State Implementation of the AIDS Drug Assistance Programs

Robert J. Buchanan, Ph.D. and Scott R. Smith, Ph.D.

Acquired immunodeficiency syndrome (AIDS) drug assistance programs (ADAPs) provide access to medications for people who lack other health coverage. In this article, the authors present the results of a 1997 survey identifying how 48 States implemented ADAPs, focusing on the number of beneficiaries, medical and financial eligibility criteria, the administration of waiting lists, and the coverage of drugs including protease inhibitors. Increased funding for ADAPs is necessary to maintain this important part of the public sector safety net for human immunodeficiency virus (HIV) care.

INTRODUCTION

Drug therapies for the treatment of infection with HIV and related opportunistic infections are the primary weapons to improve the quality of life and increase the length of survival for people with HIV disease. The combination of nucleoside antiretrovirals with protease inhibitors demonstrates the greatest potential for reducing plasma HIV and increasing CD4 cell counts (Collier et al., 1996). In fact, recent studies demonstrate that these combination drug therapies slow the progression of HIV disease (Hammer et al., 1997) and have beneficial effects lasting for as long as at least 1 year (Gulick et al., 1997). In addition, AIDS researchers presenting at an Interscience Conference on Antimicrobial Agents and Chemotherapy in Toronto, Canada, in September, 1997, concluded that the three-drug therapy continues to fight off HIV in 79 percent of the patients treated for 2 years and that the immune system strengthens the longer the drugs work (Waldholz, 1997).

Although there is limited information about the best time to initiate therapy, the International AIDS Society currently recommends that antiretroviral therapy be considered for all HIV-infected individuals with detectable plasma HIV ribonucleic acid (Carpenter et al., 1997). In addition, treatment guidelines published by the Federal Government recommend a triple-drug regimen, with the preferred treatment including at least one protease inhibitor (Fauci et al., 1997). Hence, there is a growing consensus for offering treatment at earlier stages of the disease with combinations of several drugs.

Similarly, increased knowledge and experience with treating HIV-related opportunistic illnesses resulted in the development of guidelines for the prevention of these infections by the U.S. Public Health Service and the Infectious Disease Society of America (Centers for Disease Control and Prevention, 1997b). The incidence rates of a number of opportunistic infections among people with HIV disease have declined in recent years and are being diagnosed at a later stage of HIV disease as a result of the effective use of antiretroviral drugs, targeted preventive therapy, and more comprehensive clinical

Robert J. Buchanan is with the Medical University of South Carolina, and Scott R. Smith is with the University of North Carolina at Chapel Hill. This research was funded by the Health Care Financing Administration (HCFA) under Grant Number 18-P-90286/5-02. The views expressed herein are those of the authors and do not necessarily reflect the views of the Medical University of South Carolina, the University of North Carolina at Chapel Hill, or HCFA.

management of the disease (Moore and Chaisson, 1996). Given the use of combination drug therapies to fight HIV infection and the use of medications to treat related opportunistic infections, the number of drugs needed by people with HIV disease can be extensive, particularly for those in later stages of the disease.

With the advent of highly active antiretroviral therapy and other medications, the clinical course of HIV disease is changing in the United States. The annual incidence of HIV-related opportunistic infections declined in 1996 for the first time (Centers for Disease Control and Prevention, 1997a). A study of people with HIV disease who were at the greatest risk for illness or death shows a dramatic reduction in morbidity and mortality, with these reductions in disease and death linked to the increased use of combination antiretroviral therapy, and the most dramatic reductions associated with the use of protease inhibitors (Palella et al., 1998). This study documented that mortality declined from 29.4 per 100 person-years in 1995 to 8.8 per 100 person-years during 1997. Similarly, the incidence of selected opportunistic infections declined from 21.9 per 100 person-years in 1994 to 3.7 per 100 person-years during 1997.

These trends suggest that access and adherence to HIV drug regimens, particularly combination antiretrovirals including the protease inhibitors, are increasingly important to the survival of individuals with HIV disease. However, these effective medications are expensive, with combination antiretroviral therapy including protease inhibitors costing at least $12,000 per year for each person treated (Hirschel and Francioli, 1998). Earlier and more intensive treatment of HIV carries important implications for State and Federal programs that assist individuals in obtaining medications. As more individuals with HIV seek care, public programs are faced with a growing demand for expensive drug-related benefits in an environment of limited public resources.

RYAN WHITE CARE ACT

The Ryan White Comprehensive AIDS Resource Emergency (CARE) Act (Public Law 101-381) was enacted in August, 1990, to improve both the quality and availability of care for people with HIV disease and their families (U.S. Department of Health and Human Services, 1993). The original legislation authorized: grants to metropolitan areas with the largest number of AIDS cases to help provide emergency services (Title I); grants to the States to improve the quality, availability, and organization of health and related support services (Title II); grants to State health departments for AIDS early intervention services (Title III-a) and community-based primary care facilities (Title III-b); and grants for research and evaluation initiatives, including demonstration programs for pediatric AIDS research (Title IV) (McKinney, et al., 1993). Title II of the CARE Act allows States to allocate funds among any or all of four areas to cover home-based health services, provide medication and other treatments, continue private health insurance coverage, or fund HIV care consortia (Health Care Financing Administration, 1995).

Federal appropriations for the CARE Act have increased dramatically since the law's inception. As Table 1 shows, total Federal appropriations for all CARE Act programs increased from $220.6 million in 1991 to $1.15 billion during 1998, with more than $1.3 billion requested in President Clinton's proposed budget for fiscal year 1999. Table 1 also illustrates the sharp increase in Federal appropriations for Title II programs. Federal spending on Title II

Table 1
Federal Appropriations for the Ryan White CARE Act, by Program: 1991-99

CARE Act Program	1991	1992	1993	1994	1995	1996	1997	1998	1999[1]
					(in Millions)				
Total CARE Act	$220.6	$279.1	$348.0	$579.4	$633.0	$757.4	$996.3	$1,150.2	$1,315.2
Title I—Emergency Relief	87.8	121.6	184.8	325.5	356.5	391.7	449.9	464.8	489.8
Title II—									
HIV Care	87.8	107.6	115.3	183.9	198.1	260.8	417.0	543.0	670.0
(State ADAP)[2]	0.0	0.0	0.0	0.0	0.0	(52.0)	(167.0)	(285.5)	(385.5)
Title IIIb—Early Intervention	44.9	49.8	48.0	48.0	52.3	56.9	69.6	76.3	86.3
Title IV—Pediatric AIDS	0.0	0.0	0.0	22.0	26.0	29.0	36.0	41.0	44.0
AIDS Education Training Centers	NA	NA	NA	NA	NA	12.0	16.3	17.3	17.3
Dental Reimbursements	NA	NA	NA	NA	NA	6.9	7.5	7.8	7.8

[1] President's proposed budget for fiscal year 1999.

[2] State ADAP spending levels (in parentheses) are a subset of spending for HIV care, and ADAP spending levels are included in HIV care spending levels.

NOTES: These are Federal fiscal years. HIV is human immunodeficiency virus. AIDS is acquired immunodeficiency syndrome. ADAP is AIDS drug assistance program.

SOURCE: Office of Policy and Program Development, Health Resources and Services Administration, 1998.

increased from $87.8 million during 1991 to $543 million in 1998, with $670 million requested in the President's proposed budget for fiscal 1999. In addition, Table 1 shows Title II supplemental funding for the ADAPs that began in 1996 increasing from $52 million during that year to $285.5 million during 1998, with $385.5 million requested in the President's proposed budget for 1999.

Focusing on State funding for the ADAPs, these programs may receive revenues from other sources in addition to Title II spending. Eligible metropolitan areas funded by Title I of the CARE Act may allocate some of their resources to the ADAP in their State (Health Resources and Services Administration, 1997). During Federal fiscal year 1996, 35 States contributed $53 million to the ADAPs in their respective States, and 34 States allocated more than $100 million during fiscal year 1997 (Health Resources and Services Administration, 1997). For example, California contributed more than $27 million, New York contributed more than $10 million, and Louisiana $16 million during 1997, but most States contributed less than $1 million or nothing at all to their ADAP during 1997 (Health Resources and Services Administration, 1997). Of the total ADAP funding in the United States of $387.9 million from all sources during fiscal year 1997, about $220 million (57 percent) came from Title II of the CARE Act, $41 million (11 percent) came from Title I of the CARE Act, $101 million (26 percent) came from State funding, and $26 million (7 percent) came from other sources (Health Resources and Services Administration, 1997).

Although the Ryan White legislation did not establish income eligibility restrictions for people to receive CARE Act services, the law did specify that CARE Act programs must be the payer of last resort (Health Care Financing Administration, 1995). However, CARE Act funds can be used to pay for care provided to Medicaid recipients if the State Medicaid program does not cover a needed health service or if a Medicaid recipient's need for a health

service exceeds the Medicaid program's limits on utilization. If a State Medicaid program does not cover hospice care, for example, a Medicaid recipient can receive that service through a program funded by the CARE Act, if available. Similarly, if a Medicaid recipient needs more home nursing visits then allowed by the State Medicaid program, programs funded by the CARE Act may pay for additional home nursing care (Health Care Financing Administration, 1995).

ADAPs in each State can provide access to needed drug therapies for people who lack other types of health insurance coverage. Even before the new protease inhibitors were approved by the Food and Drug Administration (FDA), budget constraints forced ADAPs in many States to reduce the number of drugs included on their formularies and to restrict eligibility for program benefits, with some States implementing waiting lists (Buchanan and Smith, 1996). The expense of the protease inhibitors, when used in combination drug therapies, will make the fiscal problems of these ADAPs even worse. The objective of this article is to identify how States are implementing ADAPs. This research presents the results of a 1997 survey that collected data on: ADAP beneficiaries, including financial and medical eligibility policies; changes in ADAP eligibility criteria; the implementation of waiting lists for ADAP coverage, with the number of people and the length of time waiting; the use of drug formularies, the number of drugs covered and a summary of how new drugs are added to the formularies; changes in the number of drugs covered by the ADAPs; and coverage of the protease inhibitors by the ADAPs in each State, as well as assessments of the impact these medications are having on the ADAPs in each State.

METHODOLOGY

This survey of the State ADAPs was part of an HIV-related project funded by a grant from HCFA. The survey questionnaire included four sections: (1) the number of people receiving benefits, with questions assessing changes in the number of people covered; (2) medical and financial eligibility policies, with questions assessing changes in financial eligibility criteria and questions relating to the implementation of waiting lists; (3) prescription drug coverage, with questions asked about the number of drugs covered, changes in the number of covered drugs, the off-label use of drugs, and how new drugs are added to the ADAP formulary; and (4) ADAP coverage of protease inhibitors and the impact this coverage is having on the ADAP in each State.

The survey began in early March 1997, with four additional mailings of the questionnaire sent to States not responding at about 6-week intervals. The questionnaires were sent to the AIDS program directors in the 50 States and the District of Columbia. The names and addresses of these program directors were initially obtained from the Health Resources and Services Administration (1995). Through contact with these program directors, an updated mailing list for 1997 was developed that focused on ADAP administrators in each State (Buchanan and Smith, 1996).

Completed questionnaires were received from 48 States when the survey ended in late September 1997.[1] The survey responses were summarized into four tables and mailed to the ADAPs for verification, corrections, or updates in October 1997. Updates and corrections received from the ADAPs are included in the tables presented in this article. The survey

[1] Survey responses were not received from the ADAPs in the District of Columbia, Iowa, and Oklahoma.

process, including verification, was completed in December 1997.

ADAP BENEFICIARIES AND ELIGIBILITY POLICIES

ADAP Beneficiaries

The questionnaire asked the ADAP administrators to estimate the number of people who received drug benefits from the ADAP in their State during 1997, with the responses presented in Table 2. The ADAPs provided prescription drug coverage to large numbers of people, especially in States with a high incidence of HIV disease. For example, the ADAP in California provided medication coverage to an estimated 20,000 people during 1997, while the program in Florida provided drug benefits to an estimated 7,000 people. The ADAP in New York provided drug coverage to more than 10,600 people, and the ADAP in Texas served more than 5,400 during 1997.

In addition, the questionnaire asked the ADAP administrators to estimate how the number of people receiving ADAP benefits in their State during 1997 compared with the number of people receiving these benefits in 1996. The ADAP administrators in almost all States estimated that the number of people receiving ADAP benefits during 1997 increased, compared with 1996, except for Illinois, Nevada, and North Dakota, where the ADAP administrators estimated that the number of people receiving benefits remained the same during 1997, compared with 1996.[2] In addition, the ADAP administrator in Alabama estimated that the number of people receiving ADAP benefits in that State decreased in 1997, and the administrator from Missouri reported that the ADAP in that State began in late 1996, thus making a comparison inappropriate.

The questionnaire also asked the ADAP administrators to estimate how the number of people expected to receive ADAP benefits during 1998 compares with the number of people receiving these benefits in 1997. The ADAP administrators in almost all States expect the number of people receiving medications from ADAPs to increase in 1998, compared with 1997, and ADAP administrators expect the number of people receiving benefits to remain the same during 1998 in Alabama, Georgia (unless additional funds are received), and South Dakota.[3] (The ADAP administrator from Missouri did not answer this question and the District of Columbia, Iowa, and Oklahoma did not respond to the survey.)

Medical Eligibility Policies

The questionnaire asked the ADAP administrators to provide medical eligibility standards for ADAP benefits in their State during 1997, (responses summarized in Table 2). In addition to a diagnosis of HIV infection, a number of States require a CD4 count below a certain level (for example, a CD4 count below 550 in Kentucky) or a viral load above a certain level (for example, a viral load of 30,000 copies or more in Mississippi) to meet ADAP medical eligibility criteria in their State. Many States only require documented infection with HIV. The ADAP in Oregon responded that its T-cell requirement for eligibility was dropped.

Financial Eligibility Policies

The questionnaire asked the ADAP administrators to provide the maximum gross monthly income during 1997 to be eligible for ADAP benefits for both an indi-

[2] Given the similarity of responses from most States, these data are not reported in Table 2.

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Table 2
Beneficiary Information and Eligibility Policies for AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Estimates of the Number of People Receiving Drugs from the ADAP	Medical Eligibility Requirements for ADAP	To Be Financially Eligible for ADAP, Gross Monthly Income During 1997 Cannot Exceed: 1-Person Household	4-Person Household	Compared With 1996, Financial Eligibility Criteria for ADAP in 1997 Became:
Alabama	750	HIV + and a CD4 Count of 500 or Less or AIDS Diagnosis	$1,556.00	$3,156.00	More Restrictive in 1997
Alaska	30-35	HIV+; Prescription From Licensed Provider for Drugs on Formulary	[1]2,468.00	[1]5,018.00	Less Restrictive in 1997
Arizona	650	HIV+, Confirmation by Lab or Physician (in Writing)	15,780.00 (per Year)	32,100.00 (per Year)	More Restrictive in 1997
Arkansas	300	Laboratory Documentation of HIV+	658.00	1,338.00	"[I]ncreased" Financial Eligibility Criteria in 1997
California	20,000	HIV+/AIDS Diagnosis; Drugs Prescribed by a California-Licensed Physician	4,167.00	NA	Remained the Same
Colorado	720	HIV Diagnosis	1,216.00	2,474.00	Remained the Same
Connecticut	991	HIV+, HIV+ Symptomatic, or AIDS	[1,2]1,973.00	[1,2]4,013.00	Remained the Same
Delaware	100	HIV+	[3]7,890.00 (per Year)	[3]16,050.00 (per Year)	Remained the Same
District of Columbia	No Response	—	—	—	—
Florida	[4] 7,000	[5] HIV+	[6]15,486.00 (per Year)	[6]31,215.00 (per Year)	Remained the Same
Georgia	1,221	HIV+ and Various CD4 and Viral-Load Counts for Different Drugs	1,972.50	4,012.50	Less Restrictive in 1997
Hawaii	105	Confirmed HIV+; Medical Indications for Some Drugs	2,972.00	5,832.00	Less Restrictive in 1997

See notes at end of table.

Table 2—Continued
Beneficiary Information and Eligibility Policies for AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Estimates of the Number of People Receiving Drugs from the ADAP	Medical Eligibility Requirements for ADAP	To Be Financially Eligible for ADAP, Gross Monthly Income During 1997 Cannot Exceed: 1-Person Household	4-Person Household	Compared With 1996, Financial Eligibility Criteria for ADAP in 1997 Became:
Idaho	50	HIV+, CD4 Count Below 500	$31,560.00 (per Year)	$64,200.00 (per Year)	Remained the Same
Illinois	[7]1,200	Documented HIV+	[6]1,290.00	[6]2,600.00	Remained the Same
Indiana	298 Active 505 in Program	Proof of HIV+ Status	1,975.00	4,012.50	Remained the Same
Iowa	No Response	—	—	—	—
Kansas	250	HIV+	(1)	(1)	Remained the Same
Kentucky	[8] 306	HIV+; CD4 Count Below 550	(1)	(1)	Remained the Same
Louisiana	320	HIV+; Recent Viral Load (Highest Priority Given to People With Viral Load Greater Than 100,000 Copies); History of Medical Compliance	15,780.00 (per Year)	32,100.00 (per Year)	Remained the Same
Maine	50	HIV+ and CD4 Count Below 400 or Viral Load Greater Than 20,000 Copies	1,290.00	2,600.00	Less Restrictive in 1997
Maryland	590	HIV+ and Taking Drugs on Formulary, or Infant Born to HIV+ Mother	2,450.00	3,367.00	Remained the Same
Massachusetts	1,537	HIV+	[9]27,000.00 (per Year)	33,600.00 (per Year)	More Restrictive in 1997
Michigan	327	HIV+ With Physician Verification Required	2,382.00	4,797.00	Remained the Same
Minnesota	313	HIV+	1,973.00	3,787.50	Remained the Same
Mississippi	792	HIV+ and CD4 Count of 500 or Less, or Viral Load of 30,000 Copies or More	1,356.00	No Answer to Question	Remained the Same
Missouri	[10] 972	HIV+	14,597.00 (per Year)	29,693.00 (per Year)	Remained the Same
Montana	25 - 30	HIV+	(6)	(6)	Remained the Same

See notes at end of table.

Table 2—Continued
Beneficiary Information and Eligibility Policies for AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Estimates of the Number of People Receiving Drugs from the ADAP	Medical Eligibility Requirements for ADAP	To Be Financially Eligible for ADAP, Gross Monthly Income During 1997 Cannot Exceed: 1-Person Household	4-Person Household	Compared With 1996, Financial Eligibility Criteria for ADAP in 1997 Became:
Nebraska	[11] 76	HIV+	$1,290.00	$2,600.00	Remained the Same
Nevada	320	HIV+, CD4 Count of 500 or Less; Developing Viral-Load Requirement	1,290.00	2,600.00	More Restrictive in 1997
New Hampshire	68	Proof of HIV+ or Prenatal Exposure for Infants	23,200.00 (per Year)	46,800.00 (per Year)	Remained the Same
New Jersey	2,700	HIV+ and Physician Certification of Need for Covered Drug	2,500.00	5,000.00	Remained the Same
New Mexico	375	Verified HIV+	1,972.50	4,012.50	Remained the Same
New York	10,642	HIV+	3,666.00	6,200.00	Remained the Same
North Carolina	Less than 1,200	HIV+	[2]822.00	[2]1,672.00	Less Restrictive in 1997
North Dakota	20	HIV+	No Upper Limit	No Upper Limit	Remained the Same
Ohio	700	HIV+ Status Verified by a Physician's Report	1,452.00	3,630.00	Remained the Same
Oklahoma	No Response	—	—	—	—
Oregon	[12] 200	HIV+ (No Longer a T-Cell Requirement)	[13]1,767.00	[13]3,562.00	Remained the Same
Pennsylvania	[14] 1,125	No Answer to the Question	[15]30,000.00 (per Year)	(15)	Remained the Same
Rhode Island	175	HIV+	2,580.00	5,200.00	Remained the Same
South Carolina	300	[16] HIV+, CD4 Count Below 500	[17]1,800.00	[17]3,750.00	Remained the Same
South Dakota	40	HIV+	(1)	(1)	Remained the Same
Tennessee	424	HIV+ or AIDS; for Protease Inhibitors, Medical Diagnostic Criteria Are Used	1,868.00	3,788.00	Remained the Same
Texas	5,402	(18)	1,315.00	2,675.00	Remained the Same
Utah	75	HIV+	No Upper Limit	No Upper Limit	Remained the Same

See notes at end of table.

Table 2—Continued
Beneficiary Information and Eligibility Policies for AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Estimates of the Number of People Receiving Drugs from the ADAP	Medical Eligibility Requirements for ADAP	To Be Financially Eligible for ADAP, Gross Monthly Income During 1997 Cannot Exceed: 1-Person Household	4-Person Household	Compared With 1996, Financial Eligibility Criteria for ADAP in 1997 Became:
Vermont	72	HIV+	(19)	(19)	"[M]ore flexible"
Virginia	1,371	HIV+, Plus Specified CD4 (or Viral-Load) Counts for Certain Drugs	[20]$15,780.00 (per Year)	[21]$21,200.00 (per Year)	Remained the Same
Washington	1,070	HIV+	(22)	(22)	Remained the Same
West Virginia	75	HIV+	1,973.00	4,013.00	Remained the Same
Wisconsin	500	HIV+ as Verified by Physician	15,780.00 (per Year)	31,200.00 (per Year)	Remained the Same
Wyoming	47	HIV+	1,868.00	3,788.00	Remained the Same

[1] 300 percent of the Federal poverty level.

[2] Figure refers to net monthly income.

[3] Without a copayment requirement.

[4] As of October 1997.

[5] Documentation of HIV+ status required. For protease inhibitors and non-nucleoside transcriptase inhibitors, must have either a CD4 count below 350 or a viral load exceeding 10,000 copies.

[6] 200 percent of the Federal poverty level.

[7] Number per month.

[8] January 1997.

[9] Increase amount by $2,200 for each dependent.

[10] Number of enrollees.

[11] As of February 28, 1997.

[12] Active.

[13] Sliding scale if higher.

[14] Fourth quarter 1996.

[15] $30,000 gross income per year, with $2,480 allowance for each additional family member.

[16] Exceptions considered.

[17] 300 percent of Federal poverty level plus a sliding scale fee.

[18] Texas resident with a diagnosis of HIV disease, meeting drug-specific eligibility criteria for drugs on the formulary, and under the care of a Texas-licensed physician who prescribes the drug.

[19] Net available income cannot exceed 200 percent of the Federal poverty level.

[20] $18,407 in Northern Virginia.

[21] $37,466 in Northern Virginia.

[22] 370 percent of the Federal poverty level.

NOTES: AIDS is acquired immunodeficiency syndrome. HIV is human immunodeficiency virus.

SOURCE: Buchanan, R.J., Medical University of South Carolina, 1997.

vidual in a one-person household and an individual in a four-person household. As Table 2 shows, these 1997 financial eligibility requirements for ADAP coverage in most States allow relatively high income levels, especially when compared with Medicaid income eligibility requirements. In most States the ADAP income eligibility levels are at least twice the Federal poverty guidelines, with a number of States allowing even more generous income levels for eligibility. The ADAP in North Dakota reported no upper limit on income during 1997.

Trends in Financial Eligibility

The ADAP administrators were asked in the survey to compare financial eligibility criteria implemented in 1996 with those in place during 1997. Compared with 1996, financial eligibility criteria for the ADAPs in the majority of States remained the same. However, financial eligibility criteria did change during 1997, compared with 1996, in a number of States, as Table 2 shows. The questionnaire also asked the ADAP administrators if they expected the financial eligibility criteria implemented in their State to become more restrictive during 1998. The financial eligibility requirements for ADAP benefits in all States are expected to remain the same during 1998, except in North Carolina, Oregon, Rhode Island, and the State of Washington, where these criteria are expected to become more restrictive.[4] In response to this question, the State of Washington further explained that "we are considering requiring enrollees with income between 200 percent FPL [Federal poverty level] and 370 percent FPL to have primary insurance, and we will only pay as a secondary payer." (The ADAP in Missouri did not answer this question.)

WAITING LISTS

The questionnaire asked the ADAP administrators if their State implemented a waiting list for people waiting to receive ADAP benefits during 1997. As Table 3 documents, ADAPs in 12 States reported the use of waiting lists for ADAP benefits in 1997. In addition to these 12, the ADAP in North Carolina responded that it "will be instituting" a waiting list for program benefits, and the ADAP in Virginia had implemented a waiting list during February 1997, although no one was waiting for benefits at the time of the 1997 survey. In contrast, during 1995, ADAPs in only Alabama, Arkansas, Delaware, Indiana, and South Carolina reported the implementation of waiting lists. Oklahoma anticipated the use of waiting lists in 1995, and Nevada reported that the mechanics for a waiting list were developed in 1995, although no one was waiting for benefits at the time of the 1995 study (Buchanan and Smith, 1996).

Table 3 presents the number of people waiting for ADAP benefits in States reporting the implementation of waiting lists during 1997. The ADAP administrator in Florida responded that 850 Floridians were waiting for ADAP coverage in late 1997, with more than 100 people waiting in Alabama, Mississippi, and South Carolina. As Table 3 also illustrates, the length of wait can be long, as much as 6 months or longer in Alabama, Mississippi, Montana, and South Dakota. The South Carolina ADAP responded that "We get 100 new cases reported in South Carolina each month. We get several 100 applications [for the ADAP] each month. Right now it takes six weeks to get on the program. That can change tomorrow, based on funding."

[4] Given the similarity of responses from most States, these data are not reported in Table 2.

Table 3
Waiting Lists for Benefits under AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Is There a Waiting List of People for ADAP Eligibility During 1997?	If There is an ADAP Waiting List, Estimate the Following for 1997	
		Number of People on Waiting List	Length of Time on Waiting List
Alabama	Yes	100+	6 Months
Delaware	Yes	50	60+ Days
District of Columbia	No Response to the Survey	—	—
Florida	[1]Yes	850	4 Months
Georgia	Yes	35	30 Days
Indiana	Yes	54	60-90 Days
Iowa	No Response to the Survey	—	—
Mississippi	Yes	138	210 Days
Missouri	[2]Yes	19	30 Days
Montana	Yes	10	6 Months
Nevada	Yes	45	60-120 Days
New Hampshire	[3]Yes	0	30 Days
North Carolina	[4]	Not Known at This Time	Not Known at This Time
Oklahoma	No Response to the Survey	—	—
South Carolina	Yes	150	[5] 6 Weeks
South Dakota	Yes	15	6-9 Months
Virginia	[6]No	NA	NA

[1] Just developing in certain counties, not statewide.

[2] "We have two programs within ADAP - General Medications and Protease Inhibitors. There is a waiting list for Protease Inhibitors." Since the program was filled in February 1997, the number on the waiting list has been less than 20.

[3] Have had wait list.

[4] "Will be instituting a waiting list."

[5] "We get 100 new cases reported in South Carolina each month. We get several 100 applications each month. Right now it takes 6 weeks to get on the program. That can change tomorrow, based on funding."

[6] At the time of the survey response (March 26, 1997), there was no waiting list; but there had been a waiting list in February 1997.

NOTES: All other States responded that they had not implemented a waiting list. NA is not applicable. HIV is human immunodeficiency disease.

SOURCE: Buchanan, R.J., Medical University of South Carolina, 1997.

PRESCRIPTION DRUG FORMULARIES

The ADAP administrators were asked in the survey to provide the number of medications on the ADAP drug formulary in their State during 1997. As Table 4 presents, the number of drugs on these formularies varies among the States, ranging at the time of the survey from three drugs (all protease inhibitors) in Louisiana to as many as 207 medications in New York. The questionnaire asked the ADAP administrators to explain how a new drug can be added to the ADAP formulary in their State, with their responses summarized in Table 4. The ADAPs in most States utilize a review process administered by a council, board, committee, or advisory group.

Table 4
Use of Prescription Drug Formularies by AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Number of Drugs on the Formulary During 1997	How are New Drugs Added to the Formulary?	During 1997 Did the ADAP Allow the Off-Label Use of Drugs on the Formulary?
Alabama	13	The Direct Care Advisory Council evaluates and decides on physician-requested additions to the formulary.	No
Alaska	12	"Antiretrovirals added as [they] receive FDA approval."	No
Arizona	19	A drug must be FDA-approved and available through a wholesaler at public health services prices; it will be added to the formulary upon review of the ADAP Advisory Council Formulary Committee. This committee reviews the formulary semi-annually and recommends to the Advisory Council which new drugs to add.	No
Arkansas	12	The Arkansas HIV Service Planning Council has an established Formulary Subcommittee that reviews the formulary and recommends additions of new drugs.	No
California	53	Medical Advisory Committee evaluates drugs for efficacy and benefit, making recommendations to the Department of Health Services (DHS). When approved by DHS, the drugs are added to the formulary.	Yes
Colorado	8	"Physicians on our Board bring formulary changes to the tables, and the Board decides."	No
Connecticut	66	ADAP Advisory Committee reviews drugs and makes recommendations. All drugs must have approval of management in Financial and Medical units in the Department.	Yes (but not monitored)
Delaware	50	Apply to the formulary committee - must be FDA-approved.	No
District of Columbia	No Response	—	—
Florida	20	ADAP Advisory Workgroup (consisting of consumers, medical professionals, and State ADAP representatives) makes recommendations to the Department. The Department reviews the recommendations and considers budget impact. The Department of Health makes final decision.	"Yes (the ADAP does not specifically exclude this possibility)."
Georgia	11	The Statewide Medical Providers Task Force reviews and evaluates new drugs and makes recommendations to the State for additions, based on availability of funds.	No
Hawaii	36	Input sought from Scientific Advisory Board and a Community Advisory Board. Approval given by Chief, Communicable Disease Division, State Department of Health.	No
Idaho	10	Reviewed by ADAP Advisory Committee and STD/AIDS Program budget review of Ryan White funds.	No

See notes at end of table.

Table 4—Continued
Use of Prescription Drug Formularies by AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Number of Drugs on the Formulary During 1997	How are New Drugs Added to the Formulary?	During 1997 Did the ADAP Allow the Off-Label Use of Drugs on the Formulary?
Illinois	63	After FDA approval, the Medical Issues Committee (MIC) makes a recommendation. After an analysis of the fiscal impact, the drug is added if funds available. The MIC reviews the formulary at least twice per year.	No—but off-label use is not monitored
Indiana	19	"Through Ryan White Medical Advisory Board and the [S]tate."	No
Iowa	No Response	—	—
Kansas	30	By recommendation of medical advisory group.	No
Kentucky	18, Plus 4 Protease Inhibitors	New drugs added to the formulary by consulting three physicians, a hospital social worker, HIV Care Coordinators, and, most importantly, client surveys.	Not monitored
Louisiana	[1]3 (All Three Are Protease Inhibitors)	FDA-approved drugs can be added to the formulary if there is significant demand from physicians and consumers.	No
Maine	[2]14	Approval of ADAP Advisory Committee.	Yes
Maryland	31	MADAP Advisory Board makes a recommendation to the Maryland AIDS Administration. If there is sufficient funding, the new drug is added.	Yes
Massachusetts	29	Once FDA-approved, the drug is added to the formulary with the advice of the HDAP Scientific Advisory Board.	(3)
Michigan	23	The formulary committee meets 3-4 times per year. The committee consists of physicians, pharmacists, case managers, PWA, and ADAP staff. This committee approves all additions to and deletions from the formulary.	[4] No
Minnesota	40	Clients advise by calling or annual surveys. Physicians and drug companies ask for additions to formulary. Physician Advisory Group makes recommendations and Program coordinator makes final decision.	Yes
Mississippi	16	New drugs are presented to the HIV/AIDS Planning Council, which acts as the advisory group for all drugs on the Ryan White formulary.	No

See notes at end of table.

Table 4—Continued
Use of Prescription Drug Formularies by AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Number of Drugs on the Formulary During 1997	How are New Drugs Added to the Formulary?	During 1997 Did the ADAP Allow the Off-Label Use of Drugs on the Formulary?
Missouri	69	The Missouri HIV/AIDS Medications Advisory Committee makes recommendations to the Missouri Department of Health.	Yes—if on the formulary
Montana	12	By committee approval.	No
Nebraska	23	The Drug Utilization Review Committee reviews and considers additions to the formulary.	No
Nevada	10	New drugs are proposed to the Physicians Advisory subcommittee and reviewed, with recommendations made to the State Health Division.	No
New Hampshire	36 (unrestricted list); 12 (restricted list)	Medical Advisory group meets about twice a year, examines cost data, funding availability, and decides.	No
New Jersey	37	Must be FDA approved and must be recommended by the ADAP Advisory Committee.	Yes
New Mexico	48	A Formulary Committee (made up of the HIV/AIDS Bureau, the New Mexico Department of Health/State Pharmacy, community physicians, HIV Clinic representatives, consumer advocates) decides what drugs to add to or delete from the formulary.	No
New York	207	"Review and recommendation by a Clinical Advisory Committee based on a drug's clinical priorities, efficacy, toxicity, cost effectiveness, etc."	Yes
North Carolina	30	FDA-approved antiretrovirals added upon approval. Drugs for opportunistic infections added after lengthy review and approval process.	No
North Dakota	59	"Review Committee (two infectious disease physicians, one doctor of pharmacy, and one Ryan White case manager) reviews biennially."	Yes
Ohio	20	HIV Drug Program Advisory Committee decides which drugs to add to the formulary.	Yes
Oklahoma	No Response	—	—
Oregon	7	"No formal procedure yet."	No
Pennsylvania	58	Must be FDA approved, cost-effective, demanded/utilized by consumers and providers, and must be affordable with ADAP funds.	No

See notes at end of table.

Table 4—Continued
Use of Prescription Drug Formularies by AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Number of Drugs on the Formulary During 1997	How are New Drugs Added to the Formulary?	During 1997 Did the ADAP Allow the Off-Label Use of Drugs on the Formulary?
Rhode Island	27	Physicians request consideration of a drug, the Director's HIV Advisory Committee develops a recommendation, and the Office of AIDS/STD/TB makes the final decision.	No
South Carolina	20	If funds available, a Physician's Advisory Committee is convened for input.	No
South Dakota	35	Advisory Council discusses new drugs at annual meeting or a physician requests a new drug be added. Request is reviewed by the State.	Yes
Tennessee	[5] 20	Each quarter attempt made to add 2 or more drugs to the formulary. During the year there is regular communication with physicians and AIDS groups to discover other drugs to add. There is currently no State Advisory Committee.	No
Texas	21	The formulary is determined by the Commissioner of Health, who considers recommendations of the HIV Medication Advisory Committee. All requests to change the formulary must be in writing to the advisory committee, which then votes to add a drug. The ADAP program director completes a form to the Commissioner of Health who decides.	Yes
Utah	9	Must be in antiretroviral class of drugs and is automatically added to formulary when FDA approved.	No
Vermont	39	With approval of ADAP Advisory Committee.	Yes
Virginia	19	ADAP Advisory Committee makes decisions on which new drugs to add to the formulary.	No
Washington	67	Requests are reviewed by the Community Steering Committee and Department of Health policymakers. A formal process for changing the formulary is in development.	No
West Virginia	19	Through ADAP Review Committee.	No
Wisconsin	21	"The State statute authorizing drug program allows Department of Health and Family Services to expand formulary in consultation with outside experts."	No
Wyoming	58	The drug would have to be recommended and approved by the Advisory Committee.	Yes

[1] "The formulary for the [S]tate public hospitals, administered through Louisiana State University Medical Center by the Health Care Services Division, covers all the medications needed for basic HIV care (approximately 115 medications). The Louisiana ADAP was established solely to cover the cost and provision of the protease inhibitors to eligible participants throughout the [S]tate."

[2] Plus approval on case-by-case basis.

[3] "All drugs on the formulary are FDA-approved for HIV-related illness. All treatment decisions are left to the individual and their physician."

[4] "Generics are encouraged when possible."

[5] In addition, 6 infusion medicines are covered.

NOTES: HIV is human immunodeficiency virus. AIDS is acquired immunodeficiency syndrome. FDA is the Food and Drug Administration. PWA is persons with AIDS.

SOURCE: Buchanan, R.J., Medical University of South Carolina, 1997.

Changes in the Number of Drugs

The questionnaire asked the ADAP administrators to compare the number of drugs on the ADAP formulary in their State during 1996 with the number of medications on this formulary in 1997. The number of drugs increased in almost all States during 1997, with decreases reported in Montana and Vermont.[5] In addition, the number of drugs on the ADAP formulary remained the same during 1997 in Arkansas, Louisiana, Maryland, Nebraska, North Dakota, Oregon, and Pennsylvania. (The District of Columbia, Iowa, and Oklahoma did not respond to the survey.)

The ADAP administrators also were asked if they expected the number of medications on the ADAP formulary in their State to change during 1998. Almost all ADAP administrators expected the number of drugs on the ADAP formulary in their State to increase during 1998, including South Carolina, which "hopes to add drugs."[6] In contrast, the ADAP administrators in New Mexico and North Dakota expected the number of drugs on their formulary to decrease in 1998. The number of drugs on the ADAP formularies is expected to remain the same during 1998 in Georgia, Nebraska, and South Dakota. ADAP administrators in Pennsylvania and Wyoming responded that at the time of the survey they were unable to determine if the number of drugs on their formularies would change in 1998. The administrators in Louisiana, Michigan, and the State of Washington responded that the number of drugs on the formulary in their States during 1998 depends on FDA approval of new medications.

[5] Given the similarity of responses from most States, these data are not reported in Table 4.

[6] Given the similarity of responses from most States, these data are not reported in Table 4.

Off-Label Use

A drug must be approved by the FDA as safe and effective for uses described in a New Drug Application before it can be marketed (Lasagna, 1989). Evidence of safety and efficacy are provided by the manufacturer from investigations of the drug's effects on controlled patient populations. These investigations substantiate the use of a drug for specific indications. Although a drug may have multiple uses, the FDA only approves labeling that reflects indications for conditions that have been researched within these trials (Laetz and Silberman, 1991).

A physician, however, may prescribe a drug approved by the FDA for other uses besides those listed in the product label. In many circumstances the standard of care for a particular condition may include a drug not labeled for that use (Nightingale, 1986). Prescribing a drug in this manner is commonly called "off-label" or "unlabeled use," with this practice supported by such organizations as the FDA, the American Medical Association, and the American Society of Hospital Pharmacists (Food and Drug Administration, 1982; American Society of Hospital Pharmacists, 1992). The absence of an indication within the product labeling, however, does not suggest that off-label use is experimental or inappropriate.

Many drugs used in the management of HIV or in the treatment of associated opportunistic infections are prescribed off label (Buchanan and Smith, 1994). In fact, off-label use of medications in HIV disease is often the community standard of practice for many HIV-related conditions (Brosgart et al., 1996). Recent FDA actions increase the importance of allowing off-label uses of drugs in HIV-related

care. In response to the spread of HIV infection, the FDA changed its policies to accelerate approval of drugs for serious and life-threatening conditions, such as HIV disease, allowing access earlier in the approval process than previously permitted (Dunbar, 1991; Edgar and Rothman, 1990). Although these policy changes expanded the number of medications available to treat HIV-related conditions, the labeling of many of these drugs has been approved with narrow indications, which can limit patient access to these drugs if ADAPs do not allow off-label use. Another reason for off-label use is that clinical expertise in the rapidly evolving field of AIDS-related care outdistances the regulatory process for approving new uses of drug therapies.

The questionnaire asked the ADAP administrators if the ADAP in their State allowed the off-label use of drugs on the ADAP formulary during 1997. The questionnaire defined off-label use as "prescribing the drug for uses other than labeled indications." As Table 4 shows, the ADAPs in many States allowed the off-label use of medications on the ADAP formulary during 1997. A number of ADAP administrators also noted, however, that the off-label use of drugs on the ADAP formulary was not monitored in their State during 1997. If the ADAPs do not monitor or enforce prohibitions on off-label use, then off-label use of covered medications may occur.

PROTEASE INHIBITORS

Coverage of the Protease Inhibitors

The questionnaire concluded with a section asking the ADAP administrators about: (1) coverage of the protease inhibitors, (2) which of these drugs were covered, and (3) the impact that coverage of these medications has had on the ADAP in their State. As Table 5 presents, almost all the ADAPs covered the four protease inhibitors approved by the FDA. However, the ADAPs in Nevada, Oregon, and South Dakota did not cover any of the protease inhibitors at the time of the survey. Although the Arkansas ADAP did not include protease inhibitors on its formulary at the time of the survey, these medications were provided through the HIV consortia funded by Title II of the CARE Act according to the survey response from that State.

Impact of the Protease Inhibitors

As Table 5 documents, coverage of protease inhibitors has had an impact on the Title II programs in all but 9 of the 48 States participating in the survey. As Table 6 summarizes, a shift in Title II funds from other programs to the ADAPs is the most common impact reported (by 21 States), followed by the implementation of waiting lists in 7 States. The "other" responses reported in Table 6 were a cautiousness and the development of a protocol for adding new drugs in Connecticut, a shift of State prevention funds in Illinois, studying cost containment in Indiana, a temporary limit on access to protease inhibitors in Ohio, the use of Title II supplemental funding to add coverage of the protease inhibitors in South Carolina, development of guidelines for the specific use of protease inhibitors in Tennessee, and increased copayment responsibilities required from patients in Utah. (All of these responses that are summarized as "other" in Table 6 are presented in detail in Table 5.)

SUMMARY AND CONCLUSIONS

The various programs funded at least in part by Title II of the CARE Act strengthen the public sector safety net that provides

Table 5
Coverage of Protease Inhibitors and the Impact of Coverage on AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Covered Protease Inhibitors	Protease Inhibitors Have Had the Following Impact on the ADAP:
Alabama	Ritonavir, Saquinavir, and Indinavir	More restrictive financial eligibility requirements and limits on the number of medications a beneficiary may receive.
Alaska	Ritonavir, Saquinavir, Indinavir, and Nelfinavir	None—the protease inhibitors "have always [been] included" in ADAP coverage.
Arizona	Crixivan, Viracept, Norvir, and Invirase	A shift in Title II funding from other Title II programs and more restrictive financial eligibility requirements.
Arkansas	[1]All Protease Inhibitors	[1]A shift in Title II funding from other Title II programs and in the process of making decisions on ADAP funding that may require "all or some" of the options presented if protease inhibitors added to the formulary.
California	Ritonavir, Saquinavir, Indinavir, and Nelfinavir	A shift in Title II funding from other Title II programs and the addition of State general funds.
Colorado	Crixivan, Norvir, Invirase, and Viracept	A shift in Title II funding from other Title II programs and a shift of Title I funding.
Connecticut	[2]Crixivan, Norvir, Saquinavir, and Viracept	The protease inhibitors have “made us more cautious and caused us to develop a protocol for adding new drugs.”
Delaware	Ritonavir, Saquinavir, Viracept, and Indinavir	Implementation of a waiting list, longer waits on the waiting list, and more people on the waiting list.
District of Columbia	No Response to the Survey	—
Florida	Indinavir, Ritonavir, Saquinavir, and Nelfinavir	A shift in Title II funding from other Title II programs and the implementation of waiting lists.
Georgia	Indinavir, Ritonavir, Saquinavir, and Nelfinavir	[3] Implementation of waiting lists.
Hawaii	Indinavir, Ritonavir, Saquinavir, and Nelfinavir	“None of the above.”
Idaho	Crixivan	None mentioned.
Illinois	Ritonavir, Crixivan, Saquinavir, and Nelfinavir	More restrictive financial eligibility criteria, a limit on the number of drugs a beneficiary may receive (“no more than 3 antiretrovirals and no more than one protease inhibitor concurrently”), a limit on the dollar value of the drugs a beneficiary may receive, a shift of State prevention funds, and increased State funding for ADAP.
Indiana	Crixivan, Viracept, Invirase, and Norvir	A shift in Title II funding from other Title II programs, longer waits on the waiting list, more people on the waiting list, and looking at cost containment.

See notes at end of table.

Table 5—Continued
Coverage of Protease Inhibitors and the Impact of Coverage on AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Covered Protease Inhibitors	Protease Inhibitors Have Had the Following Impact on the ADAP:
Iowa	No Response to the Survey	—
Kansas	Crixivan, Norvir, and Saquinavir	None mentioned.
Kentucky	Indinavir, Ritonavir, Saquinavir, and Viracept	"PIs are provided through a separate program with a limited number of slots and more restrictive medical [eligibility] criteria."
Louisiana	[4] Crixivan, Norvir, and Invirase	[4] A shift in Title II funding from other Title II programs.
Maine	All protease inhibitors are covered, with a 12-person cap	None mentioned.
Maryland	Indinavir, Ritonavir, and Saquinavir	State funds were added to make up the deficit.
Massachusetts	Indinavir, Ritonavir, and Saquinavir (will be adding Nelfinavir)	A shift in Title II funding from other Title II programs.
Michigan	Indinavir, Ritonavir, and Saquinavir (and as of 4/1/97, Viracept)	"We have not had any great impact financially as of now - anticipate greater demand in FY97-98. May then have to reconsider our present guidelines."
Minnesota	[2] Indinavir, Saquinavir, and Nelfinavir	None mentioned.
Mississippi	Invirase/Saquinavir, Indinavir/Crixivan, and Nelfinavir/Viracept	A shift in Title II funding from other Title II programs and implementation of waiting lists.
Missouri	Indinavir, Ritonavir, and Saquinavir (Nelfinavir will be considered 4/4/97)	"Because our program began [in late 1996] with the protease inhibitors on the formulary, these issues are not relevant."
Montana	Indinavir, Ritonavir, Saquinavir, and Nelfinavir	A shift in Title II funding from other Title II programs, a reduction in the number of medications on the formulary, and enrollment capped in August, 1996.
Nebraska	Indinavir, Norvir, and Saquinavir	At the March, 1997, meeting of the Drug Utilization Review Committee, the following options will be discussed: a shift in Title II funding from other Title II programs, more restrictive financial and medical eligibility requirements, and the implementation of waiting lists.
Nevada	Protease inhibitors not provided to people eligible for the ADAP	Protease inhibitors not provided by ADAP.
New Hampshire	Saquinavir, Crixivan, Ritonavir, and Nelfinavir	A shift in Title II funding from other Title II programs, more restrictive medical eligibility standards (briefly), and implementation of waiting lists (briefly).
New Jersey	Saquinavir, Indinavir, Ritonavir, and Nelfinavir	A shift in Title II funding from other Title II programs and a reduction in the number of medications on the formulary.

See notes at end of table.

Table 5—Continued
Coverage of Protease Inhibitors and the Impact of Coverage on AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Covered Protease Inhibitors	Protease Inhibitors Have Had the Following Impact on the ADAP:
New Mexico	Indinavir, Ritonavir, and Saquinavir	A shift in Title II funding from other Title II programs.
New York	Saquinavir, Indinavir, Ritonavir, and Nelfinavir	A shift in Title II funding from other Title II programs, increased Title I contributions, and new State funding.
North Carolina	Norvir, Invirase, Crixivan, and Viracept-Nelfinavir	A shift in Title II funding from other Title II programs and enrollment discontinued in 9/97.
North Dakota	Norvir, Invirase, Crixivan, and Viracept	A shift in Title II funding from other Title II programs.
Ohio	Norvir, Invirase, and Crixivan	"Temporarily limited access to protease inhibitors. As of 4/1/97, all ADAP clients will have access to these drugs."
Oklahoma	No Response to the Survey	—
Oregon	Protease inhibitors not provided to people eligible for the ADAP	Protease inhibitors not provided by ADAP.
Pennsylvania	Saquinavir, Crixivan, Ritonavir, and Viracept	"Impact is still being analyzed."
Rhode Island	"All four which are FDA approved"	A shift in Title II funding from other Title II programs and planning to cap or limit the dollar value of medications that a beneficiary may receive.
South Carolina	Indinavir, Norvir, and Crixivan	"We used Title II supplemental funding to add protease inhibitors. Our supplemental funding as $650,000 in FY96 and is $2.2 million this year."
South Dakota	Protease inhibitors not provided to people eligible for the ADAP	Protease inhibitors not provided by ADAP.
Tennessee	"Viracept, Crixivan, Norvir, and Invirase are all available based on physician preference."	"TennCare [Medicaid] asked certain HIV specialists to develop specific guidelines for the use of protease inhibitors. These guidelines considered both the medical necessity and the financial impact. Our HDAP also adopted these guidelines since most clients use our program as a bridge to TennCare."
Texas	Invirase, Ritonavir, and Indinavir	Reduction in the number of medications on the formulary and more restrictive medical eligibility standards.
Utah	Saquinavir, Ritonavir, and Indinavir	A shift in Title II funding from other Title II programs and increased copayment required from the patients.

See notes at end of table.

Table 5—Continued
Coverage of Protease Inhibitors and the Impact of Coverage on AIDS Drug Assistance Programs (ADAPs), by State: 1997

State	Covered Protease Inhibitors	Protease Inhibitors Have Had the Following Impact on the ADAP:
Vermont	Norvir, Crixivan, Invirase, and Viracept	A shift in Title II funding from other Title II programs and a reduction in the number of medications on the formulary.
Virginia	"Crixivan is first choice. All other protease inhibitors available with prior approval by VDH."	A shift in Title II funding from other Title II programs and during February, 1997 implementation of waiting lists and longer waits on the waiting list.
Washington	Saquinavir, Ritonavir, Indinavir, and Nelfinavir	"We are requesting additional [S]tate funds to support the increased costs to our ADAP."
West Virginia	"All four which are FDA approved."	A shift in Title II funding from other Title II programs.
Wisconsin	Saquinavir, Ritonavir, Indinavir, and Nelfinavir	None mentioned.
Wyoming	All protease inhibitors approved by the FDA are covered	Reduction in the number of medications on the formulary ("formulary developed to ensure "that we had money for the protease inhibitors"), implementation of a waiting list for 3 months during 1996, and a cap or limit on the dollar value of medications.[5]

[1] "Protease inhibitors are currently being provided but are not included in the present formulary. Thus far our 5 Consortia are providing limited use of all protease inhibitors."

[2] In addition, Connecticut reported coverage of Combivir (Zidovudine and Lamivudine) and Minnesota reported coverage of Epivir (Lamivudine). These drugs, while not protease inhibitors, are recommended for use in combination with protease inhibitors. The ADAPs in other States also may cover these drugs as the questionnaire asked the ADAPs only to list the protease inhibitors covered in their States.

[3] "Georgia has actually made financial [eligibility] criteria less restrictive (125 percent FPL to 300 percent FPL), increased the number of drugs from 9 to 11, and increased the number of slots [for beneficiaries] from 1,015 to 1,221, and included triple therapy rather than allow just two drugs based on availability of funds."

[4] "The formulary for the State public hospitals, administered through Louisiana State University Medical Center by the Health Care Services Division, covers all the medications needed for basic HIV care (approximately 115 medications). The Louisiana ADAP was established solely to cover the cost and provision of the protease inhibitors to eligible participants throughout the State."

[5] "There was always a cap on the amount of money we spent on drugs, with the protease inhibitors the restrictions were imposed by formulary."

NOTES: Invirase is Saquinavir; Viracept is Nelfinavir; Norvir is Ritonavir; and Crixivan is Indinavir. FY is fiscal year. FPL is Federal poverty level. AIDS is acquired immunodeficiency syndrome.

SOURCE: Buchanan, R.J., Medical University of South Carolina, 1997.

Table 6
Impact of Protease Inhibitors on AIDS Drug Assistance Programs (ADAPs): Summary of Survey Responses

Impact	Number of States Reporting Impact
A Shift of Funding From Other Title II Programs to the ADAP	21
No Impact/None Mentioned	9
Implementation of Waiting Lists for the ADAP	7
A Reduction in the Number of Medications on the ADAP Formulary	5
Planning to Impose Restrictions/ Impact Being Studied	5
Use of State Funds	5
Enrollment Capped	3
Longer Waits for People on the Waiting List for the ADAP	3
More Restrictive Financial Eligibility Standards for ADAP	3
More Restrictive Medical Eligibility Standards for the ADAP	3
Protease Inhibitors Not Covered at Time of Survey	3
A Cap/Limit on the Dollar Value of Medications Beneficiaries Receive	2
A Limit to the Number of Medications a Beneficiary May Receive	2
A Shift/Use of Title I Funds	2
More People on the Waiting List for the ADAP	2
Other	7

NOTE: AIDS is acquired immunodeficiency syndrome.

SOURCE: Buchanan, R.J., Medical University of South Carolina, 1997.

coverage of health and care-related services to people with HIV disease. These CARE Act programs provide coverage to people with HIV who lack private health insurance or who do not qualify for Medicaid or Medicare. In this article, we have focused on the ADAPs. Financial eligibility requirements for these ADAPs are generous, allowing people with incomes too high for Medicaid eligibility to qualify for ADAP benefits. The ADAP administrators in almost all States expected these financial eligibility criteria to remain the same in their State during 1998. At the same time, the ADAP administrators in almost all States expect the number of people receiving ADAP benefits and the number of drugs on the ADAP formulary to increase during 1998.

Without increased public funding for the ADAPs, the increasing number of people receiving program benefits and the increasing need for an expanding number of beneficial medications will lead to some form of rationing. This rationing could be more restrictive financial and medical eligibility criteria, a reduction in the number of covered drugs, limits on the number of medications each beneficiary may receive, the implementation of waiting lists, or some combination of these or other options. As Tables 5 and 6 illustrate, these forms of rationing are being implemented by a number of States. In addition, at least 12 States reported the implementation of waiting lists for ADAP benefits during 1997, more than double the number of States administering ADAP waiting lists in 1995. The number of people on ADAP waiting lists is increasing, along with the number of days these people must wait for prescription drug benefits to begin. Increased public spending on the programs funded by the CARE Act is necessary to provide the health services needed by people with HIV disease and maintain these important programs in the public sector safety net for HIV care.

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Reprint Requests: Robert J. Buchanan, Ph.D., Professor, Department of Health Administration and Policy, Medical University of South Carolina, Charleston, South Carolina 29425-2718.