The Fiscal Status of State AIDS Drug Assistance Programs: Findings from a January 1996 National Survey of State AIDS Directors

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National Alliance of State and Territorial AIDS Directors
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Executive Summary

A national survey conducted by the National Alliance of State and Territorial AIDS Directors (NASTAD) of State AIDS Drug Assistance Programs (ADAPs) funded by the Ryan White CARE Act reveals that increased client demand, funding shortages, uncertainty about future funding allocation levels, and the recent FDA approval of new anti-retroviral AIDS combination therapies, including the first of the new class of high-cost protease inhibitors, are having a severe impact on States' ability to provide coverage of necessary HIV/AIDS treatments to eligible individuals.

NASTAD represents the chief HIV/AIDS program managers in every U.S. State and territorial health department responsible for administering Federally funded HIV/AIDS prevention, surveillance, health care, supportive service and housing programs, including Title II of the Ryan White CARE Act. Roughly one-quarter of Federal Title II grant funds support State AIDS drug assistance programs which provide access to medications and treatments for low income individuals with HIV disease who are not covered by Medicaid or who do not receive prescription drug coverage through other means, such as private insurance.

In response to reports that several States were encountering serious budget shortfalls in providing AIDS drug assistance, NASTAD, under contract with the Health Resources and Services Administration (HRSA), Division of HIV Services, conducted a survey of all State AIDS directors in early January 1996. The objectives of the assessment were: 1) to determine the fiscal status of State ADAP programs; 2) to describe the action steps States have implemented to deal with reported budget shortfalls; 3) to document the impact of newly approved, and soon to be approved, combination AIDS therapies on ADAP programs; and 4) to document the extent to which current Ryan White CARE Act and State finances can keep pace with increasing demand.

NASTAD surveyed all 54 States and territories which receive Ryan White Title II funding (i.e., the 50 States, the District of Columbia, Guam, Puerto Rico and the U.S. Virgin Islands). Fifty (50) out of the 54 States and territories responded, representing a 93% response rate. States and territories not responding as of April, 1996 were Alabama, Montana, Vermont and the Virgin Islands. (The Virgin Islands did not apply for Ryan White Title II funding in FY 1995.)

Major Findings

The assessment findings cover a range of issues related to ADAP funding and services and the effect of budget shortfalls, including:

ADAP Funding

* In 1995, forty-four percent of all funding for State ADAPs came from Federal Ryan White Title II grants to States; one-third (33%) of the funding for ADAPs was derived from State resources, and 23% came from Federal Ryan White Title I eligible metropolitan areas (EMAs) (of which EMAs in New York State alone accounted for 84% of the national Title I contribution to State ADAPs). The overall 1995 budgets for State ADAPs increased slightly over 1994 levels.

Client Demand

* Client demand for State ADAP services showed a modest increase nationally between 1994 and 1995. In addition, client utilization of multiple prescription medications, including combination therapies for HIV disease, was reported by States to have increased between 1994 and 1995.

ADAP Budget Shortfalls

* Twenty States, representing 42% percent of all States which responded to the survey and operate ADAPs under the Ryan White CARE Act funding, reported budget shortfalls totaling over $12 million nationwide for the last quarter of the FY 1995 Federal Ryan White Title II funding period (the first quarter of calendar year 1996) in providing AIDS drug assistance to low income individuals.

* Among the factors which led to the reported ADAP shortfalls in States were: increased demand and utilization of combination therapies prescribed by physicians; increased number of clients enrolled in ADAPs; significant expansions in the number of drugs covered by State ADAPs in the past year; decreased FY 1995 funding among some States[1]; recent approval of additional high-cost anti-retrovirals to States' formularies; and increased costs per clients served in the past year.

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[1]15 states encountered reduced federal Ryan White Title II formula funding in FY 1995

Impact on ADAP Services

* In addition to the 20 States which reported funding shortfalls for meeting current demand for services, 13 other States reported that, while not incurring a shortage before the end of the March 1996, their programs have experienced serious difficulties in keeping up with demand for services. These States have reported that they have either delayed action on covering newly approved therapies for lack of funding, experienced high demand for services which may outpace resources shortly, have re-programmed resources to compensate for demand, or expect a shortage after April 1996. All told, these States represent 66% of the States responding to the NASTAD survey.

* Over 77% of the States (37) which responded to the survey and operate ADAPs report delayed or cancelled expansion of coverage of a wide range of AIDS drugs, including recently FDA-approved therapies, due to resource constraints, increased demand or uncertainty of future funding allocations for Ryan White Title II and State ADAPs. These States also reported that eligible clients who could now receive prescription drug coverage for newly FDA-approved AIDS drugs are unable to access these new therapies because State programs are unable to budget expenditures for 1996. Without adequate funding for these drugs, States report that clients have limited options for receiving coverage for combination anti-retroviral therapies which are being prescribed by clinicians.

* Seventy percent of the States facing budget shortfalls (14 States) report that they are rationing ADAP services by establishing waiting lists for new clients or by removing drugs for HIV disease from coverage due to funding shortages. Five States reported suspending HIV/AIDS drug therapies for a period of time in 1995 due to lack of funding and increased demand.

Impact of Newly FDA-Approved AIDS Therapies

* States are reporting that newly approved AIDS therapies are rapidly being considered standards of care in some areas of the country, requiring rapid approval for coverage under State ADAP formularies in order to allow eligible clients access to continuing and uninterrupted treatment. States anticipate that the additional protease inhibitors already approved by the FDA early in 1996 will further increase demand and client utilization of ADAP services at a time when resources for these services are in many cases leveling off or declining.

Use of ADAP Advisory Panels

* State health departments overwhelmingly reported that they rely on the expertise and counsel of formal and ad hoc advisory panels in making decisions regarding ADAP services. Forty-two out of the 50 States responding (84%) report that their State has an advisory panel -- including clinicians and consumers -- which provides key input into State decisions on formularies, eligibility criteria, fiscal issues, and medical and scientific guidance regarding ADAPs.

FY 1996 ADAP Planning

* Due to a variety of factors, including widespread State ADAP budget shortfalls reported, anticipated demand for AIDS drugs (particularly combination therapies), and uncertainty as a result of unfinished Federal appropriations and Ryan White reauthorization processes, planning for Title II ADAP services (as well as other care services) for FY 1996 is presenting enormous challenges for States.

* States reported a variety of planning approaches for FY 1996, and anticipated a variety of changes to their programs. Among the most common challenges expressed by States: 1) Balancing all funded care services, in addition to ADAP, in order to best serve client needs in 1996; 2) Anticipating level funding or the prospects of declining Federal funding in 1996; and 3) Planning for drug coverage in the absence of effective and practical clinical information on the most appropriate combination therapies.

Planning and Forecasting Approaches

* Only ten States out of the 50 responding (20%) described a forecasting model their State uses for anticipating costs and future demand for ADAP services. Given the vast majority of States which responded that did not use a forecasting model for projecting costs and utilization patterns, the NASTAD survey has identified a significant technical assistance need and knowledge gap.

* Additionally, several States noted that planning approaches used in prior years for predicting client utilization and costs might be inoperable given several recent factors: 1) the unpredictability of combination therapies -- which drugs?, used in which combination?, at what cost?, and at what dosage levels are physicians going to be prescribing these new anti-retroviral medications?; and 2) the relative speed with which the FDA approves drugs to enter the market -- particularly the expected rapid approval of protease inhibitors -- how many in 1996/97?, at what cost?

National Technical Assistance Needs

* Nearly every State reported that technical assistance in the form of Federal guidance, other State models, client and clinical information, and standard treatment protocols would help States to more effectively plan ADAP services.

* According to ADAP administrators, Federal guidance may assist programs in gathering more accurate information regarding new products and therapies. More relevant clinical information regarding efficacy and usage may make it easier to develop cost and utilization parameters, i.e., if disease stage information regarding benefits and projected usage by the HIV infected population were more clearly available, the ability to determine projected use would be significantly more accurate. Additional client information, such as the ability to track clients across various funding streams and clinical information on the percentage of the HIV-infected population who are appropriate candidates for new therapies would be helpful.

The following is a summary report of findings from the NASTAD survey which describe background information on ADAPs, as well as an analysis of the current and projected fiscal status of State programs, including:

* 1995 Funding Sources for ADAPs (Ryan White Title II, State, and Ryan White Title I);

* 1995 Client Enrollment, Clients Served, New Clients;

* Estimated Cost Savings through Drug Discounts, Rebates;

* Actual or Projected Budget Shortfalls Anticipated by States Prior to March 31, 1996 (the end of the FY 1995 budget and project periods for Title II grants);

* Impact of Newly Approved Therapies; Coverage of Epivir, Saquinavir, and the Role of Drug Advisory Panels;

* FY 1996 ADAP Plans; Anticipated Program Changes; Model Approaches for Forecasting; Technical Assistance Needs;

* Other issues: Statutory Requirements; ACTG 076 Impact; Medicaid Managed Care Impacts on ADAP Programs.

Funding for AIDS Drug Assistance Programs

The NASTAD survey identified three main funding sources for ADAPs nationally: Ryan White Title II (Federal), State resources, and Ryan White Title I (Federal). Total funding for ADAPs in the 50 responding States/territories from all sources reported was $92.1 million. The breakdown of contributions from the three major sources reported in the NASTAD survey in 1995 is as follows:

Title II (Federal):	$40.6 million (44%)
States:	$30.7 million (33%)
Title I (Federal):	$20.8 million (23%)[2]
Total:	$92.1 million (100%)

Title II (Federal) Funding

Forty-four (44) out of the 50 States (88%) responding to the survey contributed a portion of their States' Ryan White Title II funding for ADAP in calendar year 1995. States' use of Federal Title II funding (non-State) for ADAP ranged from a low of $30,000 (reported by Maine, Wisconsin and Wyoming) to over $8 million reported by New York State ($8.3 million) and California ($8.4 million). It is important to note that Maine and Wisconsin supplement their Federal Title II resources with State funding for medications assistance. States that did not allocate Federal Title II funding to ADAP in 1995 include: Alaska, Guam, Louisiana, New Mexico, North Carolina, Pennsylvania. It should be noted that Alaska funds consortia which have the option of providing medications to a limited number of clients (the Ryan White Title IIIb grantee in Anchorage reportedly provides the majority of medication assistance for low income clients with HIV disease in Alaska). Guam receives very limited Federal support (approximately $5,000 in FY 95) and does not have the capability of implementing an ADAP. Louisiana, New Mexico, North Carolina and Pennsylvania operate ADAPs, but relied on State funding exclusively in 1995.

The total funding provided for ADAPs in 1995 through Title II among States responding was $40.6 million.

State funding

Twenty-seven (27) out of the 50 States responding (54%) reported State funding (non-Medicaid) to support ADAPs in 1995. Funding levels ranged from $9,657 in

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[2]The survey indicated that the vast majority (84%) of financial contributions to state ADAPs from Title I EMAs nationally in 1995 was made by EMAs in New York State.

Arkansas to $9.1 million reported by California. States which contributed general revenue funding (GRF) for ADAP in 1995 were: Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, New Hampshire, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Texas, Utah, Virginia, Washington and Wisconsin. A total of $30.7 million in State funding for ADAPs was reported nationally in 1995.

Title I (Federal) funding

Twelve (12) States reported contributions from Title I eligible metropolitan areas (EMAs) in 1995 representing 24% of the States responding and 52% of the 23 States which have Title I EMAs located within the State. States reporting contributions from Title I EMAs (Federal funding) were: Colorado, Connecticut, District of Columbia, Georgia, Maryland, Massachusetts, Michigan, Missouri, New Jersey, New York, Puerto Rico and Washington.

A total of 17 individual Title I EMAs reportedly contributed to State ADAP programs, representing 40% of all EMAs (42) nationally in 1995. The EMAs reported to have contributed funding were Atlanta, Baltimore, Boston, Caguas (PR), Denver, Detroit, Dutchess County (NY), Kansas City (MO), Nassau-Suffolk Counties (NY), New Haven, New York Metro Area (including Lower Hudson Valley Region), Newark, Paterson (Bergen-Passaic) (NJ), Ponce (PR), San Juan, Seattle (WA) and Washington, D.C. Contributions from EMAs totalled $20.8 million. It is important to note that 84% of the national funding contributed by Title I EMAs was provided by EMAs in New York State ($17.5 million), the highest contribution. The lowest amount of funding contributed was $36,675 in Missouri (Kansas City).

A table indicating specific Federal and State allocations for ADAP by State is provided on the following page.

ADAP Clients

ADAP programs have various eligibility criteria (both income and medical criteria) which affect enrollment. In addition, some States differentiate between those eligible clients who are currently enrolled in the State's program from those clients who have filled one or more prescriptions for medications during the year (i.e., unduplicated clients served). NASTAD asked States to provide estimates of total client enrollment as well as clients served in 1995 in order to indicate that although "clients served" provides a measure of a past year's utilization of services, "total client enrollment" provides a measure of the total *potential* utilization.

State AIDS Drug Assistance Programs: NASTAD Assessment Findings

State	1995 ADAP Funding Sources				1995 Client Data			1995 Reported Cost Savings/Cost Recovery				
	Title II Funding	State	Title I	Total Funding	Enrollment	Clients Served	New Clients	Voluntary Rebates	PHS Drug Discounts	Private Insurance	Chase/Pay	Other Savings
Alabama *				n/a	n/a	n/a	n/a					
Alaska $				0	n/a	n/a	n/a					
Arizona	477,000			477,000	591	591	411	120,000				
Arkansas	386,163	9,657		395,820	589	589	205					
California	8,449,105	9,100,000		17,549,105	8,500	8,500	n/a					
Colorado	62,000	150,000	350,000	562,000	800	400	100					
Connecticut	564,389	592,000	209,500	1,365,889	1,447	1,447	883	247,925				
Delaware	100,000			100,000	82	78	13	500	750			
D.C.	540,000		74,801	614,801	584	392	n/a					
Florida	5,589,995	42,000		5,631,995	5,686	5,686	1,105		1,375,000			
Georgia	1,000,000	324,000	365,420	1,689,420	1,015	1,486	658					
Guam $	0			0	n/a	n/a	n/a					
Hawaii	136,451	265,000		401,451	134	134	49		125,000			
Idaho	65,000			65,000	58	58	13					
Illinois	1,300,055	2,197,493		3,497,548	5,765	2,047	1,452	152,126		140,354		
Indiana	761,117			761,117	495	368	55					
Iowa	65,406			65,406	132	132	65					
Kansas	250,000			250,000	507	418	207					
Kentucky	333,883	99,970		433,853	185	326	139					
Louisiana		2,000,000		2,000,000	n/a	n/a	n/a					
Maine	30,000	60,040		90,040	165	120	n/a					6,000
Maryland	543,999	85,688	123,581	753,268	434	386	194	60,000	45,000	3,000	2,200	
Massachusetts	216,356	1,290,000	300,000	1,806,356	950	950	n/a		80,000			
Michigan	154,637		187,500	342,137	405	300	190	70,000				
Minnesota	160,000			160,000	306	231	145		10,165			
Mississippi	640,000			640,000	500	500	120	100,000	100,000			
Missouri	600,000		36,675	636,675	842	842	273					
Montana *				n/a	n/a	n/a	n/a					
Nebraska	100,000			100,000	177	177	87					
Nevada	275,073			275,073	375	375	100					
New Hampshire	106,575	100,000		206,575	105	105	54	10,000				
New Jersey	2,100,000		516,250	2,616,250	2,000	2,000	350	250,000			30,000	
New Mexico		650,000		650,000	320	280	50		20,000			
New York	8,309,344	495,120	17,591,280	26,395,744	17,139	17,139	5,284	1,381,604		4,077,377		
North Carolina		450,000		450,000	600	450	n/a					
North Dakota	55,000			55,000	19	19	9					
Ohio	846,000	200,500		1,046,500	590	590	207	89,000				
Oklahoma	355,251	206,000		561,251	375	342	n/a	65,000				
Oregon	190,000			190,000	n/a	300	120		60,000		645	
Pennsylvania		4,703,000		4,703,000	2,000	n/a	n/a					
Puerto Rico	2,522,835	3,406,651	1,013,827	6,943,313	6,200	4,830	1,200		1,008,609			
Rhode Island	129,200			129,200	208	n/a	n/a					
South Carolina	400,000	50,000		450,000	672	479	146		64,885			
South Dakota	70,000			70,000	41	40	14					
Tennessee	225,000			225,000	300	179	142					11,250
Texas	1,475,000	2,708,838		4,183,838	5,030	4,684	2,436		2,600,000			
Utah	95,000	114,000		209,000	114	114	56					
Vermont *				n/a	n/a	n/a	n/a					
Virgin Islands *				n/a	n/a	n/a	n/a					
Virginia	626,466	786,800		1,413,266	1,400	700	455					
Washington	181,346	240,000	58,654	480,000	720	720	294					
West Virginia	77,947			77,947	179	62	18					
Wisconsin	30,000	393,700		423,700	476	286	117					
Wyoming	30,000			30,000	83	42	10			5,000		
Totals	40,625,593	30,720,457	20,827,488	92,173,538	69,295	59,894	17,426	2,546,155	5,489,409	4,225,731	32,845	17,250

* = state did not respond; $ = state does not have ADAP

Forty-seven (47) out of 50 States reported client information (Alaska, Guam and Louisiana did not). Total clients enrolled nationally was estimated at over 69,000 individuals. Total clients served by ADAPs in 1995 was reported to be nearly 60,000 clients. When compared with final data provided by States' Annual Administrative Reports (AAR) to HRSA for 1994, this total represents a modest increase (approximately 10,000 more clients) in 1995 over the 1994 level of reported clients served nationally. When comparing the survey data with AAR data from 1994, 33 States reported an increased number of unduplicated clients served by ADAP in 1995 over 1994. Even before the advent of newly approved AIDS therapies, the evidence is that many State ADAPs were experiencing greater client demand in 1995.

NASTAD also asked States to provide an estimate of new clients served during 1995. Forty (40) out of the 50 States responding (80%) reported data on new clients served by ADAPs in 1995. The total number of estimated new clients served nationally was reported to be 17,426. This number is slightly less than the new client information reported by States as detailed in the AAR for 1994.

ADAP Cost Savings and Recovery Mechanisms

Twenty-three State ADAPs reported actual dollar savings in taking advantage of a variety of mechanisms to reduce or recover the costs of prescription drugs. Among the more widely used mechanisms are: voluntary pharmaceutical manufacturer rebates; program certification by the Public Health Service's (PHS) Office of Drug Pricing to become eligible for discount prices offered through the Veteran's Health Care Act of 1992; and other mechanisms, including private insurance recovery, so-called "chase and pay" efforts; and other, special cost-saving initiatives. These mechanisms are often also sought in order to ensure that other sources of funding are exhausted before Ryan White CARE Act dollars are used.

Often the ability of States to utilize a particular cost savings mechanism is directly related to how their State's ADAP program is structured. For example, States which have received certification under the PHS Drug Pricing Program tend to have central purchase pharmacies or central warehousing, whereas States which do not qualify tend to have more complex systems or networks of providing access to medications (e.g., pharmacy networks, decentralized programs). States with more complex distribution systems, and those which correspond closely with State Medicaid pharmacy systems, are typically in a position to take advantage of rebates on aggregate prescription drug sales rather than "up-front" discounts. In keeping with the spirit of the Veteran's Health Care Act, twelve State ADAPs reported dollar savings in 1995 by entering into agreements with the manufacturers of frequently prescribed medications to obtain direct rebates based on utilization levels.

Several States reported problems with implementation of the Veterans Health Care Act which prevent many State ADAPs from benefiting from reduced drug costs. HRSA's Office of Drug Pricing Policy (ODPP) has been charged with implementing the Act and has developed regulations that provide for discount purchasing of drugs from a wholesaler or manufacturer. This mechanism reportedly does not work for State ADAPs with extensive local pharmacy networks. These pharmacy networks are needed by many States to provide adequate and convenient access for large enrolled populations, provide immediate access to drugs for acute conditions, and provide access to cognitive counseling by local pharmacists. Alternatively, States with these pharmacy networks have developed voluntary rebate systems with major AIDS drug manufacturers. According to State ADAP administrators, the legislative authority exists to implement a rebate component to the Veterans Health Care Act, which would complement the discount component, and provide all State ADAPs with the lowest possible costs.

Twenty-four (24) out of the 50 States responding (48%) reported actual dollar savings in 1995 by employing a cost savings mechanism to obtain lower cost prescription drugs or recover costs for eligible clients. Total reported savings obtained by States through the variety of mechanisms in 1995 was $12.3 million.

Voluntary manufacturers rebates

Twelve (12) States (24% of the total responding; 55% of those reporting cost saving mechanisms) report savings from voluntary manufacturers rebates. The States are: Arizona, Connecticut, Delaware, Illinois, Maryland, Michigan, Mississippi, New Hampshire, New Jersey, New York, Ohio and Oklahoma. The savings reported ranged from $500 in Delaware to $1.3 million in New York. Other States, such as California, reported that they were in the process of obtaining manufacturer's rebates, but could not report a dollar figure at this time. The total savings reported by States through voluntary rebates: $2.5 million.

PHS Drug Pricing Program Eligibility

Thirteen (13) States (26% of States responding; 54% of those reporting cost saving mechanisms) reported actual dollar savings in 1995 due to their eligibility for discount prices under the PHS Office of Drug Pricing. The States reportedly realizing savings by certification in the PHS Drug Pricing Program are: Colorado, Delaware, Florida, Hawaii, Maryland, Massachusetts, Minnesota, Mississippi, New Mexico, Oregon, Puerto Rico, South Carolina and Texas. The savings reported ranged from $750 in Delaware to $2.6 million in Texas. Colorado, which did not report a specific dollar savings, estimates that because of PHS pricing, their Assistance for AIDS-

Specific Drugs Program is able to purchase drugs at 45% less than the average wholesale price. In addition, several other States, including Nebraska and Nevada, reported substantial savings from PHS Drug Pricing, but did not report an actual dollar figure. The total savings reported by States through discount PHS prices: $5.5 million.

Other cost savings -- private insurance, chase/pay

Eight States reported other mechanisms for offsetting costs of drug coverage, the most significant savings reported by New York State through private insurance recovery (savings of over $4 million). In addition to New York, the seven other States are: Illinois (private insurance recovery); Maine (Medicaid reimbursement); Maryland (private insurance recovery and "chase and pay"); New Jersey (chase and pay); Oregon (chase and pay); Tennessee (discount pricing through a wholesaler); and Wyoming (private insurance recovery). Total savings reported through these other mechanisms: $4.2 million.

Ryan White Title II FY 95 Budget Shortfalls

NASTAD asked States to report whether they have encountered a shortfall in providing AIDS drug assistance in 1995, or whether they anticipate a budget shortfall before the end of the current Ryan White Title fiscal cycle (March 31, 1996). Out of the 48 States which provide funding for AIDS drug assistance (excluding Alaska and Guam) and responded to the survey, 20 States (42%) reported a budget shortfall.

States reporting shortfalls in providing AIDS drug assistance through Ryan White CARE Act (with projected dollar shortfall in parentheses) are:

State	$ Budget Shortfall
Arizona	($140,000 shortage)
Arkansas	($99,465)
California	(est. $4 million)
Colorado	($250,000)
Delaware	($150,000)
Indiana	($200,000)
Illinois	(between $62,000 - $265,000)
Iowa	(caps on medications at local level)
Kansas	(State stopped authorizing new services to avert shortfall, projected to be $200,000)
Maine	($30,000)
Massachusetts	($150,000 - $300,000)

Minnesota	($60,000)
Missouri	($50,000; required Kansas City and St. Louis to handle medications through March 1996, capitated contracts for medications in rural areas.)
Nebraska	($15,000)
New Hampshire	($40,000)
New York	($5.9 million)
Oklahoma	(instituted cap on expenditures and number of individuals covered 6 months into FY 95)
Oregon	($100,000)
South Carolina	(established waiting list; $500,000 may cover demand not being served.)
Texas	(will cut other existing services to avert shortfall -- $200,000 projected)

Over $12 million in total dollar shortfalls reported nationally for the last quarter of the FY 1995 grant project period (first quarter of calendar year 1996).

Factors which led to shortfalls

The most frequently reported factors which have led States to report shortages in funding to meet client demand and client utilization were:

* Increased number of combination therapies prescribed by physicians (45% of States reporting shortages);

* Increased number of clients utilizing program (40%);

* Significant expansion of the number of drugs covered by State's ADAP formulary in the past year (25%);

* Decreased FY 1995 funding of Title II in State (15 States received reduced Federal Title II formula grants in FY 1995 compared with FY 1994) (20%);

* Recent approval of additional high cost anti-retrovirals (e.g., Epivir, D4T, or Saquinavir) to State's formulary (20%); and

* Increased costs per clients served in the past year (15%).

Among the other factors cited less frequently which contributed to funding shortages for ADAP included: 1) improved outreach in the past year to make the

program more widely accessible; 2) insufficient screening by local providers of client eligibility for other payment sources (e.g., Medicaid, private insurance); and 3) increase of income eligibility criteria.

States Report Demand Outpaces Resources

In addition to the 20 States which reported shortages in funding for meeting current demand for services, 13 other States reported that, while not incurring a shortage before the end of the March 1996, their programs have experienced serious difficulties in keeping up with demand for services. These States have reported that they have either delayed action on covering newly approved therapies for lack of funding, experienced high demand for services which may outpace resources shortly, have re-programmed to compensate for demand, or expect a shortage after April 1996.

These States are: Alaska (high demand), District of Columbia (high demand, delay coverage) Florida (delay coverage), Georgia (high demand, delay coverage), Hawaii (expected shortage after July 1996), Kentucky (expected shortage between April-June 1996), Maryland (delay coverage, additional resources sought from EMAs), Nevada (delay coverage), New Jersey (delay coverage), Puerto Rico (delay coverage); Virginia (delay coverage); West Virginia (delay coverage); and Wisconsin (delay coverage). **Together with the 20 States which reported actual dollar shortages, these States represent 66% of the States responding to the NASTAD survey.**

Action steps taken to respond to the shortages

States have taken a variety of steps to respond to the funding crisis. For example:

In **Arkansas**, where the State has opted for consortia to administer medications assistance for eligible clients, the funding shortfall has led to a decision to cease all other additional services provided by the consortia and move funding to medication line items. Case managers are aggressively accessing Medicaid for eligible clients, and consortia have undertaken fundraising activities to support the need for client medications.

In **California**, the State is studying available options including the development and implementation of voluntary pharmaceutical rebate agreements. Other areas that will be implemented: 1) recapture of funds expended on participants who are now eligible for other payment sources (private insurance, Medicaid); 2) the identification of funds

available from under-utilized programs; and 3) the encouragement of local providers (local health departments and pharmacies) to implement cost management and cost containment practices.

In **Colorado**, regional case managers are focusing their work on accessing manufacturers' indigent drug programs for clients. All drugs were temporarily removed from Colorado's ADAP formulary in October 1995 due to the funding shortage. (The addition of emergency State funding has allowed the program to restart in early 1996.)

In **Illinois**, the lack of available funding for the newly approved therapies may necessitate dropping coverage of several other drugs (e.g., anti-microbial category) that were recently added to the formulary. The State's ADAP advisory committee has determined that the program's first priority should be provision of anti-retrovirals. Consideration is being given to requesting additional funding from the State's General Assembly or to instituting a co-payment policy for clients.

In **Indiana**, the ADAP program is working closely with State Medicaid to get eligible clients onto Medicaid and off ADAP; and is working to obtain rebates for Medicaid eligible clients who accessed drugs for which Medicaid will reimburse ADAP for costs accrued during the clients' approval process for Medicaid. The State is also working with drug companies to obtain rebates for drugs purchased.

In **Maryland**, although no budget shortfall is reported, it is only through successfully obtaining manufacturers' rebates, utilizing additional funds from the State's Title I EMAs, and tight fiscal management, that the State is able to offer unrestricted services through the end of the project period (March 31, 1996) without the addition of drugs to the formulary. An increase in demand for the program with the current formulary will result in the establishment of waiting lists. Although the program has sufficient funds to carry it through the project year, this has been accomplished by: carefully verifying eligibility; pursuing all available manufacturers' rebates; and maintaining the current 25 drug formulary without additions.

Missouri's AIDS program has taken the following actions since a September 1995 funding crisis affected all Title II services Statewide: 1) providing additional State-based funding and coordinated with its two Title I EMAs and pharmaceutical companies to ensure access to medications to eligible clients; 2) coordinating the Statewide consortium to prioritize medications and cap program expenditures; 3) considering block grants to local consortia for medications under a capitated contract to ensure maximum fiscal management and consortia ownership of medications prioritization process; and 4) requesting Title I EMAs to handle medications for

period 10/95-3/96 and providing capitated contracts for medications to rural area consortia.

New York's ADAP program has eliminated the coverage of 129 drugs (including antibiotics, psychotropics and analgesics) on the State's formulary effective 1/1/96 to save $2.35 million. The State, working in collaboration with Title I EMAs, has also transferred $3.55 million in savings from other Title I and Title II program areas to ADAP. Earlier in 1995, prior to cutting services, New York took the following additional steps to respond to the impending funding crisis: 1) received a 10% drug price reduction and the Federal Upper Limits program for pricing of generics (April, 1995); 2) increased insurance recovery and rebates; 3) implemented additional prospective utilization review controls on drugs; 4) implemented an automated control system for Medicaid spenddown participants; and 5) increased efforts to transition all eligible participants to Medicaid.

Impact of budget shortages on services for eligible clients

The 20 States reporting ADAP budget shortfalls reported the following range of effects on service delivery for eligible clients:

* Thirteen States delayed or cancelled planned expansions of drug assistance program formularies (including newly FDA-approved therapies) (65% of the 20 States);

* Eight States removed drugs from covered formulary (40%);

* Seven States established waiting lists for new applications (35%);

* Five States suspended dispensing of drugs for a period of time (25%);

* Four States reduced or ceased outreach activities (20%);

* Four States shifted other AIDS services or prevention program resources into ADAP (20%);

* Three States established monthly/yearly ceilings on client per capita expenditures for drugs (15%);

* Three States required prior authorization for certain therapies (15%);

* Three States capped client enrollment (15%).

Seventy percent of the States facing budget shortfalls (14 States) report that they are rationing ADAP services by establishing waiting lists for new clients or by removing drugs for HIV disease from coverage due to funding shortages. Five States reported suspending HIV/AIDS drug therapies for a period of time in 1995 due to lack of funding and increased demand.

The fiscal impact on ADAPs has been witnessed in other States which have not encountered an actual budget nor anticipate a shortfall before the end of March 1996. Over 77% of the States (37) which operate ADAPs report delayed or cancelled expansion of coverage of a wide range of AIDS drugs, including recently FDA-approved therapies, due to resource constraints, increased demand or uncertainty of future funding allocations for Ryan White Title II and State ADAPs. These States also reported that eligible clients who could now receive prescription drug coverage for new FDA-approved AIDS drugs are unable to access these new therapies because State programs are unable to budget expenditures for 1996. Without adequate funding for these drugs, States report that clients have limited options for receiving coverage for combination anti-retroviral therapies which being prescribed by clinicians.

Specific examples of the impact of budget shortages on client services include the following:

Arkansas

Case management approval must be obtained before any prescriptions are filled at any of the contract pharmacies. The District 4 consortium suspended all expenditures for about 3 weeks to get a handle on the total budget. All consortia have established monthly ceilings on the total amount spent on drugs. Clients are served on a first come, first served basis. Each consortium has been instructed to establish waiting lists if necessary; however none have yet been established.

Colorado

All clients were notified 3 months in advance that drugs would no longer be dispensed. Case managers were hired in each consortium area to assist clients in accessing manufacturers' free drug programs.

Delaware

A waiting list of approximately 25 persons was established for accessing the AIDS Drug Reimbursement Program (ADRP). The Medical Center of Delaware is currently covering those 25 persons.

Indiana

All new client applicants are being placed on a waiting list. As cases are closed usually due to Medicaid approval, new applications will be approved. The State health department works very closely with Medicaid consultant and advisory committee to make decisions and to add new drugs to the formulary.

Iowa

All consortia case managers work diligently with clients to increase enrollment in Medicaid, if eligible. Medicaid does not have prescription caps; the State's Ryan White consortia do.

Kansas

The State stopped authorizing new services on November 1, 1995. Case managers are not publicizing the program as before. Planned discussions for adding newly approved drugs have been postponed until April, 1996.

Missouri

Specific actions taken: 1) decreased income eligibility from 300% to 185% Federal Poverty Level; 2) decreased formulary (differentiated on a regional basis; some areas limited to anti-retrovirals/combination therapies; others antibacterials; 3) implemented waiting list or cap on the number of clients accessing services.

New York

A review of available resources and expenditure trends was conducted early in 1995. It became apparent that resources would not keep pace with expenditures. The Advisory Councils for the programs were convened to review all covered services and establish coverage priorities for the programs. Based on this process and review of available resources, recommendations were made to remove specific classes and individual drugs from the formulary effective 1/1/96.

Texas

New client applications are denied access to Rifabutin; access to Fluconazole is severely limited, with provision based on lab tests to verify cryptococcal meningitis or candida esophagitis diagnosis.

Actions taken by States in prior year shortfalls

Nineteen States (38% of States responding) reported that they had experienced ADAP budget shortfalls in prior years. Among the action steps taken by States in the past to deal with funding emergencies:

In **Florida**, the State did the following:

1. Maximized Medicaid enrollment;
2. Mandated Medicaid eligibility screening for everyone;
3. Established an ADAP funding allocation methodology to distribute ADAP funds Statewide by county; and
4. Established a six-month program enrollment cycle

In a prior year shortage, **Georgia**:

1. Established a waiting list: currently there is no waiting list;
2. Capped client enrollment: the program maintains 1,015 slots;
3. Title I (Atlanta) contributed more money in the past as needed to cover costs;
4. In 1993, the Governor awarded emergency funds and appropriated State funds to support the program.

In **Illinois**, at the end of the 1992 funding year, with an expected budgetary shortfall, the Department expected to implement a waiting list. Illinois State General Revenue funds were appropriated for the AIDS Drug Reimbursement Program (ADRP) to meet the need. State GRF funds have continued to meet the growing demand for HIV/AIDS related therapies through the ADRP.

Michigan took the following actions to respond to its funding emergency several years ago:

1. Changed financial eligibility;
2. Changed medical eligibility;
3. Changed formulary -- removed 25-30 drugs from formulary;
4. Closely monitored program expenditures;
5. Required pharmacies to bill within 30 days of dispensing medications;
6. Worked with case management agencies closely and encouraged efforts to aggressively tap into every pharmaceutical program for indigent patients.

In the past, **Missouri's** response to a funding shortfall was: 1) EMA reallocation of Title I dollars; 2) emergency money using reallocated HOPWA dollars; 3) access to

compassionate care programs; 4) assistance from the State's Department of Mental Health for coverage of psychotropics.

Impact of Newly Approved Therapies

In late 1995, the Food and Drug Administration (FDA) considered and rapidly approved marketing for two new anti-retroviral treatments for AIDS -- Epivir (formerly known as 3TC) and Saquinavir (Invirase). Epivir is considered -- like AZT, ddI, ddc, and D4T -- a nucleoside analogue, and is recommended to be used in combination with other nucleoside analogues for individuals with HIV disease. Saquinavir is the first of a new class of drugs known as protease inhibitors which has received FDA approval for treating HIV disease. This drug is also approved for use in combination with other anti-retroviral treatments. The FDA approved applications for two additional protease inhibitors from manufacturers in early 1996.

The anti-retroviral drugs approved in late 1995 have already accelerated client demand and increased utilization of combination therapies in many States. In addition, tens of thousands of individuals living with HIV disease in the U.S. have participated in AIDS clinical trials and manufacturers' compassionate use programs and have been receiving Epivir and Saquinavir prior to FDA retail marketing approval.

It is unknown how many of these individuals are currently eligible to receive assistance under State ADAP programs. However, according to NASTAD's survey, States are reporting that these newly approved therapies are rapidly being considered standards of care in some areas of the country, requiring rapid approval for coverage under State ADAP formularies in order to allow eligible clients access to continuing and uninterrupted treatment. States anticipate that the additional protease inhibitors approved by the FDA early in 1996 will further increase demand and client utilization of ADAP services at a time when resources for these services are in many cases leveling off or declining.

In order to gauge the level of coverage of the most recently-approved FDA anti-retroviral therapies, as well as to understand the decision-making processes within States for considering State approval for ADAP coverage, NASTAD asked AIDS directors to describe their State's decisions and plans regarding addition of Epivir and Saquinavir to State ADAP formularies, and the role of advisory bodies in recommending decisions on coverage of these combination therapies.

For the purposes of this report, specific State references to plans for adding these recently approved therapies will not be described; State information on coverage is described only in the aggregate.

Epivir

The survey findings indicate that as of mid-January 1996, 30 out of the 50 States responding (60%) have added Epivir to their State ADAP formularies, or are covering Epivir for eligible clients seeking assistance. Several other States report that their States' decisions regarding addition or coverage of Epivir are expected within 1-2 months. A significant number of those States which have yet to add or provide coverage for Epivir generally report that they are delaying decisions regarding coverage until after April 1996 -- the anticipated beginning of the next fiscal cycle for Ryan White Title II funding.

Among the major factors cited by States which are postponing coverage of Epivir are:

* Current budget shortfalls;
* Per client cost of the drug would exceed current availability of funds;
* Uncertainty of FY 1996 Title II funding, both in terms of finalized action on Ryan White CARE Act FY 1996 Federal appropriation and reauthorization, and impact of short-term continuing resolutions on FY 1996 Title II grant awards;
* Underfunded contribution to State ADAP program by Title I EMAs within States;
* Addition of the drug would result in previously approved drugs being removed from the formulary;
* Formulary advisory committees have yet to meet and formally consider recommended revisions to ADAP program; and
* States currently have waiting lists for new applications for drugs covered under existing formularies.

The demand for coverage of Epivir has reportedly led to several States to implement adjustments to their ADAP programs to accommodate the addition of the drug. For example, one State reports that the additional coverage of Epivir is a contributing factor in its decision to remove a significant portion of drugs from its formulary, including categorical coverage of antibiotics, analgesics and psychotropic medications for eligible clients.

Saquinavir

Eleven States out of the 50 responding (22%) indicated that their ADAP programs were covering Saquinavir by mid-January 1996. An additional four States reported that a decision regarding addition of Saquinavir to their ADAP formularies was expected within 1-2 months. Several of the States which are providing coverage

of Saquinavir routinely cover all FDA approved drugs related to HIV disease. Others have recently instituted policies (recommended by State formulary advisory committees) to cover categories of drugs and approve coverage of anti-retroviral AIDS treatments automatically upon FDA approval.

Nonetheless, the pace with which Saquinavir is being covered by ADAPs nationwide up to now is clearly slower than coverage of Epivir. Many of the same factors cited by States as reasons for delaying coverage of Epivir hold true for Saquinavir. However, many States indicate that these factors appear to be compounded in considering coverage of the first of the new protease inhibitors.

Among the key additional factors cited by States for postponing addition of Saquinavir to ADAP formularies were:

* Per client cost of the drug -- reportedly as high as $6,900 per year in some States -- is seen as too prohibitive for coverage;

* Without the availability of additional funding, the addition of Saquinavir (or other expected protease inhibitors in the near future) will result in the deletion of currently covered drugs, increases in program eligibility criteria, or limits on per client expenditures;

* The State recently expanded its coverage of drugs and is providing the maximum available coverage based on budget projections;

* Approval of Saquinavir by the FDA was unexpectedly fast and inadequately predicted when State ADAP budget plans were made at the beginning of the FY 1995 project period;

* The drug was not recommended for addition to State's formulary by clinical advisory panels due to either cost constraints or clinical concerns about the drug's effectiveness;

* Uncertainty and concern about the impact and anticipated demand for other soon-to-be-approved protease inhibitors, causing States and advisory panels to postpone decisions on Saquinavir until the fiscal and clinical impact of other protease inhibitors can be adequately evaluated;

* Advisory panels decided that, given the financial status of the States' ADAP program, not adding the newly approved drugs -- and therefore being able to serve current enrollees -- is preferable to establishing waiting lists for new clients.

* Potential program clients are already on waiting lists due to budget shortfalls. If Saquinavir is added to formulary without other drugs being removed from formulary and/or increases in ADAP budget, existing ADAP clients would need to be put onto a waiting list.

* State reports that they have not experienced the immediate client demand for the drug as witnessed with other anti-retroviral drugs.

Advisory Panels

State health departments overwhelmingly reported that they rely on the expertise and counsel of formal and ad hoc advisory panels in making decisions regarding ADAP services. Forty-two out of the 50 States responding (84%) report that their State has an advisory panel -- including clinicians and consumers -- which provides key input into State decisions on formularies, eligibility criteria, fiscal issues, and medical and scientific guidance regarding ADAPs.

In addition to clinicians and consumers, which make up the majority of advisory panel members according to States, other participants may include: pharmacists, dentists, nurses, consumer advocates, State and local health department staff, community-based organization representatives, case managers, Title II consortia members, Title I planning council members, AIDS Clinical Trials Unit investigators, epidemiologists, Medicaid program staff, and social workers, among others cited.

Varying from State to State, formal ADAP advisory panels may be solely responsible for ADAP issues, provide recommendations for planning for a State's Ryan White funded programs (e.g., a Statewide consortium), or be responsible for drug utilization review and decision-making for other State public health programs in addition to HIV/AIDS. Ad hoc committees, cited less frequently by States, are also used by State HIV/AIDS programs to provide recommendations periodically.

Among the States which do not report that they have ADAP advisory bodies, several report that they do not because they have do not administer an ADAP program per se (e.g., Alaska, Arkansas, Iowa) but rather allow consortia to provide medication assistance to clients. These States work with individual consortia to determine coverage of treatments. Other States report that, although they do not currently have ADAP committees, health department staff periodically survey AIDS care coordinators, infectious disease specialists, clients and case managers, as to current medication needs of clients.

FY 1996 Plans

Due to a variety of factors, including widespread State ADAP budget shortfalls reported, anticipated demand for AIDS drugs (particularly combination therapies), and uncertainty as a result of unfinished Federal appropriations and Ryan White reauthorization processes, planning for Title II ADAP services (as well as other care services) for FY 1996 is presenting enormous challenges for States. States reported a variety of planning approaches for FY 1996, and anticipated a variety of changes to their programs. Among the most common challenges expressed by States:

* Balancing all funded care services, in addition to ADAP, in order to best serve client needs in 1996;

* Anticipating level funding or the prospects of declining Federal funding in 1996; and

* Planning for drug coverage in the absence of effective and practical clinical information on the most appropriate combination therapies.

Below are some examples of 1996 plans for providing AIDS drug assistance and anticipated program revisions reported by selected States:

Alaska

According to the State AIDS Director, if Alaska receives additional funds (if its minimum Title II grant award is increased) the State will develop a drug assistance program. Currently, local consortia and a Title IIIb grantee provide access to medications for eligible clients.

Arizona

The State's medications program will be decentralized effective April 1, 1996 and administered by regional consortia. Protease inhibitors are expected to be included on the minimum formulary, required contractually to be provided by consortia via their consortia-administered, decentralized program. Consortia will need to project and allocate resources necessary to provide coverage for all eligible persons. Financial eligibility, together with the minimum formulary will be mandated. The formulary for FY 1996/97 will be reduced from that which the State Health Department administered in FY 1995/96.

Arkansas

During FY 96, there will be strict adherence to the Statewide drug formulary to ensure that funds will be available to local consortia during the funding period. The major concern in the provision of combination therapies is cost. Limited funding will place a tremendous strain on the consortia. It is anticipated that the State's HIV Services Planning Council, which is in the early phases of development, will be successful in developing a comprehensive plan for the State that will convince legislators to appropriate funding for services. Additional funding streams will be researched. Since level Federal funding is anticipated for FY 96, the drug formulary will be reassessed in February and necessary changes will be made. Any purchases that will be made outside of the formulary must receive prior approval by the State's HIV Services Program Coordinator.

California

The cost impact of the addition of other protease inhibitors has not been calculated although the impact is being considered in the decision regarding Saquinavir. The State must identify additional revenue, most likely State general funds, to meet the anticipated demand. In terms of ADAP changes, increased funding (level not determined) is needed, increased rate utilization, increased recovery of expenditures on ineligible clients, increased demand, and increased number of drugs on the formulary are all expected.

The California Title II Working Group has recommended that the Office of AIDS investigate the efficacy of revising the program to add drugs upon FDA approval and evaluating drug utilization at six months. Because cost information is not available prior to FDA approval, States' ability to recommend the addition of new drugs is inhibited.

Colorado

Colorado was recently successful in seeking emergency supplemental funds of $151,000 from its State Legislature to continue the State's AIDS Drug Assistance Program. Historically, the State General Assembly has awarded the program $150,000 per year for assistance for AIDS-specific drugs. The State's yearly commitment has now doubled to $301,000.

Connecticut

The State reports that it has been cautious in adding new drugs because of the unknown impact on current resources. Connecticut reports that it will be closely monitoring expenditures of the first of the approved protease inhibitors. It has not yet determined what the financial impact would be for other protease inhibitors approved by FDA in 1996. In terms of changes to ADAP, plans are to revise the State law governing administration of the program to allow for coverage of nutritional supplements and related drug supplies, if sufficient funding is available. However, there is concern that the program may not have sufficient funding if future FDA approved HIV therapies are very costly.

Delaware

The State Health Department is currently working to assure that any AIDS care provider may be able to obtain PHS drug pricing. The State is also working on voluntary manufacturer rebates. However, the current waiting list for new clients will continue until the funding situation is improved. Changes to ADAP: the State has added some small additional funding pending Federal formula allocations and Federal budget reconciliation. Plans are to re-evaluate and allocate some additional resources for medications.

Florida

Florida anticipates a financial shortfall in 1996 to in excess of $4.3 million based on the previous year's drug usage, the recent addition of lamivudine (3TC, Epivir) to the ADAP, and the proposed addition of Saquinavir (Invirase). At this time, the ADAP resources allocated are expected to be fully utilized by the current 10 drug formulary. Adding another drug will likely result in changing eligibility criteria for the ADAP, or causing the deletion of a current drug or drugs, unless additional financial resources can be secured. At the local level, entities such as the county public health units and Title II consortia have pharmaceutical line item budgets that assist clients with drugs not covered in the ADAP, or assist those individuals who are not eligible for the ADAP. Depending upon the locality, new therapies may be funded by these non-State ADAP resources.

Georgia

The State's Medical Providers Task Force estimates that the cost of protease inhibitors along with the addition of Epivir could be as high as $6.3 million. The Task Force will continue to meet to monitor and make recommendations regarding the addition of

drugs to the formulary and criteria for eligibility and priority for receiving therapies. Based on current Titles I, II, and State funding levels (total $14 million), the program expects a shortage in funds for ADAP. No additional State funding is anticipated in 1996. The priorities and allocations committees of the Title I planning council in Atlanta have proposed a $2 million setaside for overall drug increases to meet the need of increased numbers of clients being served in the EMA. Availability of Title II funds for ADAP will have to be evaluated.

Illinois

Effective September 1, 1995, the State's ADRP was expanded to cover categories of drugs. Prior to the expansion, the ADRP subcommittee prioritized the categories of drugs in order to quickly make decisions concerning additions and deletions of drugs. Budgetary constraints may require elimination of Category IV (treatment for neoplasms) and V (epoetin alfa; gancyclovir-oral; neuporen; IV immune globulin).

Funding is expected to decrease and rollover funds will not be available in FY 1996. Demand is expected to increase as additional persons begin receiving protease inhibitors. Additional protease inhibitors will be covered as they become FDA approved. Eligibility levels may be decreased depending upon budgetary constraints. The FY 1995 estimated ADRP expenditures were $4 million and the FY 1996 estimated ADRP expenditures are $6 million at current program levels. In addition, the number of other drugs covered by the ADRP (besides anti-retrovirals) may be decreased and clients may be required to co-pay.

Indiana

The State Health Department is working with physicians across the State and with the Infectious Disease Research Clinic in Indianapolis to assess need. Also, a client survey is being developed to acquire information on how clients perceive existing services. In Congressional funding proposals contained in Ryan White reauthorization, Indiana is expected to receive substantial increases in Title II funding. Increased funding will allow for an increase in funding for ADAP.

Maryland

At its ADAP Advisory Board meeting in December, the following issues were discussed in relation to the demand for coverage of additional drugs in Maryland:

* Request for State funding for drugs;
* Collaboration with other State ADAPs to push for price breaks from

manufacturers -- to advocate for lower drug costs;

* Request that EMAs allocate funding for additional drugs for EMA residents;
* Establish a drug approval process based on clinical indications for the appropriate use of certain drugs; this would require regulatory changes in Maryland;
* Establish a block agreement with certain pharmacies to reduce the costs of drugs; this would also require regulatory changes;
* Request that local jurisdictions provide funding for drugs for their clients who use the program.

New York

In the short term, the ADAP program is working with the Department of Health and the Division of Budget to find additional resources for the program to restore cut drugs and services and to allow for the addition of new therapies and treatments. Long term: The program will continue to identify savings opportunities and streamline administrative activities. A review of the financial criteria will likely result in a change in the financial eligibility. The advisory committee will be charged with the task of reviewing covered drugs and services and making hard recommendations on services and drug coverage with respect to available resources.

Ohio

The State is currently looking at several ways to conserve current expenditures in order to include protease inhibitors in 1996. Prior authorization for certain drugs on the formulary and clinician education to ensure appropriate use of medications are also planned. Because House and Senate versions of Ryan White reauthorization legislation provide for significantly different levels of increased funding for Ohio, future programming activity will reflect whichever version is funded. If funding levels stay the same, the State reports it will not be able to add new therapies. The demand for the program is steadily increasing, and the result could be dropping covered therapies, limiting number of enrollees, or creating a stricter medical criteria for enrollment.

Oklahoma

As of now, there have not been any formal assessments and no other possible sources of revenue identified. The State's Ryan White Advisory Council has formed a legislative committee to come up with a plan to educate, then advocate for more State funds.

In terms of expected changes to ADAP: no changes in funding are anticipated, but demand is expected to increase. Additional new therapies are expected to be covered and program eligibility will likely remain the same. Persons who receive a Medicaid prescription card (limited to 3 drugs a month) will be considered to have a pay source for prescriptions and will not qualify.

Rhode Island

Since Title II drug funding will most likely be inadequate to cover protease inhibitor approvals and use will only add to the fiscal problem, the health department is exploring additional State funding options (possibly a legislative initiative), diverting Title II funding from other services, and ADAP restrictions re: eligibility, number of medications, and capping per client cost.

Washington

The State will analyze and assess fiscal impacts based on utilization of new medications. Consideration is being given to conducting a survey of providers to determine common practices regarding combination therapies.

Planning and Forecasting Models

A variety of external factors led to a dynamic and somewhat unpredictable year for ADAP programs which collapsed some States' plans for FY 1995. However, given the fact that almost half the States reported shortfalls in their ADAP budgets in 1995/96, there is obvious interest in assuring that States have access to effective planning and forecasting approaches.

Ten States out of the 50 responding (20%) described a forecasting model their State uses for anticipating costs and future demand for ADAP services. Given the vast majority of States which responded that did not use a forecasting model for projecting costs and utilization patterns, the NASTAD survey has identified a significant technical assistance need and knowledge gap.

Additionally, several States noted that planning approaches used in prior years for predicting client utilization and costs might be inoperable given several recent factors:

* the unpredictability of combination therapies -- which drugs?, used in which combination?, at what cost?, and at what dosage levels are physicians going to be prescribing these new anti-retroviral medications? and

* the relative speed with which the FDA approves drugs to enter the market -- particularly the expected rapid approval of protease inhibitors -- how many in 1996/97?, at what cost?

However, there is value in examining the approaches described by States which volunteered their ideas for forecasting ADAP expenditures and service utilization.

Among the planning models cited:

Arizona

For each medication, demand is tracked since the drug's addition to the program. Projected number for future use is increased 10%. Simply put, the program assumes a 10% increase in demand, and budgets $50,000 per year per new medication. Last year Arizona assumed one new (additive, non-substitutable) FDA approved anti-retroviral.

Connecticut

Connecticut estimates expenditure growth for most drugs added to its formulary based on the experience of other States (most often New York) weighted by the ratio of that State's ADAP population to Connecticut's ADAP population.

Massachusetts

Based on past utilization of AZT and current use of PCP prophylaxis, the program can estimate stage of disease of clients. The program then estimates projected utilization of combination therapies and estimated numbers expected to enroll in Medicaid.

Mississippi

Forecasting includes regular polling of State infectious disease specialists, review of client enrollment trends (particularly by CD_4 levels and OI drugs), and review of current and proposed medications/therapeutic dosage information.

New Jersey

Forecasting increased demand and associated expenditures is based on a combination of factors which include the following: 1. average wholesale price; 2. product insert information (i.e., dosage and administration); 3. prescribing patterns; and 4. utilization patterns for the New York ADAP program. A rough estimate of potential

clients for the new therapies is made and combined with pricing data to come up with an estimate of new expenditures.

New York

For existing products, the program has been able to utilize the State's Medicaid data and make some assumptions regarding utilization and cost based on that information. For new products, it is more difficult because the program relies upon data and information from the product manufacturer which may not neeessarily reflect actual demand and usage.

Oklahoma

In terms of demand, forecasting is done by looking at previous year's program usage rate (number of individuals certified/number of individuals who accessed program per month). The State also tracks those who would have been certified in excess of cap limits.

Wisconsin

Forecasting is conducted based on past data illustrating number of program users, cost per user and cost per prescription. The State also incorporates the usage projections of manufacturers in calculating cost estimates of new drugs. State Medicaid utilization statistics are another source of information.

Technical Assistance Needs

According to States, the volatility and unpredictability of the FDA approval process for HIV medications, along with current uncertainty about level of resources available, makes planning enormously difficult. Nearly every State reported that technical assistance in the form of Federal guidance, other State models, client and clinical information, and standard treatment protocols would help States to more effectively plan ADAP services. States described several key needs in order to better forecast and plan for the demand for additional therapies. Specific examples cited by AIDS directors and ADAP services administrators, in their own words, are:

* "Need more specific information on the per capita cost of new drug therapies and the number expected to be approved in 1996/97. Also need information on expected client population that will utilize the new drug therapies."

* "Additional client information, such as the ability to track clients across various

funding streams would be helpful. We encourage the continuation of the "State of the art" teleconferences, which have been very helpful to the health department's clinicians."

* "The Department would benefit from technical assistance from HRSA concerning forecasting and planning for the demand for additional therapies. Additional pharmaceutical information on expected FDA approval and drug cost would be beneficial. Specifically, we would benefit from advance information concerning price and projected utilization of the drug."

* "History of cost projections (for combination therapies); Federal and State models; clinical information; epidemiological data; client histories/information; any available studies on combination therapies."

* "Whatever Federal guidance is available. It is difficult to anticipate: 1) what new drug will be approved and when; 2) how much it will cost; 3) how many people will take it; 4) what new combinations of existing drugs will be used."

* "About the most difficult factor in determining what to do next is whether or not Federal (i.e., Title II) funds are a) going to be authorized and b) what amount we're going to receive. Even a flat guarantee of an "at least" level funding would help.

* "Federal guidance on anticipated cost per drug; client information from medical providers (intent to prescribe); clinical information: best use when."

* "Clinical information on percent of HIV population who are appropriate candidates for new therapies. (More clinical information in terms of the percent of the general HIV population that would be appropriate candidates for the therapy.) Helpful to also know what types of combination therapies are utilized."

* "Federal guidance may assist programs in gathering more accurate information regarding new products and therapies. More relevant clinical information regarding efficacy and usage may make it easier to develop cost and utilization parameters, i.e., if disease stage information regarding benefits and projected usage by the HIV infected population were more clearly available, the ability to determine projected use would be significantly more accurate. For example, the actual use and expenditures for 3TC (Epivir) have been twice what the (State's ADAP) program expected in the first month. The program used data and information provided by the manufacturer to make these projections

regarding utilization."

* "We need to be able to predict future Title II funding. Also, we need information re: other States' programs/models. Also, unbiased analysis of clinical information (for non-clinician program managers), especially re: the progress of the approval process, appropriate patients/protocols, and medication costs would be helpful."

* "Statistical data on health outcomes and community standards. Data on community practice regarding therapies."

* "Forecasts predicting how client drug usage will change with addition of new therapies. How many clients are likely to use each drug? Still think someone with the resources to do it should create an Internet page for ADAP program managers to "chat" about these issues on a regular basis."

Other Issues

NASTAD's survey also explored other issues which may affect State ADAP decision making, planning and services, including: statutory or regulatory requirements; the impact of ACTG 076 on AZT use among pregnant women; and the potential effect of Medicaid managed care arrangements.

Statutory/Regulatory Requirements

Eleven (11) of the 50 States responding (22%) reported that their States have statutes or regulations governing aspects of decision-making on providing AIDS drug assistance. The States reporting statutes or regulations are: Arizona, California, Connecticut, Illinois, Maryland, Mississippi, New York, North Carolina, Oregon, Texas and Wisconsin. With few exceptions, however, States report that these laws or regulations do not overly constrain decision-making or program flexibility. Specific examples of the kinds of State laws or regulations affecting ADAPs include:

California

Addition of drugs to the State's ADAP formulary must be approved by the Director of the Department of Health Services.

Connecticut

Current law limits coverage to payment for the cost of drugs prescribed for the prevention or treatment of HIV/AIDS.

Illinois

The Department's rules and regulations allow for the automatic approval of drugs to the ADRP formulary if they fall within one of five approved categories or classes of drugs.

Maryland

The Maryland ADAP is governed by State regulations which can be amended as needed to add to the formulary or change program criteria. The AIDS Administration formulates the language for the proposed regulatory change; therefore, this process would be unlikely to impede program decision-making. After internal review within the Department of Health and Mental Hygiene, the Secretary of the Department of Health and Mental Hygiene submits the draft of the proposed changes to a joint legislative oversight committee which has advisory (not veto) authority over all regulations proposed by the Executive Branch. If the joint legislative committee took exception to a proposal, it would be very difficult for the Department to adopt the proposal. At the completion of a public comment period, if comments have not resulted in any changes to the proposal, the Secretary of the Department of Health and Mental Hygiene adopts the proposal and sets an effective date.

Mississippi

Regulations internal to the agency requires approval of any new medication by the Formulary Committee.

New York

The program's eligibility criteria and enrollment for both providers and participants are in State regulation. There is no statutory language regarding service or drug coverage due to the changing trends in treatment practices.

North Carolina

The program must go through a rules process to change the eligibility or formulary. Requires public hearings and publication of rule changes.

Texas

The drug formulary must be approved by the Commissioner of Health.

Wisconsin

Statute lays out a process for adding new drugs, but gives wide scope for which drugs can be added.

Slight Impact of ACTG 076 on ADAP Reported

Generally States reported only slight increases in AZT use among women in 1995, and did not generally report that they are tracking whether clients are pregnant (ADAP enrollment applications generally do not ask whether clients are pregnant). Universally, States reported that pregnant women with HIV infection in their State are either eligible for Medicaid or have private insurance and are not accessing Ryan White-funded ADAP programs. It is unclear whether this will change in the future, given the greater degree to which ACTG076 protocols are being implemented nationwide. However, according to States, the burden for providing prescription drug coverage for low income pregnant women is likely to continue to fall on State Medicaid programs rather than Ryan White-funded programs.

Potential Impact of Medicaid Managed Care

States generally reported that Medicaid managed care plans are still in formative stages of development in most areas, so it is unclear what impact these arrangements will have on ADAP programs. In Maine, for example, the State's ADAP program may be brought into the State's emerging Medicaid managed care program as a bill-paying mechanism, but it is still too early to determine whether this will occur. Several States noted that, potentially, clients may find it more difficult to become Medicaid eligible, therefore, more people may be trying to access ADAP to obtain the drugs they need. Also, existing Medicaid clients may not necessarily receive coverage for their HIV/AIDS drugs, and may need to look for resources like ADAP for help. Several States reported that HMOs in their State have been slow to add newly approved AIDS drugs, which may continue to force demand on ADAPs.

Other States reported that State health department staff are in the process of working with managed care organizations (MCOs) to ensure appropriate medications access for Medicaid eligible clients with HIV disease. Concern was raised in several places that struggles are anticipated with some MCOs in transitioning clients that are in late stages of HIV disease from ADAP to Medicaid plans and maintaining

continuum of care.

Several States reported that changes in ADAP programs need to be closely coordinated with Medicaid programs to assure continuity of services for eligible clients. Arizona reports that the State's Medicaid program is comprised of many different providers, each with its own prescription drug formulary. The State's ADAP program has historically covered what the State's Medicaid program did not. Some of the recent changes in the State's ADAP program -- in terms of a revised minimum formulary and variations in coverage by consortia -- may make coordination with the State's Medicaid program increasingly difficult in the future.

Summary Conclusions

The resource needs of State ADAPs are evident, given the fiscal shortages encountered by many States in trying to keep pace with the increased demand for services, and given the anticipated costs associated with the range of treatments which are rapidly becoming the standards of care for HIV disease. The assessment findings show that the most significant obstacle States face in providing access to the range of HIV therapies has been a shortage of funds -- both Federal and State.

The findings also indicate that there are other obstacles, in addition to lack of funding, which complicate ADAP program management and improved access to HIV therapies. The following is a list of prominent program areas and ADAP issues referenced by States which require a coordinated response from States and the Federal government working in partnership:

* Improved planning and forecasting approaches for projecting ADAP costs and utilization patterns;

* Federal guidance on appropriate and flexible standards of treatment for HIV disease, developed in consultation with States, clinicians and consumers, to assist in the determination of ADAP formularies and appropriate coverage of core HIV therapies nationwide;

* Models for effective use of limited resources -- models for assuring cost-effectiveness and widest possible client access to HIV therapies;

* Barriers lifted on wider implementation of the Veterans Health Care Act of 1992 to provide a vehicle for <u>all</u> state ADAPs to benefit from reduce costs on prescription drugs. Currently, the PHS Office of Drug Pricing Policy, which is charged with implementing the Act, has developed regulations that provide only

for discount purchasing of drugs from a wholesaler or manufacturer. This mechanism does not work for States with extensive local pharmacy networks. According to State ADAP administrators, the legislative authority exists to implement a rebate component to the Veterans Health Care Act, which would complement the discount component, and provide all State ADAPs with the lowest possible costs.

* Accurate and timely notice from the Public Health Service of impending FDA AIDS drug approval, allowing for reasoned planning for demand and ADAP resource needs;

* Improved and wider access to clinical information -- besides the information provided by the manufacturer -- regarding new products and therapies. According to States, if disease stage information regarding benefits and projected usage by the HIV infected population were more clearly available, the ability to determine projected use would be significantly more accurate. Additional client information, such as the ability to track clients across various funding streams and clinical information on the percentage of the HIV-infected population who are appropriate candidates for new therapies would also be helpful.

* Improved protocols for screening by States and local providers of client eligibility for other payment sources (e.g., Medicaid, private insurance) to assure that the ADAP program is the payor of last resort for eligible clients; and

* Examination of State income eligibility criteria for ADAPs to determine impact on cost containment and resource limitations.