the replication of the virus) with other drugs, are effective in reducing the amount of virus in many people with HIV, thereby delaying the onset of AIDS. These therapies have also been effective in reducing some of the severe immune system suppression in people with AIDS.

Increased use of combination drug therapies has potential implications for federal and state budgets, since many HIV and AIDS patients are entitled to prescription drug assistance under Medicaid or are served by other joint federal and state programs, such as those authorized under title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Therefore, you asked us to describe (1) federal and state spending on HIV and AIDS drug treatment, by major programs, over the last several years; (2) the estimated number of people with AIDS and HIV on combination drug therapy who are covered by Medicaid or other publicly funded programs, and measures that have been taken to stretch the resources in the CARE Act programs; and (3) the potential impacts of new drug therapies on federal and state government outlays.

To conduct our work, we interviewed officials at the Department of Health and Human Services (HHS), including those at the Health Resources and Services Administration (HRSA) and the Health Care Financing

¹John M. Karon and others, "Prevalence of HIV: Infection in the United States, 1984 to 1992," Journal of the American Medical Association, July 10, 1996, and interview with Karon, July 15, 1997.

²HIV (human immunodeficiency virus) is characterized by a gradual deterioration of the immune system. As HIV progresses, individuals become particularly vulnerable to illnesses that are typical of AIDS (acquired immunodeficiency syndrome).

Administration (HCFA). We also analyzed budget information for fiscal years 1995, 1996, 1997, and 1998. We synthesized data and documents from a number of sources, including the Centers for Disease Control and Prevention (CDC) and associations that represent state and industry providers of HIV and AIDS drugs. We also interviewed officials from states' AIDS Drug Assistance Programs (ADAP) and consulted with HIV and AIDS researchers and with officials from pharmaceutical companies that manufacture HIV and AIDS drugs.

Combination drug therapy is new; as a result, our findings are limited by the many unknown factors regarding the effects of these drugs. In addition, federal program eligibility requirements are subject to change. We conducted our evaluation between November 1996 and June 1998 in accordance with generally accepted government auditing standards.

Results in Brief

While state governments and private payers share in the financing of medical care for people with HIV and AIDS, the federal government currently funds more than half the cost of such care. For fiscal year 1998, estimated federal spending on treatment for individuals with AIDS or HIV is expected to total over \$5 billion, an increase of about 5 percent over fiscal year 1997. We estimate that a substantial portion of federal spending for AIDS or HIV medical care—at least one-sixth—is for prescription drugs, primarily through Medicaid and funding under title II of the CARE Act for states' ADAPs.³ With recent research developments in HIV and AIDS treatment—especially the new combination drug therapies—the demand for federal and state funding for HIV and AIDS treatment is expected to increase. Between 1995 and 1997, the expenditures for HIV- and AIDS-related drugs more than doubled in the Medicaid and ADAP programs from \$606 million to \$1.3 billion—primarily because of the increase in the percentage of people with HIV and AIDS seeking combination drug therapy, which costs about \$10,000 per patient annually. These increases are especially apparent in programs funded under the CARE Act.

More than half of the 240,000 people with AIDS in the United States are estimated to be receiving combination drug therapies that include a protease inhibitor and other drugs. Of the AIDS patients on Medicaid, we estimate that at least 67,500 are receiving combination drug therapy in 1998. Data on the number of individuals who are HIV positive but do not have AIDS are insufficient, so it is difficult to develop reliable estimates of

³For this report, "state ADAPs" refers to ADAPs in the states, the District of Columbia, and Puerto Rico.

the total number of Medicaid- and ADAP-eligible individuals who would likely qualify for and seek combination drug therapy. However, some ADAPS report that a great majority of their clients are receiving combination therapy in 1998. ADAPS have taken several steps to stretch available funds and thereby maximize the number of clients they are able to serve. For example, most ADAPS are purchasing drugs at a discount and the ADAP programs we reviewed have taken steps to ensure that clients who are eligible for Medicaid coverage are in fact enrolled in Medicaid. Nonetheless, some ADAPS have been required to restrict enrollment or limit benefits for qualifying individuals.

Other factors—such as evolving standards of care, the long-term effectiveness of current therapies, and new research developments—also influence projections of the impact of new drug therapies on federal and state government programs. Although the effect of the demand for the new combination therapies is difficult to estimate, ADAPS will likely experience greater financial pressure than Medicaid in caring for individuals with AIDS or HIV who seek assistance. This is in part because Medicaid primarily provides coverage for those individuals whose HIV infection has progressed to AIDS, and there are some indications that Medicaid costs for drug therapy might be offset by reductions in hospitalizations. In contrast, ADAPS cover drug costs for both AIDS patients and others who are HIV positive—a rapidly growing candidate population for drug therapy—and who have fixed incomes. Since ADAPS only cover drugs, cost offsets are not likely to occur.

Background

The results of research on the prevention and treatment of AIDS—a disease first identified in the United States in 1981—have only recently begun to accrue. Over the past 11 years, a number of therapies have been developed to fight both HIV and its associated infections and cancers. The Food and Drug Administration (FDA) has approved several dozen drugs for treating HIV infection or AIDS-related conditions, many of which have only been made available during the last 2 to 3 years.

In December 1995, FDA approved the first protease inhibitor, saquinavir (Invirase).⁴ Following this, the agency approved three other protease inhibitors: ritonavir (Norvir), indinavir (Crixivan), and nelfinavir (Viracept). In November 1997, FDA approved a new formulation of

⁴HIV and AIDS treatment has relied on two classes of antiviral drugs: reverse transcriptase inhibitors and protease inhibitors. Reverse transcriptase inhibitors affect HIV's ability to combine with the cells it infects at an early stage of the infection process. Protease inhibitors interrupt virus replication at a later stage in the life cycle, after cells have been infected.

saquinavir, Fortovase. Most recently, in September 1998, FDA approved efavirenz (Sustiva), a drug that requires less frequent dosing and has milder side effects than other drugs. Because HIV can develop a resistance to these and other AIDS treatment drugs, several drugs are often combined. Combination therapy is likely to include three to five drugs, including reverse transcriptase inhibitors combined with protease inhibitors. For many patients, combining protease inhibitors with other drugs greatly reduces the amount of HIV.

Before it was possible to readily measure the amount of virus in patients, most drug therapies were targeted to patients whose infection had progressed, as evidenced by a decline in their immune system function or by the onset of clinical signs and symptoms of HIV. Of the 650,000 to 900,000 people with HIV infection in the United States, the CDC estimates that about 500,000 of those people know their HIV status; and for almost 240,000 of these individuals, HIV has progressed to AIDS. In June 1997, the National Institutes of Health (NIH) released standards of clinical care for HIV and AIDS combination drug therapy.⁵ The standards recommend that therapy be initiated as early as possible and that HIV and AIDS drugs be used in combination rather than individually. Under the treatment guidelines, all patients with HIV infection are considered to be candidates for the combination drug therapy, greatly expanding the group requiring treatment.

New combination therapy standards also call for continuity of therapy and optimum dosages to suppress HIV replication. According to NIH, underdosing and lapses in a patient's therapy regimen greatly increases the risk of the patient's developing drug-resistant HIV variants. Optimum regimens and dosing are under study and continually changing. Combination therapies of as many as five drugs currently are prescribed. Aggressive regimens such as these must be coupled with, and are driven by, results of frequent blood testing to monitor immune system status and levels of HIV. This focus on early and aggressive treatment, coupled with NIH's call for frequent monitoring of HIV-positive individuals, is expected to result in greater numbers of people seeking combination drug therapy and possibly more complex and costly drug treatment regimens, and more treatment-associated costs such as laboratory testing.

⁵To date, much of the care of HIV and AIDS has been fairly decentralized; these guidelines are designed to provide structure to clinical care. For more on these guidelines, see HHS, CDC, Report of the NIH Panel to Define Principles of Therapy of HIV Infection and Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents (Atlanta, Ga.: Apr. 1998).

The cost of combination therapy—taking into account all federal drug discount pricing—is estimated to be about \$10,000 per patient annually. While some people with HIV or AIDS are covered by private medical insurance, many others are either uninsured or have limited prescription drug coverage and must rely on one or a combination of federal and state programs and assistance programs offered by manufacturers of HIV and AIDS treatment drugs.

Federal, State, and Private Funding Sources for HIV and AIDS Drug Therapy

The majority of federal assistance for AIDS patients is provided through Medicaid and programs funded under the CARE Act, which was enacted in 1990 to help alleviate the burdens placed on a public health system generally unprepared for the AIDS epidemic.^{6,7} In 1998, Medicaid is estimated to cover 55 percent of adult AIDS patients and about 90 percent of pediatric AIDS cases.⁸ Applying those percentages to the current number of AIDS cases, we estimate that at least 108,000 individuals with AIDS are covered by Medicaid in 1998. The CARE Act provides funding for states' ADAPS, which rely on federal, state, and local partnerships to provide drug therapy on an outpatient basis. ADAPS are designed to provide assistance to those HIV-positive individuals who have no, or limited, private third-party prescription drug coverage; cannot afford to pay for drugs themselves; and are ineligible for Medicaid or have limits on the prescription drug benefit offered by Medicaid. In calendar year 1996, ADAPS served a total of about 80,000 clients nationwide.

Funding for HIV and AIDS drug therapy as well as other treatments is also provided by other federal sources, including the Departments of Defense (DOD) and Veterans Affairs (VA). DOD programs currently treat about 5,000 active duty service personnel with HIV or AIDS. In 1996, VA treated more than 12,000 eligible veterans. While the total number of individuals served in these programs is much smaller than the number served through Medicaid and programs funded under the CARE Act, VA is the nation's largest provider of direct care for people with HIV and AIDS. In addition, VA clients could be eligible for care from more than one program.

⁶Medicaid is a joint federal and state program that pays for health care services for eligible low-income individuals.

⁷In addition, the Medicare program covers qualified individuals with AIDS. Most who qualify are disabled and meet criteria for the Social Security Disability Insurance program. However, since Medicare does not generally cover prescription drugs except for patients who are hospitalized, we did not focus on this program in our analysis.

⁸Interview with John Klemm, HCFA Office of the Actuary, HHS, Aug. 27, 1998.

The remainder (less than half) of the individuals with AIDS rely on sources other than ADAPS, VA, DOD, or Medicaid to finance their drug therapy. Some have private health insurance and others are uninsured and rely on personal resources and charitable organizations. Uninsured and underinsured individuals with AIDS tend to rely on a combination of public and private funding sources. For example, pharmaceutical companies that manufacture HIV and AIDS drugs have programs to provide limited temporary assistance to individuals who are financially disadvantaged and ineligible or waiting for other sources of prescription coverage.⁹

Eligibility Criteria for HIV and AIDS Drugs Through Public Programs

Medicaid enrollees have access to the new drug therapies if prescription drugs are offered by their state Medicaid program and these drugs are deemed the appropriate therapy. Medicaid provides health coverage for certain low-income families, the elderly, and disabled persons. States vary in their Medicaid eligibility requirements (see app. I). States have discretion regarding the quantities and duration of use for prescription drugs, although all FDA-approved drugs must be offered. Historically, program eligibility has been linked to receipt of cash assistance under a welfare program, such as Aid to Families With Dependent Children (AFDC) or the Supplemental Security Income (SSI) program. In recent years, the program has been expanded to provide health coverage for low-income children and pregnant women with no ties to welfare. An individual with AIDS or HIV infection could qualify for Medicaid on the basis of eligibility for a cash assistance program or alternative eligibility criteria.¹⁰ Most adults with AIDS or HIV infection become eligible for Medicaid by meeting the disability criteria of the federal SSI program, usually not until they have developed AIDS and have become too disabled by their disease to work.¹¹

Patients who do not qualify for Medicaid may seek assistance from ADAPS, which are primarily designed to fill gaps in prescription drug coverage. To

⁹Assistance is typically limited to 90 days, after which time patients must reapply for benefits. Patients may also be required to make copayments for the drugs.

¹⁰Under rules adopted since welfare reform, the Medicaid population can be divided into three broad categories: (1) people whose Medicaid eligibility is primarily based on receipt of cash assistance; (2) people who do not receive cash assistance; and (3) people who receive cash assistance but could qualify for Medicaid under an alternative eligibility category such as the so-called Medicaid “expansion” population—pregnant women, infants, and children born after September 30, 1993. In addition, states can extend Medicaid coverage to certain categories of individuals with too much income to receive cash assistance but who are considered medically needy because of their high medical costs.

¹¹A disabled adult is one who is unable to engage in any substantial gainful activity because of a medically determined physical or mental impairment that is expected to result in death or that has lasted (or can be expected to last) at least 12 months.

qualify for ADAP benefits, they must have a medical need and an income below a certain amount, which is generally higher than that permitted for Medicaid. Unlike Medicaid, ADAPs do not require disability as a criterion for eligibility of HIV-positive adults and thus can cover those who have not developed AIDS. (For more detail on each state's financial criteria for Medicaid and ADAP eligibility, see app. I.)

Recent Federal and State Spending on HIV and AIDS Drugs Through Medicaid and ADAPs Has Increased

The care of HIV and AIDS patients for all types of treatment, including drugs, involves a variety of programs funded by the federal government, states, and private payers, but the largest share of federal funding is through the Medicaid program. Within these programs, expenditures for drugs have increased rapidly in recent years and account for most of the growth in the CARE Act programs.

A Variety of Programs Provide Funding for HIV and AIDS Patients

The federal government, states, and private payers all help to finance the care of HIV and AIDS patients for all types of treatment, including drugs. The federal portion of Medicaid is the largest share of federal funding; however, most states match federal Medicaid funds on nearly a one-to-one ratio.¹² Other programs also provide supportive services for low-income individuals with HIV or AIDS. For example, in fiscal year 1997, about \$133 million was allocated by formula to 53 metropolitan areas and to 27 states for areas outside qualifying cities under the Department of Housing and Urban Development's (HUD) Housing Opportunities for People With AIDS program.¹³

In fiscal year 1997, total federal spending on medical care, including inpatient and outpatient services and prescription drugs, for individuals with AIDS or HIV was estimated at \$4.8 billion.¹⁴ This amount includes federal matching payments that HCFA estimates at \$1.8 billion for fiscal year 1997.¹⁵ Total federal spending for HIV and AIDS medical care in fiscal

¹²In fiscal year 1996, states paid 43 percent—\$66 billion—of the total Medicaid program costs for all programs.

¹³HUD's Housing Opportunities for People With AIDS program provides grants, allocated by formula, to states and metropolitan areas with the largest number of cases and incidence of AIDS. HUD also selects grantees through national competition of projects proposed by state and local governments and nonprofit organizations. These programs, however, do not provide funding for HIV and AIDS drugs.

¹⁴Federal spending on treatment includes funding through HCFA for the Medicaid and Medicare programs, the CARE Act, VA, Office of Personnel Management, DOD, and the Department of Justice.

¹⁵The federal government matched an estimated \$1.5 billion in state funds.

year 1998 is estimated by HHS at \$5 billion; the precise amount of Medicaid spending for HIV- and AIDS-related treatment is not yet known.

Federal Spending for HIV/AIDS Drugs Has Increased Rapidly

We estimate that a substantial proportion of federal spending for AIDS or HIV medical care—at least one-sixth—is for prescription drugs, primarily through Medicaid and the ADAPs. Between 1995 and 1997, the combined expenditures in the Medicaid and ADAP programs for HIV- and AIDS-related drugs more than doubled, rising from \$606 million to \$1.3 billion. Spending on drug therapies represented about one-fourth of federal and state Medicaid spending on HIV- and AIDS-related drugs and exceeded \$950 million in calendar year 1997, up \$449 million (or 90 percent) since 1995. Similarly, spending through ADAPs is estimated at \$359 million for fiscal year 1997, up \$254 million (or 242 percent) since 1995. (See table 1.) Much of this increase can be attributed to an increase in the percentage of people with HIV and AIDS seeking combination drug therapy and the increased expense of combining drugs as opposed to a single medication.¹⁶

Table 1: Recent Federal and State Spending Estimates for All HIV- and AIDS-Related Drugs Through Medicaid and ADAPs

Budget period ^a	Medicaid		ADAP			
	Federal	State	Total	Federal	State ^b	Total
	CY 1995	\$258.7	\$242.6	\$501.3	\$70.8	\$34.3
CY 1996	329.0	308.5	637.5			
FY 1996				145.6	69.6	215.2
CY 1997	490.0	460.0	950.0			
FY 1997				242.8 ^c	116.2	359.0
Percentage change, 1995-97	89	90	90	243	239	242

Note: Estimates are based on preliminary reports, grant applications, or other estimates.

^aMedicaid spending is calculated on a calendar-year basis. After 1995, ADAP spending has been calculated on a fiscal-year basis.

^bThe state share for ADAP takes into account funds generated through cost-saving efforts by states, including manufacturers' rebates and strategies that seek reimbursement from third parties.

^cThis number includes \$167 million earmarked from title II of the CARE Act plus discretionary resources committed by grantees and title I contributions.

Source: HCFA.

¹⁶The increased cost is not likely related to an increase in people with HIV/AIDS. The estimated prevalence of HIV in the population has remained relatively stable in the United States since 1990. Statistical models suggest that each year, roughly the same number of Americans become infected with HIV as die from AIDS-related illnesses.

Federal ADAP Funding Accounts for Most CARE Act Increases

Over the past several years, overall federal funding for the CARE Act has increased more than 50 percent, from about \$760 million in 1996 to about \$1.2 billion in 1998. However, in this 3-year period, increases in funding for CARE Act services other than ADAPs have been minimal, while ADAP funding has more than quintupled. (See table 2.)

Table 2: CARE Act Federal Funding Levels, by Title

Title	Fiscal year		
	1996	1997	1998
I—Assistance to eligible metropolitan areas	\$392	\$450	\$465
II—Care services	209	250	258
II—ADAP	52	167	285
IIIb—Early intervention services	57	70	76
IV—Demonstrations and evaluations	29	36	41
V—Special projects and evaluations	19	24	25
Total	\$758	\$997	\$1,150

Sources: HHS budget office, Feb. 10, 1997, and Congressional Research Service, Nov. 8, 1997.

States also provide considerable resources to fund ADAPs through the CARE Act. The fiscal year 1997 state contributions of \$98 million represented almost a doubling of state dollars from fiscal year 1996. However, between fiscal years 1995 and 1997, the portion of ADAP funding from state dollars dropped from 31 percent to 25 percent because federal funding grew even more quickly than state funding. (See app. II for state contributions.)

Certain metropolitan areas that are disproportionately affected by the AIDS epidemic are eligible to receive funding under title I of the CARE Act for the delivery of comprehensive HIV and AIDS medical care and support services. Some of these title I programs make eligible metropolitan area (EMA) contributions to the state ADAP programs. Between 1995 and 1997, when direct federal funding for ADAPs under title II increased dramatically, title I contributions to ADAPs remained flat. EMA contributions totaled \$20.8 million in fiscal year 1995, \$25.9 million in fiscal year 1996, and \$24.2 million in fiscal year 1997. There is no requirement that contributions be made from title I programs to ADAP. (See app. III for a list of title I EMA contributions to ADAPs, by state.)

In addition, title I pays for HIV/AIDS drugs exclusive of the ADAPs. In general, EMAs report that these expenditures have risen during this time frame. In

several cases, the expenditures rose significantly after 1996, which could reflect the introduction of the protease inhibitors and other new therapies. However, detailed information on these expenditures is not available.

Current Estimates Show an Increase in People Seeking New AIDS Drugs, Requiring ADAPs to Take Steps to Stretch Resources

At least half the people infected with HIV were estimated to have been on combination therapy in 1997, increasing to over 60 percent of patients in 1998. Developing such estimates by insurance coverage or payer source is difficult. It is possible to estimate the number of Medicaid beneficiaries with AIDS who are likely receiving combination therapy. However, given the lack of data on the number of Medicaid beneficiaries with HIV that has not yet progressed to AIDS, it is not possible to develop estimates of the number of these individuals who will seek combination therapies. It likewise is difficult to estimate the number of individuals who will ultimately seek ADAP coverage for combination drug therapy because of the lack of good data on the characteristics of those served. However, recent experiences show a steadily increasing demand for ADAP services. ADAPs have taken a number of steps to stretch their limited resources, including cross-checking program enrollment with Medicaid and obtaining discounts for drug purchases.

An Increasing Number of Medicaid Beneficiaries With AIDS Will Likely Seek Combination Drug Therapy

Although there are a number of FDA-approved drugs for the treatment of HIV, at least half of the people with AIDS in the United States are estimated to be receiving therapies that combine a protease inhibitor with other drugs. These drugs are also available for individuals who are HIV positive but do not have AIDS, but data on this population are of insufficient quality to pinpoint the number of HIV cases receiving combination drug therapy. Only 30 of the states report HIV status, and the comprehensiveness of the reporting varies by state. Some of the states without HIV reporting have a large number of AIDS cases, such as New York and California, suggesting that many HIV cases are not reported.

On the basis of their clinical experience and research, two AIDS researchers developed formulas to determine the number of people who might seek combination drug therapy in 1997 and 1998.¹⁷ They estimated that of the total number of people in the United States with AIDS or who are HIV positive, 50 percent would be on combination therapy in 1997 and 60 to

¹⁷Interview, February 10, 1997, with John Bartlett, Professor of Medicine, and Richard Moore, Associate Professor, Johns Hopkins University School of Medicine.

65 percent in 1998.¹⁸ They assumed that about 20 percent of people who try combination therapy will not be able to tolerate the side effects and will therefore discontinue it. They also assumed that some patients will choose not to (or cannot because of their lifestyle) take the medication and that some HIV-positive individuals will be unaware of the infection and thus will not seek treatment.

We developed estimates of the number of Medicaid beneficiaries with AIDS who will likely seek combination drug therapy in 1997 and 1998. In 1998, Medicaid covered an estimated 55 percent of all adult AIDS cases and 90 percent of all pediatric AIDS cases, while in 1997 these percentages were estimated to be 54 percent for adult cases and 90 percent for pediatric cases. Medicaid currently covers at least 108,000 AIDS patients and covered at least 104,000 AIDS patients in 1997. Therefore, using the AIDS researchers' formulas, we estimate that for the Medicaid beneficiaries with AIDS, at least 52,000 (50 percent of 104,000) would have been on combination therapy in 1997 and at least 67,500 (62.5 percent of 108,000) are on therapy in 1998.¹⁹

Given the lack of data on the number of Medicaid beneficiaries with HIV that has not yet progressed to AIDS, it is not possible to develop estimates of the number of these individuals who will seek combination therapies. However, the gender and age distribution of HIV-positive individuals who do not have AIDS will likely differ from the gender and age distribution of beneficiaries with AIDS who have qualified for Medicaid on the basis of disability. This HIV-positive group includes pregnant women, women and their dependent children, and children in low-income families who qualified for Medicaid because they met federal and state income and categorical eligibility requirements. Although they may be asymptomatic, they could qualify for Medicaid—and thus for coverage of their HIV-related care—for an extended period of time, depending on their income and other qualifying characteristics. HCFA has estimated that there may be as many as 50,000 such HIV-infected individuals covered by Medicaid.

¹⁸As of June 1, 1997, 44 percent of participants in HIV Insight—IMS America's longitudinal database of more than 7,500 individuals with HIV/AIDS—were receiving triple combination therapy.

¹⁹These estimates are conservative. The researchers' percentages are for all HIV-infected individuals, both those with AIDS and those whose disease has not yet progressed to AIDS, some of whom may not be seeking treatment because they are unaware of their infection. However, under current treatment guidelines, all AIDS patients are considered candidates for the combination therapy.

Increases in ADAP Participation Also Likely as a Result of Those Seeking Combination Therapy

It is difficult to estimate the number of individuals who will ultimately seek ADAP coverage for combination drug therapy. However, recent experiences show a steadily increasing demand for ADAP services.

Unlike estimates of the number of people seeking coverage through Medicaid, estimates of the number of individuals who qualify for combination therapy under the ADAPS cannot be made. This is because, in addition to AIDS patients, ADAPS' clients include people who are HIV positive but do not yet have AIDS. It is this latter group for whom limitations on data make it impossible to estimate the total candidate population for the therapy. In addition, states have varying financial and medical standards individuals must meet to qualify for ADAP services, so this subset of candidate patients cannot be computed. Furthermore, because these individuals finance their care through multiple funding sources, some individuals only qualify for ADAP benefits for part of the year.

The only information that is available for predicting the likely future demand for ADAP coverage is the recent experience of the ADAP programs. Since 1992, the number of people seeking funding for AIDS therapies through ADAPS has increased rapidly. In calendar year 1996, ADAPS served a total of about 80,000 clients nationwide, compared with about 50,000 in 1994. Comparing states' ADAP caseloads for July 1996 and July 1997—the most recent data available—shows that per-month client use of ADAPS increased 39 percent overall, from about 31,000 to more than 43,000. A survey by the National Alliance of State and Territorial AIDS Directors shows the number of patients served by ADAPS increasing at a rate of 1,000 per month.²⁰ Per-month expenditures increased 78 percent overall, from nearly \$15 million to more than \$27 million. (For a state-by-state profile of ADAPS, see app. IV.)

HHS has reported that as early as mid-1996 some ADAPS had 80 percent or more of their clients receiving combination drug therapy.²¹ The ADAP Working Group has made projections for expected ADAP enrollment and drug utilization through the year 2000.²² It projects that the rate of ADAP clients receiving combination drug therapy over the next 2 years will be

²⁰National Alliance of State and Territorial AIDS Directors and AIDS Treatment Data Network, National ADAP Monitoring Project: Interim Technical Report, prepared for the Henry J. Kaiser Family Foundation (Washington, D.C.: Mar. 1998).

²¹HHS, Office of the Deputy Secretary, Access to HIV-Related Drug Therapies (Washington, D.C.: June 1997).

²²The ADAP Working Group is a consortium of AIDS activist organizations, pharmaceutical companies, and other organizations.

90 percent. The higher proportion of ADAP clients receiving combination therapy, compared with expected rates for Medicaid patients, likely reflects the somewhat different patient population who may seek coverage by the ADAP precisely because they have been prescribed high-cost drug treatment.

Increase in ADAP Participation Has Prompted States to Seek Measures to Stretch Strained ADAP Resources

ADAPs have implemented a number of measures in an effort to stretch their limited resources. These measures include cross-checking program enrollment with Medicaid, discount drug pricing, and emergency measures such as establishing waiting lists.²³ Yet even with these cost containment efforts, the National Alliance of State and Territorial AIDS Directors found that more than one-fifth of the programs expect budget shortfalls for 1998.²⁴

ADAPs Check Client Eligibility for Medicaid

To ensure that program dollars are spent wisely, a number of ADAPs have taken steps to help identify the most appropriate source of assistance for clients and individuals seeking prescription drug benefits. Many individuals seeking ADAP coverage may not be aware that they are eligible for assistance through other sources, such as Medicaid. Additionally, some may be eligible for prescription drug benefits under more than one program.

In our contacts with officials from the 10 largest ADAPs²⁵—which collectively account for about 70 percent of total federal ADAP funding—we found that most cross-check Medicaid eligibility and verification files at initial enrollment and on an ongoing basis, although the frequency with which they updated Medicaid eligibility status varied significantly. For example, New York updates the information weekly, while others do so monthly or less often. Most of these ADAPs are linked to the Medicaid files via computer for both initial screening and cross-checks. States also use other means to verify eligibility. For example, Virginia requires all ADAP clients to apply to Medicaid within 90 days of enrollment. In Puerto Rico, in lieu of computer linkages to Medicaid, case managers work with clients to check for Medicaid or ADAP coverage. (See table 3.)

²³HRSA officials told us that states may also take other, less direct measures, that can reduce the need for ADAP services, such as limiting the caps that insurers can place on prescription drug benefits or extending health care coverage to the working poor.

²⁴National ADAP Monitoring Project: Interim Technical Report (Mar. 1998).

²⁵Size was based on the proportion of federal funding, using the CARE Act title II base funds and ADAP supplemental funding. These programs also serve the most clients, based on recent reports.

Table 3: Procedures Used by 10 Largest ADAPs to Check Client Eligibility for Medicaid

State	Procedure(s) for determining Medicaid eligibility
New York	Checks applicants initially for Medicaid eligibility and does a weekly computerized check against Medicaid rolls.
California	Gives applicants provisional coverage while Medicaid application is pending; does monthly cross-checks with Medicaid status.
Florida	Initially checks Medicaid eligibility; pharmacies also check before dispensing drugs. Periodically cross-matches ADAP and Medicaid files.
Texas	Uses a computer link to check Medicaid status of applicants; 20-25% of ADAP clients are on Medicaid. ADAP covers drugs beyond the state Medicaid limit of three prescriptions per month.
New Jersey	Does an initial check of Medicaid eligibility and a monthly check against Medicaid file.
Puerto Rico	Checks applicants for eligibility for Medicaid and local government health insurance programs; reevaluates eligibility periodically but does no computerized checks.
Georgia	Requires applicants to apply for Medicaid and gives them provisional coverage while Medicaid application is pending. They are accepted into ADAP only if rejected for Medicaid. Does no computerized checks against Medicaid database.
Illinois	Checks applicants against Medicaid database and checks again each time applicant fills a prescription.
Virginia	Requires applicants to apply for Medicaid and show proof of application within 90 days, cross-checks them against Medicaid database, and reassesses eligibility annually.
Pennsylvania	Does an initial check of Medicaid eligibility, a periodic reassessment of eligibility, and has a direct computer link to cross-check against applicant Medicaid enrollment.

Note: State ADAPs are listed in decreasing order of size.

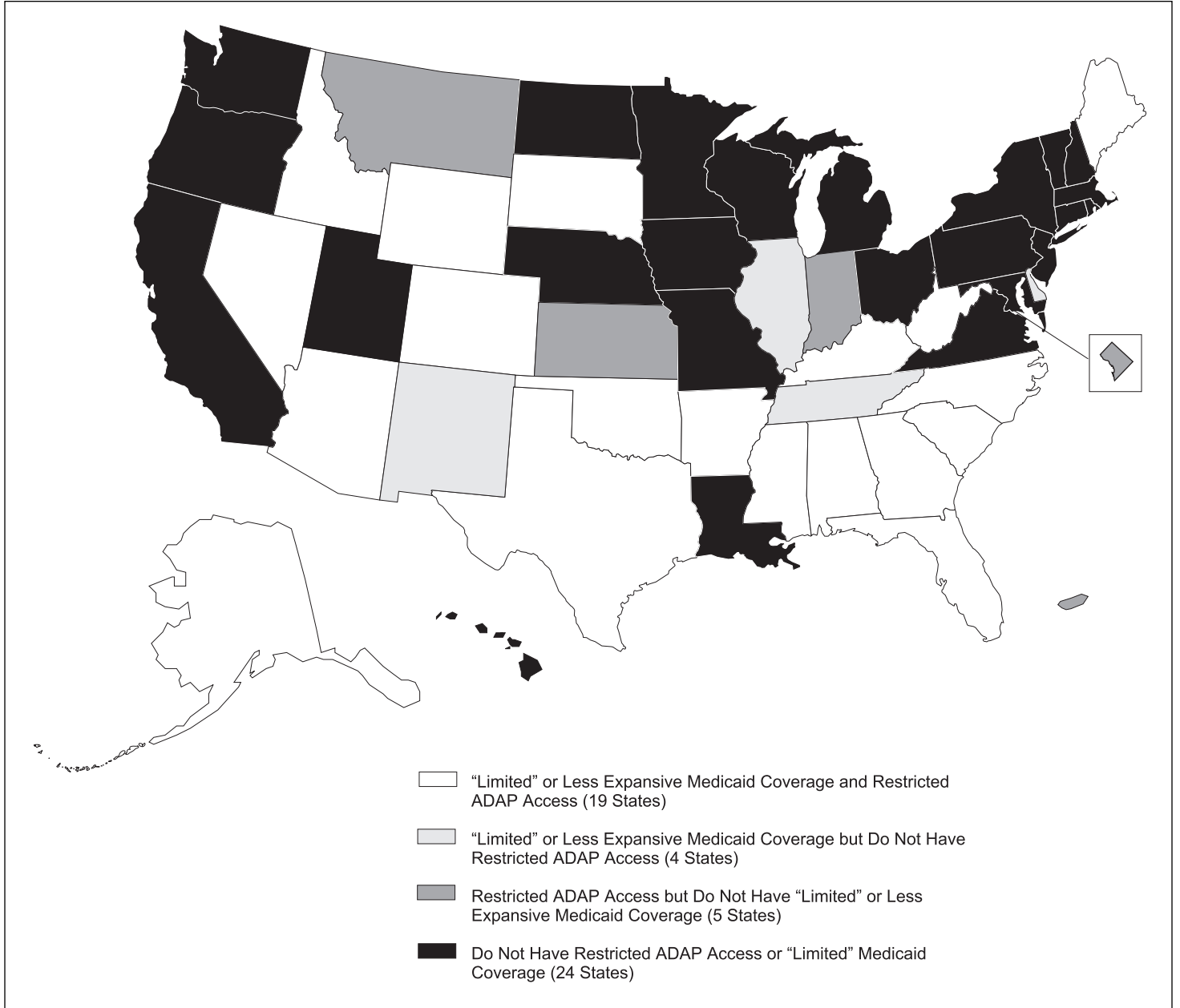
A recent study of all ADAPs similarly found that 39 states require their ADAPs to cross-check client eligibility for Medicaid, mostly through direct access to Medicaid data or through screening by case managers.²⁶ The study points out that 19 of the 23 states with limited Medicaid coverage have restricted ADAP access.²⁷ This suggests that the expansiveness of a state's Medicaid program may directly affect the demand for ADAP services. For example, the Medicaid programs in Mississippi, Oklahoma, and Texas are among 11 state programs that have placed limits on the number of prescriptions available each month; at the same time, the ADAPs in these

²⁶See National ADAP Monitoring Project: Interim Technical Report.

²⁷The study defines "limited" Medicaid programs by one or more of the following: (1) no medically needy eligibility category, (2) low spend-down income eligibility threshold (less than 50 percent of the federal poverty level), and (3) monthly prescription limits with no exceptions for chronic illnesses (for example, HIV/AIDS).

states have not been able to meet the demand and have had to develop waiting lists. Figure 1 shows the restrictiveness of the Medicaid and ADAP programs in the various states.

Figure 1: Restrictiveness of Medicaid and ADAP Coverage in States



Source: National Alliance of State and Territorial AIDS Directors and the AIDS Treatment Data Network, March 1998.

Discount Pricing Reduces ADAP Expenditures

Most ADAPs have reduced their expenditures on HIV and AIDS drugs through several discount pricing methods. For example, under the Veterans' Health Care Act of 1992 (which enacted section 340B of the Public Health Service Act), ADAPs—as well as state Medicaid programs—can obtain drugs at a minimum 15.1-percent discount below the average manufacturer price. ADAPs that cannot obtain up-front drug discounts may negotiate voluntary manufacturer rebates of certain drugs. Some ADAPs seek discounts from retail pharmacies, receive third-party partial insurance reimbursements (when available), collect copayments for drugs from clients, or obtain reimbursement coverage from Medicaid if a client becomes eligible for that program.

However, not all ADAPs have obtained the lowest prices available in purchasing drugs. According to a recent HHS Inspector General's report, only 19 of the 53 ADAPs participated in the 340B drug pricing program in fiscal year 1996.²⁸ Many of the nonparticipating programs cited the list of administrative burdens as a disincentive. However, a recent HHS policy change will allow ADAPs to participate more readily in this program by the use of a rebate mechanism. For the sample of nonparticipating ADAPs that it examined, the Inspector General estimated that they could have purchased an additional 8 percent of drug therapies if they had participated in the 340B program.

Emergency Measures Taken by Some ADAPs

Regardless of these efforts, with the increase in the number of people seeking assistance, many states have found it difficult to adequately fund their ADAPs. Some states have cut costs by restricting patient access to ADAPs and implementing other emergency measures.

According to a study published by the National Alliance of State and Territorial AIDS Directors, in fiscal year 1997, 22 states implemented emergency measures to contain costs.²⁹ These problems have occurred most frequently near the end of the time period for which the title II funding grant is provided. Twelve states moved funds from other CARE Act budget categories, such as home health care, and other sources; 10 states capped program enrollment; and 9 states restricted access to protease inhibitors. Thirteen states noted that they would likely exhaust their funds before more funding would be made available. Nine states reported that

²⁸HHS, Office of Inspector General, Audit of State AIDS Drug Assistance Programs' Use of Drug Price Discounts, No. A-01-97-01501 (Washington, D.C.: Jan. 1998).

²⁹See National ADAP Monitoring Project: Interim Technical Report.

they maintained waiting lists for ADAP enrollment, while seven states maintained waiting lists for current clients to obtain protease inhibitors.³⁰

As of July 1998, 19 ADAPs had some type of restrictions on their services. As shown in table 4, these limitations included capping enrollment and expenditures and maintaining waiting lists.

Table 4: Summary of Program Limitations Reported by Grantees for ADAP Services, July 1998

Type of program limitation	Number of ADAPs reporting limitation	Grantees reporting limitation
All ADAP services		
Capped enrollment	11	Alabama, Alaska, Florida, Georgia, Idaho, Indiana, Montana, Nevada, North Carolina, Oklahoma, and South Dakota
Waiting list	9	Florida, Georgia, Idaho, Indiana, Montana, Nevada, North Carolina, Oklahoma, and South Carolina
Capped expenditures	5	Illinois, Missouri, Oklahoma, South Dakota, and Wyoming
Protease inhibitors		
Capped enrollment	7	Idaho, Kentucky, Maine, Mississippi, Missouri, Nevada, and Oklahoma
Waiting list	6	Arkansas, Idaho, Maine, Mississippi, Nevada, and South Carolina
Other limits	3	Arkansas and South Dakota (not dispensing protease inhibitors) and Mississippi (medical criteria vary by medication)

Source: HHS.

Impact of New Therapies on Public Programs Is Difficult to Assess, but Effects on Programs Would Likely Vary

As discussed, it is not possible to accurately project the number of patients who will be on combination drug therapy in the future. It is therefore difficult to assess the likely impact of the new therapies on public programs. Many factors—such as the long-term effectiveness of current therapies, evolving standards of care, and new research developments—influence future demand and cost. Regardless of the overall effect of the new therapies on public programs, the impacts are

³⁰ADAP programs in 22 states have transferred funds from other health programs, capped program enrollment, or capped or restricted access to protease inhibitors: Alabama, District of Columbia, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Maine, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, North Carolina, Oklahoma, South Carolina, South Dakota, West Virginia, and Wyoming.

likely to be different for the Medicaid program and for health care funded through the CARE Act.

Long-Term Impact of Drug Therapies Would Influence Demand and Associated Costs

Rapid advances in HIV and AIDS treatment have occurred in the last 2 years. Researchers are identifying optimal standards of care, which are now a part of federal treatment guidelines. Such information—as well as ongoing research and discoveries—will likely influence the demand for these new drugs and therapies and their effect on public programs.

The long-term effectiveness of protease inhibitors and combination drug therapies is largely unknown. Patient outcomes will likely influence the number of individuals who seek combination therapy in the future. For example, patients responding well to drug therapy may be removed from the therapy after a few years to determine whether the virus has been eliminated. Patients whose conditions cannot be stabilized may also be removed from the therapy or they may continue to receive therapy because they still benefit from the drugs. Other patients may over time develop a resistance to drugs that initially succeeded in stabilizing or reducing their viral load. Some patients may not be able to tolerate the drugs because of side effects and would thus be removed from the therapy after a brief period.

Standards of care will also likely influence the demand for combination drug therapy treatment and the associated costs. Just as the recently released NIH standards of clinical care for HIV and AIDS have greatly expanded the candidate population who qualify for treatment, changes in these standards could alter the number of individuals seeking the therapy.

Other new drugs and therapies would also likely have an effect on demand and cost. The National Institute of Allergy and Infectious Diseases is currently supporting research on the development of HIV vaccines, and a number of new drugs for HIV infection and AIDS-associated opportunistic infections are either being developed or tested. At the same time, investigations into exactly how HIV damages the immune system is suggesting new and more effective methods of treatment.

Researchers do not yet know how many years people with HIV or AIDS might maintain a combination therapy regimen or how long their lives might be extended. If the new drugs and therapies slow or halt HIV's progression to AIDS, other costs associated with the care of people with

AIDS—such as hospitalizations, support services, and long-term care—may be effectively delayed.

Some evidence already suggests that the new combination therapies have noticeably lowered the current utilization of inpatient hospital services. For example, at the 4th Conference on Retroviruses and Opportunistic Infections held in January 1997, state and hospital officials demonstrated reduced hospitalization rates, suggesting new HIV and AIDS drugs as a possible cause.³¹ A recent study by VA attributes a 37-percent decrease in the number of hospitalizations and a 41-percent decrease in the number of hospital days at 173 VA medical centers to the combination therapies. This study cites an \$18 million net cost savings in 1997 in contrast with 1996.³² Public health officials in New York City also announced a 50-percent drop in AIDS deaths from the last quarter of 1995 to the same quarter in 1996, citing as a partial reason the new HIV and AIDS drugs. Researchers at Johns Hopkins University pointed out that if a person with AIDS avoided a single hospitalization—which averages \$7,000 per stay—in 1 year, the costs associated with combination drug therapy for the same individual could be completely offset. However, if the drugs extended the life of a person with HIV or AIDS, it is possible that at some point the cost of the drugs would exceed the amount that would have been spent on hospitalizations and other treatments. Finally, hospitalization costs might simply be delayed.

Another analysis by the Johns Hopkins University AIDS researchers sought to examine the cost-effectiveness of combination therapy.³³ The model used in this study projected an incremental cost-effectiveness for triple therapy of \$10,000 to \$18,000 per life-year gained. They compared the cost per life-year saved of triple-drug therapy with the cost per life-year saved for accepted treatments for other medical conditions and found that it is within the range of other treatments for other diseases and conditions. (See table 5.)

³¹Ramon Torres, Medical Director of the AIDS Center at St. Vincent's Hospital and Medical Center in New York, showed that the new HIV and AIDS drugs have significantly reduced hospitalizations, many of which were for patients who were more likely to receive assistance from Medicaid and the ADAPs than from private insurance companies.

³²R.D. Moore, *The Hopkins HIV Report* (Baltimore, Md.: Johns Hopkins AIDS Services, Sept. 1998).

³³R.D. Moore and J.G. Bartlett, "Combination Antiretroviral Therapy in HIV Infection: An Economic Perspective," *PharmacoEconomics*, Vol. 2, No. 10 (1996), pp. 109-13.

Table 5: Cost per Life-Year Saved of Protease Inhibitor Regimens Compared With Other Selected Medical Treatments

Medical treatment	Cost per life-year saved
Triple-drug therapy for HIV	\$10,000-\$18,000
Enalapril for congestive heart failure	9,700
Lovastatin to prevent coronary disease	21,000
Renal hemodialysis	50,000
Warfarin for nonvascular atrial fibrillation, patients aged 75 years or older	110,000
Coronary bypass surgery, 50-year-old men with triple-vessel disease	113,000

Source: Moore and Bartlett, *PharmacoEconomics*, p. 111.

Different Impacts of Drug Therapies Anticipated for Medicaid and ADAPs

Although drug treatment costs per person would essentially be the same for individuals receiving assistance from Medicaid and from ADAPs, the effect on these two programs would likely be different. For Medicaid, reductions in hospitalizations could, in the short-term, offset the costs associated with HIV and AIDS combination drug therapy. However, in the longer term, program costs may not be offset if hospitalizations are merely delayed.

For ADAPs, increases in the number of people who seek assistance for combination drug therapies would not be offset by fewer hospitalizations, because ADAPs only cover the cost of prescription drugs, not hospitalizations. However, delaying the onset of AIDS, its symptoms, and associated diseases and conditions could, in the short term, reduce the need for other services funded under the CARE Act. For example, under title I, the CARE Act provides 49 metropolitan areas disproportionately affected by the AIDS epidemic with funding for mental health treatment, case management, support services, and substance abuse programs for HIV and AIDS patients. Arguably, if the new HIV and AIDS drugs successfully delayed the onset of AIDS, the demand for a number of these services might be postponed, at least for the period of time the drugs are effective. On the other hand, the success of drug therapies might increase the amount of time that clients are enrolled and the use of related support and diagnostic services. Moreover, it is not clear that clients served under other titles of the CARE Act are the same as those served under ADAP.

In light of NIH's recently published standards of care, people with HIV who are asymptomatic may seek combination therapies in greater numbers. The development of new drugs and therapies, such as quadruple therapy,

would likely add to the prescription drug demand. Although insurance coverage for the estimated 410,000 to 660,000 individuals who are HIV positive but have not developed AIDS is unknown, ADAPs are the most likely to see increases in the number of individuals who are uninsured or underinsured and seeking funding for combination drug therapy in 1998. HHS officials anticipate that welfare reform efforts will likely cause ADAP enrollment to increase. As individuals transition from Medicaid and obtain employment, they will more likely become qualified for ADAP benefits. And if treatment fails, individuals will still need care provided through other services funded through CARE Act programs.

Agency Comments

We obtained comments on a draft of this report from HHS and from two expert reviewers. HHS and the expert reviewers made technical comments, which we incorporated where appropriate. In particular, HHS was concerned that we had not accounted for the different characteristics and service needs of clients served by the ADAPs and other programs funded by the CARE Act. We added information to the report to take these complexities into account. In addition, HHS provided projections of the number of people with AIDS covered by Medicaid in 1998 that HCFA actuaries believed were more precise than those in our draft. We modified our report to reflect the HCFA estimate.

We will make copies of this report available to interested parties upon request.

Please call me at (202) 512-7119 or Marcia Crosse, Assistant Director, at (202) 512-3407 if you have any questions about this report. Other contributors to this report include Lawrence S. Solomon, Project Manager; Nila Garces-Osorio, Social Science Analyst; and Karen Sloan, Communications Analyst.



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Figure

Figure 1: Restrictiveness of Medicaid and ADAP Coverage in States

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Abbreviations

ADAP	AIDS Drug Assistance Program
AFDC	Aid to Families With Dependent Children
AIDS	acquired immunodeficiency syndrome
CARE	Comprehensive AIDS Resources Emergency
CDC	Centers for Disease Control and Prevention
DOD	Department of Defense
EMA	eligible metropolitan area
FDA	Food and Drug Administration
FPL	federal poverty level
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HMO	health maintenance organization
HRSA	Health Resources and Services Administration
HUD	Department of Housing and Urban Development
NIH	National Institutes of Health
SSI	Supplemental Security Income
VA	Department of Veterans Affairs

Financial Criteria for Medicaid and ADAP Eligibility

Within broad federal guidelines, states have flexibility in developing their Medicaid programs, including requirements for eligibility and prescription drug benefits. Medicaid covers all prescribed HIV and AIDS drugs approved by the Food and Drug Administration (FDA) consistent with the requirements of 1927(d) of the Social Security Act. The Health Care Financing Administration (HCFA) surveyed state Medicaid programs and found that all states were covering protease inhibitors, as required. Because of prescription limits, however, combination therapy, with its dependence on multiple drugs, can rapidly exceed these limits (for example, 11 states limit the number of allowable drugs to as few as three per month).³⁴ Thirty-one programs require nominal copayments for the drugs.

Generally, state AIDS Drug Assistance Programs (ADAP) cover many FDA-approved HIV and AIDS drugs, but not all drugs are covered by each program. To assess financial eligibility for ADAP enrollment, most states use federal poverty guidelines; income limits are often expressed as a percentage of the federal poverty level (FPL). The financial requirements range from 100 percent of FPL in one state to 558 percent of FPL in another state. Some states list the requirement in terms of absolute income levels: for example, as long as liquid assets total less than \$25,000, New York requires a household of one to earn no more than \$44,000; a household of two, less than \$59,200; and three or more, less than \$74,400. Other states also use specific income levels unrelated to the federal poverty guidelines. Some programs consider out-of-pocket medical expenses when determining income. Ten of the programs restrict financial assets. (See table I.1.)

States have both financial and medical requirements for ADAP enrollment. For example, a person must have an income or assets below a certain dollar amount or demonstrate financial hardship. At a minimum, a person must be diagnosed as having HIV infection. Almost half of the states have only these basic requirements. Other states also require that a client have CD4 counts less than a certain level (CD4 is a measure of the immune system level). For example, six states require a CD4 level of less than 500. Twelve states require a doctor's prescription for the HIV and AIDS drugs. Some states also test the HIV viral load in order to determine medical eligibility.³⁵

³⁴Arkansas, California, Florida, Georgia, Mississippi, Nevada, North Carolina, Oklahoma, South Carolina, Texas, and Wyoming all impose limits on the number of prescriptions. However, some states allow exceptions for chronic illnesses.

³⁵Tests of the viral load assess the level of HIV RNA, a genetic material, in the blood.

**Appendix I
Financial Criteria for Medicaid and ADAP
Eligibility**

Table I.1: Medicaid and State ADAP Financial-Based Criteria for Program Eligibility

State	Medicaid criteria as of 1997:^{a,b} applicant qualified for AFDC as of July 1996 or SSI, or had income . . .	ADAP criteria
Alabama	at or below 133% of FPL for pregnant women and infants	Income at or below 250% of FPL; no third-party insurance that pays for more than 50% of the cost of covered medications
Alaska	at or below 133% of FPL for pregnant women and infants	Income at or below 300% of federal poverty guidelines for Alaska
Arizona	at or below 140% of FPL for pregnant women and infants	Income at or below 200% of FPL
Arkansas	at or below 133%-200% of FPL for pregnant women and infants ^c	Income at or below 100% of FPL less medical expenses; usually covers any uninsured person until insurance begins
California	at or below 200% of FPL for pregnant women and infants	Income at or below 400% of FPL; if income is above limit, sliding-scale copayment is based on annual state income tax liability and family size, up to annual earnings of \$50,000; applicant's health insurance does not provide drugs as a benefit, or the copayment plan is causing financial hardship, or applicant is not enrolled in a health maintenance organization (HMO), health insurance program, or public program
Colorado	at or below 133% of FPL for pregnant women and infants	Income at or below 185% of FPL
Connecticut	at or below 185% of FPL for pregnant women and infants ^d	Income at or below 300% of FPL; no asset limitations
Delaware	at or below 185% of FPL for pregnant women and infants	Income at or below 230% of FPL, no copayment; sliding-scale copayments for cost of service, and total allowable annual charges cannot exceed either 7% or 10% of gross income, depending on the copayment
District of Columbia	at or below 185% of FPL for pregnant women and infants	Income at or below 300% of FPL
Florida	at or below 185% of FPL for pregnant women and infants	Income at or below 200% of FPL; enrollees with incomes 100%-200% of FPL are assessed for sliding-scale copayments
Georgia	at or below 185% of FPL for pregnant women and infants	Income at or below 125% of FPL
Hawaii	at or below 300% of FPL for pregnant women and infants ^{d,e}	Income at or below 400% of FPL set for Hawaii; assets less than \$10,000, excluding home and car
Idaho	at or below 133% of FPL for pregnant women and infants	Income at or below 400% of FPL
Illinois	at or below 133% of FPL for pregnant women and infants ^d	Income at or below 200% of FPL; insurance provides less than 80% of cost of prescription medication
Indiana	at or below 150% of FPL for pregnant women and infants ^d	Indiana residency requirement and income at or below 300% of FPL
Iowa	at or below 185% of FPL for pregnant women and infants	Income at or below 200% of FPL
Kansas	at or below 150% of FPL for pregnant women and infants	Income at or below 300% of FPL; will assist with spend-down

(continued)

**Appendix I
Financial Criteria for Medicaid and ADAP
Eligibility**

State	Medicaid criteria as of 1997,^{a,b} applicant qualified for AFDC as of July 1996 or SSI, or had income . . .	ADAP criteria
Kentucky	at or below 185% of FPL for pregnant women and infants	Income at or below 300% of FPL, adjusted for family size; cash assets less than \$10,000; access to protease inhibitors requires income at or below 200% of FPL, adjusted for family size
Louisiana	at or below 133% of FPL for pregnant women and infants	Income at or below 200% of FPL; assets less than \$4,000, excluding home and car; not qualified for Medicaid or private insurance
Maine	at or below 185% of FPL for pregnant women and infants	Income at or below 200% of FPL
Maryland	at or below 185% of FPL for pregnant women and infants ^e	Income equal to or less than \$29,400, adjusted for household size; sliding-scale copayments for incomes over \$26,000
Massachusetts	at or below 185% of FPL for pregnant women and infants	Income at or below \$27,000; limit raised by \$2,200 for each dependent
Michigan	at or below 185% of FPL for pregnant women and infants	Income at or below 362% of FPL; must have applied for Medicaid within the past 60 days and have pending or denial status; not eligible for VA benefits
Minnesota	at or below 275% of FPL for pregnant women and infants ^{d,e}	Income at or below 300% of FPL; liquid assets less than \$25,000, excluding home and car; uninsured or responsible for 20% or more of prescription cost or \$15 or more per prescription; cannot be in state Medical Assistance or General Assistance Medical Care programs
Mississippi	at or below 185% of FPL for pregnant women and infants	Household income below 200% of FPL
Missouri	at or below 185% of FPL for pregnant women and infants ^d	Income at or below 185% of FPL
Montana	at or below 133% of FPL for pregnant women and infants	Applicant must provide evidence that the cost of the covered medications will create a severe household financial burden
Nebraska	at or below 150% of FPL for pregnant women and infants	Income at or below 200% of FPL
Nevada	at or below 133% of FPL for pregnant women and infants	Income at or below 200% of FPL; less than \$4,000 in assets, excluding home and car
New Hampshire	at or below 185% of FPL for pregnant women and infants ^d	Income at or below 300% of FPL (income limit may be adjusted on basis of medical expenses incurred)
New Jersey	at or below 185% of FPL for pregnant women and infants	Income equal to or less than \$30,000 for one person; limit increased by \$10,000 for each member of household, up to \$70,000 per year
New Mexico	at or below 185% of FPL for pregnant women and infants	Income at or below 300% of FPL, adjusted for family size; liquid assets of less than \$10,000
New York	at or below 185% of FPL for pregnant women and infants	Income at or below \$44,000 for a household of one, less than \$59,200 for two, less than \$74,400 for three or more; liquid assets less than \$25,000
North Carolina	at or below 185% of FPL for pregnant women and infants	Income at or below 125% of FPL
North Dakota	at or below 133% of FPL for pregnant women and infants ^d	Income at or below 150% of FPL; sliding-scale coverage above 150% of FPL
Ohio	at or below 133% of FPL for pregnant women and infants ^d	Income at or below 281% of FPL, currently less than \$1,410 per month after taxes (additional allowance for dependents)
Oklahoma	at or below 150% of FPL for pregnant women and infants ^d	Income at or below 150% of FPL (out-of-pocket drug costs can spend-down)

(continued)

**Appendix I
Financial Criteria for Medicaid and ADAP
Eligibility**

State	Medicaid criteria as of 1997,^{a,b} applicant qualified for AFDC as of July 1996 or SSI, or had income . . .	ADAP criteria
Oregon	at or below 133% of FPL for pregnant women and infants	Income at or below 250% of FPL
Pennsylvania	at or below 185% of FPL for pregnant women and infants	Gross income less than \$30,000, with an allowance of \$2,480 for each additional family member
Puerto Rico	Not available	Certified medically indigent by Medicaid or limited or no coverage by a drug prescription plan, as documented by the state, health insurance plan, consortia, or community-based organization; guidelines for income start at between \$400 and \$800 per month for one person
Rhode Island	at or below 250% of FPL for pregnant women and infants ^e	Income at or below 400% of FPL
South Carolina	at or below 185% of FPL for pregnant women and infants	Income at or below 300% of FPL for free medications; a sliding fee scale determines applicant's payment above this threshold
South Dakota	at or below 133% of FPL for pregnant women and infants	Income at or below 300% of FPL
Tennessee	at or below 400% of FPL for pregnant women and infants ^e	Income at or below 300% of FPL; liquid asset limit of \$8,000
Texas	at or below 185% of FPL for pregnant women and infants	Income at or below 200% of FPL (if married, spouse's income is counted); not eligible for Medicaid or used up the month's Medicaid pharmacy benefit; copayment of \$5 per prescription may be required for clients not eligible for Medicaid; income guidelines for households of 1 person, less than \$15,480, 2 people, less than \$20,720, 3 people, less than \$25,960, 4 people, less than \$31,200, 5 people, less than \$36,440
Utah	at or below 133% of FPL for pregnant women and infants	Full coverage at or below 100% of FPL; sliding scale and copayment for incomes over 100% of FPL
Vermont	at or below 200%-225% of FPL for pregnant women and infants ^f	Income at or below 200% of FPL; sliding scale and copayments for incomes over 200% of FPL
Virginia	at or below 133% of FPL for pregnant women and infants ^d	Income at or below 200% of FPL (residents of northern Virginia may have incomes up to \$17,428)
Washington	at or below 185%-200% of FPL for pregnant women and infants ^f	Income at or below 370% of FPL; assets less than \$10,000, excluding home and car
West Virginia	at or below 150% of FPL for pregnant women and infants	Income at or below 300% of FPL
Wisconsin	at or below 185% of FPL for pregnant women and infants	Income at or below 200% of FPL; must have applied for coverage under, and have been denied eligibility for, medical assistance within 12 months of application
Wyoming	at or below 133% of FPL for pregnant women and infants	Income at or below 300% of FPL

(Table notes on next page)

Appendix I
Financial Criteria for Medicaid and ADAP
Eligibility

^aStates are required to provide Medicaid coverage to children aged 6 and older born after September 30, 1983, living in families with incomes below 100 percent of the federal poverty level. Since 1989, states have been required to cover all pregnant women as well as children below age 6 living in families with incomes at or below 133 percent of the federal poverty level.

^bWelfare reform generally severed the link between cash assistance programs and Medicaid eligibility. Under the Temporary Assistance for Needy Families block grant, the open-ended entitlement to cash assistance for eligible families was eliminated. To ensure continued Medicaid coverage for low-income families, the law generally set Medicaid eligibility standards at AFDC levels in effect on July 16, 1996.

^cIn Arkansas, pregnant women are covered at 133 percent of FPL and infants are covered up to 200 percent of FPL.

^dEleven states elected to retain the more restrictive Medicaid eligibility criteria that were in place for blind, disabled, and elderly beneficiaries before SSI was established in 1972. These states may use more restrictive definitions of disability or more restrictive financial eligibility criteria than SSI.

^eHawaii, Maryland, Minnesota, Rhode Island, and Tennessee operate programs under Section 1115 waivers. Some populations receive fully subsidized Medicaid services. Other populations are required to pay a portion of the premium and may have a different benefit package.

^fIn Vermont, pregnant women are covered at 200 percent of FPL and infants are covered up to 225 percent of FPL. In Washington, the income eligibility criterion for pregnant women is 185 percent of FPL; the income eligibility criterion for infants is 200 percent of FPL.

Sources: National Governors' Association, Medicaid Eligibility of Pregnant Women, Infants, and Children, Effective October 1997 (Washington, D.C.: Oct. 1997); National Alliance of State and Territorial AIDS Directors and AIDS Treatment Data Network, National ADAP Monitoring Project: Interim Technical Report (Washington, D.C.: Mar. 1998) and State AIDS Drug Assistance Programs: A National Status Report on Access (Washington, D.C.: July 1997).

State ADAP Funding

In fiscal year 1997, a total of 34 states (plus the District of Columbia and Puerto Rico) provided funds to their ADAPs in addition to the funds provided by the federal government. The state contributions have increased from a total of \$28.7 million in 1995 to \$98.1 million in 1997 (see table II.1).

Table II.1: State Funding Contributions for ADAP and Percentage Change, Fiscal Years 1995, 1996, and 1997

State	State funding amounts				State % of total funding			
	FY 1995	FY 1996	FY 1997	Percentage change, 1995-97	FY 1995	FY 1996	FY 1997	Percentage change, 1995-97
Alabama	^a	\$150,000	\$150,604	^b	^a	6%	5%	^b
Alaska	^c	0	0	^b	^c	0	0	^b
Arizona	0	0	600,000	^b	0	0	18	^b
Arkansas	9,657	0	0	(-100)	2	0	0	(-100)
California	9,100,000	15,600,000	40,200,000	342	52	41	51	(-4)
Colorado	150,000	301,000	301,000	101	27	24	11	(-59)
Connecticut	592,000	592,000	592,000	0	43	24	14	(-67)
Delaware	0	35,000	0	0	0	8	0	0
District of Columbia	0	147,000	800,000	^b	0	6	15	^b
Florida	42,000	0	1,500,000	3,471	1	0	5	400
Georgia	324,000	324,450	324,450	0	19	7	4	(-79)
Hawaii	265,000	300,000	291,000	10	66	42	26	(-61)
Idaho	0	0	0	0	0	0	0	0
Illinois	2,197,493	5,200,000	8,325,000	279	63	58	58	(-10)
Indiana	0	75,000	442,000	^b	0	5	17	^b
Iowa	0	0	0	0	0	0	0	0
Kansas	0	0	0	0	0	0	0	0
Kentucky	99,970	110,000	127,944	28	23	13	11	(-52)
Louisiana ^d	0	0	0	0	0	0	0	0
Maine	60,040	60,040	60,000	0	67	25	15	(-78)
Maryland	85,688	1,100,000	600,000	600	11	24	10	(-9)
Massachusetts	1,290,000	1,100,000	6,800,000	427	71	34	60	(-15)
Michigan	0	0	0	0	0	0	0	0
Minnesota	0	150,000	150,000	^b	0	26	15	^b
Mississippi	0	0	0	0	0	0	0	0
Missouri	0	600,000	600,000	^b	0	37	11	^b
Montana	^a	95,000	0	^b	^a	42	0	^b
Nebraska	0	0	0	0	0	0	0	0
Nevada	0	0	1,300,000	^b	0	0	46	^b

(continued)

**Appendix II
State ADAP Funding**

State	State funding amounts				State % of total funding			
	FY 1995	FY 1996	FY 1997	Percentage change, 1995-97	FY 1995	FY 1996	FY 1997	Percentage change, 1995-97
New Hampshire	100,000	73,833	0	(-100)	48	17	0	(-100)
New Jersey	0	875,000	700,000	^b	0	9	4	^b
New Mexico	650,000	740,000	740,000	14	100	64	38	(-62)
New York	495,120	8,400,000	9,900,000	1,900	2	15	14	600
North Carolina	450,000	750,000	750,000	67	100	35	20	(-80)
North Dakota	0	0	0	0	0	0	0	0
Ohio	200,500	200,000	3,124,500	1,458	19	10	48	153
Oklahoma	206,000	206,000	431,000	109	37	20	21	(-43)
Oregon	0	0	0	0	0	0	0	0
Pennsylvania	4,703,000	5,200,000	6,659,347	42	100	76	56	(-44)
Puerto Rico	3,406,651	3,406,651	4,168,036	22	49	42	32	(-35)
Rhode Island	0	0	0	0	0	0	0	0
South Carolina	50,000	350,000	500,000	900	11	21	14	27
South Dakota	0	0	0	0	0	0	0	0
Tennessee	0	0	610,050	^b	0	0	25	^b
Texas	2,708,838	2,697,376	2,697,736	0	65	32	14	(-80)
Utah	114,000	114,800	114,800	0	54	17	15	(-72)
Vermont	^a	0	150,000	^b	^a	0	38	^b
Virginia	786,800	687,200	687,200	(-13)	56	18	11	(-80)
Washington	240,000	417,500	3,263,000	1,260	50	26	53	6
West Virginia	0	25,000	74,833	^b	0	11	9	^b
Wisconsin	393,700	295,800	373,500	(-5)	93	35	25	(-73)
Wyoming	0	0	0	0	0	0	0	0
Total	\$28,720,457	\$50,378,650	\$98,108,000	242	31	24	25	(-19)

^aNot available.

^bPercentage change cannot be calculated.

^cState had no ADAP that year.

^dLouisiana does not fund its ADAP directly. The state operates an independent system that provides outpatient HIV/AIDS drugs through hospitals to those in need. This system was funded at \$2 million in fiscal year 1995, \$3.3 million in fiscal year 1996, and \$20 million in fiscal year 1997.

Sources: National Alliance of State and Territorial AIDS Directors, The Fiscal Status of State AIDS Drug Assistance Programs: Findings From a January 1996 National Survey of State AIDS Directors (Washington, D.C.: Apr. 1996); National Alliance of State and Territorial AIDS Directors and the AIDS Treatment Data Network, State AIDS Drug Assistance Programs: A National Status Report on Access (Washington, D.C.: July 1997). and National ADAP Monitoring Project: Interim Technical Report (Washington, D.C.: Mar. 1998).

EMA Contributions to ADAPs

Currently, 49 communities in 21 states, the District of Columbia, and Puerto Rico have been designated under title I of the CARE Act as EMAs disproportionately affected by the AIDS epidemic. In 1997, these EMAs contributed some \$24 million to the ADAP programs. The level of these contributions has been generally flat over the past few years, increasing from 1995 to 1996, and then declining slightly in 1997 (see table III.1).

Table III.1: Title I EMA Contributions to ADAPs and Percentage Change, Fiscal Years 1995, 1996, and 1997

States with EMAs	Contribution amount			Change, FY 1995-97	
	FY 1995	FY 1996	FY 1997	Amount	Percentage
Arizona	0	0	\$407,000	\$407,000	^a
California	0	0	0	0	0
Colorado	\$350,000	\$261,000	774,749	424,749	121
Connecticut	209,500	421,500	443,892	234,392	112
District of Columbia	74,801	800,000	1,150,873	1,076,072	1,439
Florida	0	0	0	0	0
Georgia	365,420	1,064,645	1,000,000	634,580	174
Illinois	0	825,000	0	0	0
Louisiana	0	0	0	0	0
Maryland	123,581	453,963	330,394	206,813	167
Massachusetts	300,000	350,000	1,177,465	877,465	293
Michigan	187,500	400,000	300,000	112,500	60
Minnesota	0	0	0	0	0
Missouri	36,675	0	0	(-36,675)	(-100)
New Hampshire	0	72,308	102,388	102,388	^a
New Jersey	516,250	792,024	1,410,738	894,488	173
New York	17,591,280	19,858,730	16,043,941	(-1,547,339)	(-9%)
Ohio	0	0	0	0	0
Oregon	0	0	537,000	\$537,000	^a
Pennsylvania	0	0	0	0	0
Puerto Rico	1,013,827	0	0	(-1,013,827)	(-100)
Texas	0	217,000	0	0	0
Washington	58,654	342,500	575,000	516,346	880
Total	\$20,827,488	\$25,858,670	\$24,253,440	\$3,425,952	16

^aPercentage change cannot be calculated.

State-by-State Profile of ADAPs

From January 1997 to July 1997, 39 states' ADAPs experienced growth in the number of clients served; 42 experienced increases in monthly expenditures for the same period. Six states experienced a 50-percent or greater increase in clients served. For example, clients served through Delaware's ADAP increased 327 percent—the greatest increase experienced by a state; conversely, Mississippi saw a 56-percent decrease in clients served. Only five states experienced minimal change (a less than 5-percent increase or decrease). (See table IV.1.)

Table IV.1: Number of Clients Served by ADAPs and ADAP Expenditures, July 1996, January 1997, and July 1997

State	Clients served				Expenditures			
	July 96	Jan. 97	July 97	Percentage change, July 96-July 97	July 96	Jan. 97	July 97	Percentage change, July 96-July 97
Alabama	500	454	486	(-3%)	\$167,000	\$222,779	\$316,359	89
Alaska	^a	5	11	^b	^a	3,319	7,614	^b
Arizona	335	435	448	34	116,761	226,611	287,075	146
Arkansas	259	351	426	64	45,260	85,536	119,713	165
California	6,258	7,431	8,539	36	3,557,218	4,487,075	5,914,041	66
Colorado	379	^a	534	41	161,598	^a	296,516	83
Connecticut	334	634	519	55	188,563	385,320	367,286	95
Delaware	55	11	47	(-15)	29,900	4,243	20,240	(-32)
District of Columbia	543 ^c	^a	312	(-43)	299,497 ^c	^a	^a	^b
Florida	4,322	4,565	4,868	13	1,748,679	1,576,631	2,590,826	48
Georgia	922	662	1,041	13	308,400	274,126	307,949	0
Hawaii	60	84	104	73	45,730	55,642	67,680	48
Idaho	30	50	48	60	7,215	23,179	29,410	308
Illinois	1,303	1,203	1,319	1	769,232	733,251	763,364	(-1)
Indiana	217	252	280	29	88,738	107,287	185,903	109
Iowa	43	35	45	5	8,630	21,656	38,519	346
Kansas	86	90	110	28	40,524	60,192	75,560	87
Kentucky	113	161	191	69	45,071	89,979	101,519	125
Louisiana	^a	87	175	^b	^a	32,910	64,872	^b
Maine	65	45	52	(-20)	24,145	23,600	34,404	42
Maryland	243	409	493	103	130,234	285,859	402,426	209
Massachusetts	792	860	858	8	309,851	494,361	607,585	96
Michigan	177	212	259	46	124,568	166,109	206,785	66
Minnesota	203	198	201	(-1)	36,258	58,019	50,039	38
Mississippi	301	427	188	(-38)	26,174	157,642	100,809	285

(continued)

**Appendix IV
State-by-State Profile of ADAPs**

State	Clients served				Expenditures			
	July 96	Jan. 97	July 97	Percentage change, July 96-July 97	July 96	Jan. 97	July 97	Percentage change, July 96-July 97
Missouri	^a	294	371	^b	^a	128,761	215,180	^b
Montana	23	18	18	(-22)	17,600	18,000	19,500	11
Nebraska	57	62	85	47	17,054	26,773	46,081	170
Nevada	217	281	336	55	81,900	62,556	64,428	(-21)
New Hampshire	45	43	57	27	21,745	22,582	40,828	88
New Jersey	994	1,700	1,960	97	380,000	900,000	1,200,000	216
New Mexico	330	421	465	41	125,094	213,546	218,175	74
New York	4,859	6,422	7,595	56	3,313,519	5,199,838	6,838,895	106
North Carolina	268	342	470	75	161,861	205,320	415,241	157
North Dakota	15	15	12	(-20)	4,417	^a	^a	^b
Ohio	323	449	596	85	136,220	207,286	430,264	216
Oklahoma	139	242	293	111	61,686	115,430	165,507	168
Oregon	90	103	91	1	46,100	56,000	27,104	(-41)
Pennsylvania	1,060	997	1,268	20	467,808	656,745	908,362	94
Puerto Rico	1,920	1,980	2,320	21	750,000	^a	^a	^b
Rhode Island	69	89	140	103	16,216	30,170	60,000	270
South Carolina	149	198	310	108	68,220	127,113	215,606	216
South Dakota	25	19	17	(-32)	6,800	10,047	6,499	(-4)
Tennessee	113	155	145	28	43,694	60,042	64,502	48
Texas	1,910	2,727	3,215	68	587,289	1,188,790	1,571,340	168
Utah	47	79	95	102	24,736	52,718	68,089	175
Vermont	37	32	41	11	20,053	14,115	22,526	12
Virginia	583	1,437	1,189	104	45,424	369,310	545,000	1100
Washington	338	492	543	61	147,342	210,451	313,782	113
West Virginia	31	39	43	39	15,206	29,176	29,554	94
Wisconsin	133	156	202	52	66,966	87,074	150,576	125
Wyoming	56	53	63	12	1,500	^a	^a	^b
Total	31,371	37,506	43,494	39	\$14,907,699	\$19,568,167	\$26,593,535	78

Note: Expenditure totals may not add because of rounding.

^aNot available.

^bPercentage change cannot be calculated.

^cAugust 1996 data.

Source: National Alliance of State and Territorial AIDS Directors, March 1998 and July 1997.

Appendix IV
State-by-State Profile of ADAPs

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