Fiscal Status Update of State AIDS Drug Assistance Programs: Preliminary Findings from an August 1996 National Survey of State AIDS Programs

The National Alliance of State and Territorial AIDS Directors

September 9, 1996

### Introduction

Preliminary findings from a follow-up national survey conducted in August 1996 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 and state governments continue to show that many states are anticipating significant funding shortages which hamper their efforts to provide adequate coverage of therapies for low income individuals with HIV/AIDS. The findings also indicate that despite funding level increases realized by all state programs in fiscal year 1996, some state ADAPs are having difficulties initiating coverage of protease inhibitors while many others are struggling to ensure sustained coverage of these new HIV/AIDS therapies for eligible clients into the next fiscal year.

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 services, and housing programs, including Title II of the Ryan White CARE Act. ADAPs 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 third party payors, such as private insurance.

This is an update of a NASTAD report published in April 1996 which documented the fiscal crisis among many state ADAPs prior to the finalized FY 1996 budget process which included a \$52 million increase in federal Title II funding dedicated to ADAPs and before the reauthorization of the Ryan White CARE Act which bolstered the federal funding for many states under Title II. The survey focuses solely on Ryan White Title II and state-funded ADAP programs and does not examine access to HIV/AIDS medications through other public or private reimbursement programs such as Medicaid.

This report is based on a preliminary analysis of a survey of 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). Forty-six (46) out of the 54 states and territories have responded to the entire survey, representing an 85% complete response rate. States and territories which have not completed the entire survey as of September 6, 1996 are: Colorado, Georgia, Guam, Maine, Mississippi, New Mexico, Puerto Rico and the U.S. Virgin Islands. All states and territories except Guam and the Virgin Islands have responded to some portion of the survey.

The following is a preliminary summary analysis of the major NASTAD survey findings<sup>1</sup> which includes descriptions of ADAP client demand and costs so far in 1996, current coverage of protease inhibitors by state ADAPs, summaries of currently projected budget shortages in states, actions to respond to shortages, plans to sustain coverage of combination therapies, and efforts underway in states to control and monitor ADAP expenditures.

### **ADAP Client Demand and Drug Costs**

As indicated in NASTAD's April 1996 report on the fiscal status of state ADAPs, even before the advent of protease inhibitors, most state programs had been experiencing sharp increases in client demand and costs associated with anti-retroviral combination therapies, in some places as early as the summer of 1995. In order to gauge more recent client demand and costs, NASTAD asked states in August 1996 to compare the number of clients served (clients filling at least one prescription) and monthly program expenditures in January 1996 and in July 1996 (or the most recent month for which data was available). Seventy-four percent of the 46 states responding thus far (34 states) have provided all data elements to answer this question.

Of those states providing complete data thus far, 71% (24 states) report significant increases in clients served (over 10% growth) and increased monthly program costs (over 20% growth) since the beginning of 1996. Only ten states reported less than 10% increases in either clients served or expenditures during the reporting period; four of those states indicated decreases in either clients served or costs. Table 1 shows the data reported by states which have experienced significant growth in demand and costs since the beginning of 1996.

Growth in clients served by state ADAPs ranged from 10% in Texas to 167% in Montana for the first seven months of 1996. States which report more than twice the number of clients served from January to the most recent month in 1996 are Tennessee (134%), North Carolina (129%), and the District of Columbia (117%).

Growth in clients served during 1996 is relatively modest when compared with the growth in monthly costs experienced by ADAPs during the same period. Cost increases ranged from 20% in Texas to 427% in North Carolina. Other states which report that they more than doubled their monthly expenditures since January 1996 include: Arizona (113%), the District of Columbia (207%), Florida (123%), Montana (388%), South Carolina (101%), Vermont (149%), Washington (152%) and Wisconsin (164%). The likely reasons for the surges in expenditures: modest to significant increases in client demand, increased demand for combination anti-retroviral therapies with most clients filling prescriptions for multiple drugs, including dual and triple combination

<sup>&</sup>lt;sup>1</sup> A final survey report will be produced by NASTAD pending completion of all surveys from all states and territories and verification and analysis of data tables related to FY 1996 state ADAP budgets.

Table 1

## States Reporting Significant Increases in Clients Served and Monthly Program Costs Between January 1996 and July 1996

(except where noted)

State	Clients 1/96	Clients 7/96	Increase in Clients	Costs 1/96	Costs 7/96	Increase in Costs
Arizona <sup>1</sup>	198	316	60%	\$52,660	\$112,000	113%
Connecticut	284	334	18%	\$130,580	\$186,175	43%
Delaware	22	29	32%	\$22,641	\$33,946	50%
D.C. <sup>2</sup>	250	543	117%	\$97,473	\$299,496	207%
Florida <sup>3</sup>	2912	4156	43%	\$782,474	\$1,748,679	123%
Hawaii	54	60	11%	\$28,607	\$44,920	57%
Illinois <sup>4</sup>	1130	1344	19%	\$614,254	\$786,153	28%
Maryland	210	242	15%	\$90,810	\$127,209	40%
Massachusetts <sup>5</sup>	1250	1510	21%	\$180,000	\$300,000	67%
Montana	9	24	167%	\$3,600	\$17,556	388%
Nevada	260	315	21%	\$67,600	\$81,900	21%
New Hampshire <sup>6</sup>	53	68	28%	\$15,453	\$21,118	37%
North Carolina <sup>7</sup>	117	268	129%	\$31,300	\$165,000	427%
Ohio	241	323	34%	\$90,610	\$136,220	50%
Oklahoma	101	139	38%	\$39,142	\$61,686	58%
Oregon	73	90	23%	\$34,682	\$46,324	34%
South Carolina	232	366	58%	\$34,073	\$68,558	101%
South Dakota	37	41	11%	\$7,166	\$9,287	30%
Tennessee	47	110	134%	\$25,840	\$43,694	69%
Texas	1,733	1,907	10%	\$500,797	\$602,284	20%
Vermont	53	65	23%	\$6,700	\$16,700	149%
Washington <sup>8</sup>	208	338	62%	\$58,412	\$147,342	152%
West Virginia <sup>9</sup>	20	34	70%	\$5,793	\$10,259	77%
Wisconsin <sup>10</sup>	97	135	39%	\$20,507	\$54,239	164%

<sup>&</sup>lt;sup>1</sup> Arizona's data from January - June 1996.

<sup>&</sup>lt;sup>2</sup> D.C.'s data from January - August 1996, according to DC CARE Consortium.

<sup>&</sup>lt;sup>3</sup> Florida' data from last six months of 1995 and first six months of 1996, aggregate.

<sup>&</sup>lt;sup>4</sup> Illinois' drug formulary reduced from 110 to 28 drugs on July 1, 1996.

<sup>&</sup>lt;sup>5</sup> Massachusetts' data from January - April 1996, total prescriptions filled.

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<sup>&</sup>lt;sup>6</sup> New Hampshire's data from January - June 1996.

<sup>&</sup>lt;sup>7</sup> North Carolina's expenditures from July 1996 includes 1.5 months worth of payments.

<sup>&</sup>lt;sup>8</sup> Washington's data from December 1995 - July 1996.

<sup>&</sup>lt;sup>9</sup> West Virginia's data from January - June 1996.

<sup>&</sup>lt;sup>10</sup> Wisconsin's data from December 1995 - June 1996.

therapies, and the increased costs associated with the new therapies, including protease inhibitors. It is notable that states which have been covering protease inhibitors for several months (e.g., D.C., Massachusetts, North Carolina, and Washington), as well as those which have yet to cover them (e.g., Florida, Ohio, Oklahoma) have each experienced substantial increases in drug costs, though relatively higher among states which have been covering the new treatments longer.

### **Coverage of Protease Inhibitors**

NASTAD has ascertained from all states and territories (with the exception of the Virgin Islands) whether their ADAP program currently provides access to the new class of HIV/AIDS therapies called protease inhibitors. There are currently three FDA-approved protease inhibitors available in the U.S.: Invirase by Roche (saquinavir), Norvir by Abbott (ritonavir) and Crixivan by Merck (indinavir).

As of September 6, 1996, 32 state ADAPs report that they cover at least one of the three protease inhibitors. Twenty-six (26) states report that their ADAP covers all three. Five (5) ADAPs report that they expect to begin coverage of protease inhibitors for eligible clients by October 1, 1996. In 14 states, decisions are still pending as to when and if the ADAP program will be providing coverage for the new drugs in the near future. Table 2 indicates the current status of protease inhibitor coverage in all state ADAPs, along with clarifying notes.

Due to the high cost and high demand of the new therapies, coupled with finite resources, states have implemented or are expected to implement approaches to control or limit access to the protease inhibitors. These steps are generally taken with the consultation and recommendations of ADAP advisory committees comprised of clinicians and consumers, and are based in measure on medical practice guidance as well as fiscal concerns. Among the states which report that they are limiting or expect to limit access to protease inhibitors (22 states as of 9/6/96) are:

State Action

Alaska (will limit once coverage is provided)
California (limitations on combination therapy)
Delaware (waiting list to be implemented)

Idaho (will only approve PIs for clients if funding is available)

Indiana (waiting list implemented)

Kansas (implemented a per client cap on expenditures)
Kentucky (pilot program will cover up to 30 clients for PIs)

Louisiana (program will provide coverage for up to 200 clients for PIs)

Missouri (client caps on expenditures for services)

Montana (closed enrollment)

Nevada (expects to institute waiting list)
New Hampshire (restricted formulary for PIs)

# Ryan White CARE Act-Funded State AIDS Drug Assistance Programs (ADAPs) Covering At Least One FDA-Approved Protease Inhibitor (32 States as of 9/6/96)

- 2. California
- 3. Colorado
- 4. Connecticut
- 5. Delaware
- 6. District of Columbiai
- 7. Hawaii
- 8. Iowa
- 9. Illinois
- 10. Kansas
- 11. Maryland
- 12. Massachusetts
- 13. Michigan
- 14. Minnesota
- 15. Mississippi
- 16. Montana<sup>ii</sup>

#### 17. Nebraska

- 18. New Hampshireiii
- 19. New Mexico
- 20. New York
- 21. North Carolina
- 22. North Dakota
- 23. Pennsylvania
- 24. South Carolina
- 25. Tennesseeiv
- 26. Texas<sup>v</sup>
- 27. Utah
- 28. Vermont
- 29. Washington
- 30. West Virginia
- 31. Wisconsin
- 32. Wyoming<sup>vi</sup>

## State ADAPs Covering All Three FDA-Approved Protease Inhibitors (26 States as of 9/6/96)

- 1. Arizona
- 2. California
- 3. Colorado
- 4. Connecticut
- 5. Delawarevii
- 6. District of Columbia
- 7. Hawaii
- 8. Iowa
- 9. Kansasviii
- 10. Massachusetts
- 11. Michigan
- 12. Minnesota
- 13. Montana

- 14. Nebraska
- 15. New Mexico
- 16. New York
- 17. North Carolina
- 18. North Dakota
- 19. Pennsylvania
- 20. Texas
- 21. Utah
- 22. Vermont
- 23. Washington
- 24. West Virginia
- 25. Wisconsin
- 26. Wyoming

## State ADAPs Expected to Begin Coverage of Protease Inhibitors (PIs) by 10/1/96 (5 States as of 9/6/96)

1. Alabama

4. New Jersey<sup>xi</sup>

2. Kentuckyix

5. Virginia

3. Missouri<sup>x</sup>

## State ADAPs With Decisions Pending on Coverage of PIs (14 States as of 9/6/96)

1. Arkansas

2. Florida

3. Georgia

4. Indiana

5. Idaho

6. Louisianaxii

7. Maine

8. Nevadaxiii

9. Ohio

10. Oklahoma<sup>xiv</sup>

11. Oregon

12. Puerto Rico

13. Rhode Islandxv

14. South Dakota

Note that the state of Alaska is currently in the process of developing a state AIDS drug assistance program. In addition, Guam does not have funding to support an ADAP.

<sup>&</sup>lt;sup>1</sup> In D.C. as of 8/15/96, access to PIs is limited to those ADAP clients who have already received a prescription for a PI through ADAP.

ii Montana has currently frozen enrollment in the program and will not be approving new clients.

<sup>&</sup>lt;sup>iii</sup> New Hampshire currently has resources to cover 12 clients on PIs; all others will be placed on a waiting list. September 1, 1996 formulary revision allows restricted coverage of Crixivan; other PIs will be available to clients only with program approval.

<sup>&</sup>quot; Tennessee has added Crixivan to its ADAP formulary (9/1/96); other PIs will be covered on a prior approval basis.

<sup>`</sup>Texas began accepting applications for PIs beginning 9/1/96. Access to one PI and a maximum of 2 reverse transcriptase inhibitors for 400 ADAP program clients will be available through participating pharmacies after 10/1/96.

<sup>&</sup>quot;Wyoming has a waiting list for access to its CARE program, and access to PIs is limited.

<sup>&</sup>quot;Delaware will be covering all three PIs beginning 10/1/96. At that time a waiting list for new ADAP clients will be instituted.

<sup>&</sup>quot;Kansas expects to cover all three PIs (the state has been covering two) before the end of 9/96.

<sup>&</sup>quot;Kentucky is subcontracting with a community-based organization to provide coverage of all three PIs for up to 30 eligible applicants with coverage expected to begin 9/15/96. Clients may access only one PI.

<sup>\*</sup> Missouri will add PIs to its statewide formulary as of 10/1/96. Funding will be allocated by slots with annual client expenditure caps set. Once caps are reached, a waiting list will be instituted.

<sup>&</sup>quot; New Jersey will be covering 2 PIs (Crixivan and Saquinavir) effective 10/1/96.

<sup>\*&</sup>quot; In Louisiana, a pilot program to cover 200 individuals for PIs is under discussion.

Nevada's physician's advisory subcommittee recommended delaying coverage of PIs until such time as resources are available to sustain coverage and avoid removing existing clients from ADAP enrollment.

No Oklahoma's ADAP physician advisory committee recommended coverage of PIs. The program is in the process of determining the budget needed to allow coverage of clients whose expenditures for services are currently capped.

<sup>&</sup>lt;sup>xv</sup> Rhode Island is instituting a revised ADAP program 10/1/96; the program is assessing coverage of PIs for eligible clients based on financial and medical need.

State Action

New Jersey (medical guidelines, limitations on combination therapy)

Ohio (expects prior authorization for PIs)

Oklahoma (individual cap on expenditures for service)

Rhode Island (restricted formulary, access tied to funding available)

South Carolina (waiting list)

South Dakota (no funding currently available to cover PIs)

Texas (access to PIs limited to 400 applicants, other drugs expected to be

removed from coverage in November 1996)

Utah (may limit new enrollment)

Vermont (waiting list)

Virginia (expects waiting list for certain drugs)

### **Funding Shortages Reported**

Although nearly two-thirds of all state ADAPs are currently providing coverage of protease inhibitors (32 states, 63%) and nearly three-quarters of all ADAPs (37 states, 73%) will be providing coverage by October 1, 1996, the financial burden is evident among those already providing coverage. Fifteen states which currently cover protease inhibitors report that they anticipate budget shortages in providing AIDS drug assistance before the end of the current Ryan White CARE Act Title II fiscal cycle (March 31, 1997). These states are:

State <u>Estimated Budget Shortage</u>

Arizona \$312,000

Colorado Budget estimate not available, program expected to run out of

funds before the end of 1996.

Delaware \$300,000 District of Columbia \$1,200,000

Illinois \$3.12 million (\$2.34 million after manufacturers' rebates)

\$5.34 million (\$4.3 million after rebates) projected before end of

state fiscal year in June 1997

Massachusetts \$4 million

\$6-\$9 million before the end of state fiscal year in June 1997

Michigan \$240,000 by January 1997

Montana\$90,000Nebraska\$10,000Nevada\$285,000Texas\$1,183,383

Vermont Estimated between \$20,000 - \$100,000

Virginia \$2 million Washington \$4,551,270 Wyoming \$30,000

## Total estimated shortage for states (15 states with PIs under current formulary) before March 31, 1997: \$16,641,653

Among states which have not yet added protease inhibitors to their ADAP formularies, four states currently report that they would experience shortages before the end of March 1997 if they expanded their formularies to include protease inhibitors. These states are:

State Estimated Budget Shortage

Florida \$18-20 million

Idaho \$300,000 - \$400,000

Louisiana Estimated \$1 million shortage with addition of protease inhibitors

before end of state fiscal year

Oklahoma \$729,000

Total estimated shortage before March 31, 1997 among states currently not covering protease inhibitors if PIs are covered: Between \$20,029,000 -- \$22,129,000

All told, the survey indicates that as of September 6, 1996, 19 states (41% of states reporting) indicate that their ADAPs will run short of funding to meet anticipated client demand and increased costs by the end of the current Ryan White Title II fiscal cycle (March 31, 1997). The total reported shortage estimated by the 19 states equals \$36,670,653.

## Actions to Respond to Projected Shortages

News of individual state ADAP crises have arrived sooner than similar reports documented nationally last year; and the shortages appear in some cases to be more profound this year. For example:

#### Colorado

The state expects the program to run out of funding by the end of December 1996 due to the increase demand and costs associated with combination anti-retroviral therapy. Discussions are ongoing as to assuring uninterrupted coverage for clients currently accessing the ADAP program.

#### District of Columbia

On August 5, the ADAP office of the DC CARE Consortium reports that it suspended new enrollments in ADAP at the direction of the District's Agency for HIV/AIDS. Case managers were notified of this situation and all new applicants were given a notice

explaining the current fiscal status. At the end of August there were 33 applicants on a waiting list. On August 15, the ADAP office instructed its Care Pharmacy Network to discontinue filling new protease inhibitor prescriptions for ADAP clients unless the clients had already received a prescription for one of these drugs through the program. A notice explaining the cap on access to PIs was sent to all eligible clients. Shortly thereafter, Care Drug pharmacies were also instructed to fill only one protease inhibitor prescription per client per month.

In D.C. during the month of August, 1,727 prescriptions were filled at a total cost of nearly \$300,000. This represented a 14% increase in expenditures over the previous month. Anti-retroviral drugs represented 73% of the total costs; protease inhibitors constituted 25%.

#### Florida

The state has not added any of the new protease inhibitors to its ADAP formulary because current funding will not enable the state to sustain coverage into the next fiscal year. ADAP expenditures increased 46 percent in the 1995-96 program year without adding any of the new drugs. The state estimates that it will need \$18 million in additional funding to provide coverage for protease inhibitors and sustain coverage of the present formulary of 10 drugs.

The state has convened an ADAP advisory working group to examine the challenges facing the program. If protease inhibitors are added, access to drugs would be limited to available resources. The state is making a formal request to its legislature for \$5 million in funding for protease inhibitors. If approved, these funds would not be available until July 1, 1997.

#### Illinois

Due to the increased demand and costs associated with new anti-retroviral therapies covered in late 1995 (Epivir and saquinavir), the state's formulary was reduced from 110 drugs to 28 drugs and eligibility was reduced to 200% of poverty from 400% of poverty. In addition, the program has implemented a co-payment of \$10 per prescription with an annual cap of \$380 for clients with incomes exceeding 100% of the federal poverty level. The program is considering the following additional steps: capping annual expenditures per client and halting enrollment and stopping new prescriptions for saquinavir.

#### Massachusetts

Currently, the MA HDAP formulary covers all FDA-approved protease inhibitors. In June 1996, a waiting list was started to ensure that there was sufficient funding in last year's state budget as the fiscal year closed. These individuals are slowly being processed as HDAP clients while additional funding sources and program controls are being examined. Current projections are that the program will need between \$6 - \$9 million in

additional funding before the end of June 1997 in order to sustain coverage of its existing formulary; this represents an estimated shortfall of between \$5.6 - \$8.6 million.

#### Montana

The state will not be approving new triple therapy clients. Currently the program has 14 clients on triple therapy and may approve a new client when and if one of the 14 moves to Medicaid. Montana has a Ryan White Title IIIB program (early intervention clinic) which works in close cooperation with the state's Title II program. The IIIB grantee has applied for supplemental funds-which will be used to pick-up ADRP clients when Title II money runs out. The state forecasts that Title II will be out of funding by October 1, 1996 and that Title IIIB funding will only get them through December 1996.

#### Nebraska

Nebraska currently covers all three FDA-approved protease inhibitors. Should program expenditures warrant drug coverage revisions, protease inhibitors would be on the list of priority drugs. A shortage of \$10,000 is projected by end of March 1996. The state has already begun dealing with the projected shortage. All participating providers have received a letter detailing upcoming projected shortfalls and have been asked to strictly abide by the established formulary.

#### New Hampshire

A September 1, 1996 formulary revision will cover Crixivan as the ADAP program's protease inhibitor of choice. Saquinavir and ritonavir will be available only with program approval. Clients currently on saquinavir will continue to be covered. Currently, the program has resources to cover approximately 12 clients on protease inhibitor combination therapy. All of the clients will be placed on a waiting list. Clients with low CD4 counts (less than 100) and high viral loads will be given priority.

#### **Texas**

The FY 1997 estimated budget for the program is \$8.8 million. The estimated cost to maintain all anti-retroviral therapy (except protease inhibitors) and medications aimed at opportunistic infections for 5000 clients on the program in \$7.8 million. With the current projection of resources, that leaves about \$1 million for purchase of protease inhibitors. Based on current funding, Texas' program is able to provide 1 protease inhibitor and a maximum of 2 reverse transcriptase inhibitors to be used in combination therapy for 400 clients. Clients who are currently active on the program must have their physicians apply during September. If more than 400 requests are made, the 400 recipients will be determined by a lottery.

The program's available drugs were categorized into three priority areas. Effective September 1, no additional clients will be added to the drugs classified at Priority 3,

which includes Mepron a PCP medication, amphotericin-B an anti-fungal, Myambutol and Mycobutin for mycobacterial infections and Roferon-A a neoplasm. The program will then discontinue the provision of these drugs to all clients on November 15, 1996. These medications will be provided again if additional funding become available and all Priority 1 medications are fully funded. It is estimated that \$4 million in additional funding is needed to provide all of the current formulary drugs next year.

#### Vermont

In order to respond to the anticipated shortage, the state's ADAP expects to consider:

- 1. Establishing a waiting list for protease inhibitors;
- 2. Cutting back its drug formulary;
- 3. Restructuring program administration; and
- 4. Reviewing eligibility criteria and strengthening clients' recertification process.

#### Virginia

The program is currently setting up a waiting list process for Crixivan and Epivir. Clients who receive either drug will be assigned a unique number and the cost to provide the medication to the client for a year will be determined and reserved. When the maximum number of clients have been reached the state will initiate the waiting list system.

#### Washington

The state Department of Health closed enrollment in its ADAP program on July 17, 1996 after enrollment increased from 475 in January to 835 in July. Program costs grew from an average of \$53,000 per month in 1995 to \$143,083 in July. While the department anticipated that program costs would increase, the magnitude of the increase in enrollment and claims costs far exceeded projections. The Governor reopened the program in early August. The program currently has a \$3.4 million projected shortfall that will grow to \$5 million in the next year.

## **Sustaining Coverage of Protease Inhibitors**

To ensure uninterrupted coverage of newly approved drugs – a critical issue for clients on protease inhibitors as well as other HIV/AIDS treatments – state AIDS programs report that they are facing difficult obstacles in the months ahead. In order to sustain coverage of existing treatments, or to initiate coverage of new therapies, states are taking a variety of actions which do not adversely affect client services but which may generate significant revenue or cost savings. Most notably, these include:

 advocating for additional resources, both in terms of increased federal funding and state support;

- seeking the lowest possible costs for medications or rebates from drug manufacturers;
- expanding insurance coverage, where possible, for eligible clients, through the use of insurance continuation programs.

However, if programs fail to acquire additional funding, or the prospects are dim for advocating for state or federal resources, other, more adverse options have been and are expected to be considered by state ADAPs in order to sustain coverage of priority medications and services. These include:

- removing existing drugs from formularies to offset the high demand and high costs of anti-retroviral therapies;
- freezing or capping client enrollment on the program;
- limiting access to certain drugs;
- restricting eligibility for the program in terms of income level or medical criteria;
- instituting caps on per client or per drug expenditures; and
- reimbursing for only one protease inhibitor, or limiting the number of prescribed drug combinations.

Among the specific remedies already taken or planned in states are:

#### Arizona

All five of the state's Ryan White CARE consortia will meet later in the year and will have to decide the course to take the following year beginning April 1, 1997 in order to continue to provide protease inhibitors. Some of the options are:

- 1. restrict income eligibility;
- 2. restrict medical eligibility;
- 3. institute a dollar cap per client;
- 4. institute a dollar cap per medication; or
- 5. eliminate other medications from the formulary

MAC prophylaxis and acyclovir were eliminated from the minimum pharmaceutical requirement for this year in Arizona in order to add Epivir and the protease inhibitors and to allow for the increased cost of combination therapy.

Health care providers will be notified when it is anticipated that ADAP funds will be exhausted and alerted that they should begin enrolling their clients on manufacturers' compassionate use programs before their medications run out.

#### Illinois

A supplemental allocation will be sought in the fall session of the Illinois General Assembly, both to sustain coverage of the one protease inhibitor currently covered (saquinavir) and to add the other two protease inhibitors to the formulary. Without additional funds, coverage will need to be further restricted.

#### Kentucky

The state is subcontracting with a community-based organization to provide coverage of all three protease inhibitors for up to 30 eligible applicants. Clients may only access one protease inhibitor at any one time.

The program has established eligibility criteria for the protease inhibitors which includes: state residency, income of less than 200% FPL, CD4 count less than or equal to 200, failed combination therapy, viral load of greater than 10,000 copies/ml, and ineligibility for any other third party payor source.

#### Massachusetts

The program is considering the following steps:

- 1. Establishing new, tighter eligibility restrictions;
- 2. Requesting additional state funding;
- 3. Investigating expansion of insurance opportunities;
- 4. Working with pharmaceutical companies to reduce drug costs; and
- 5. Organizing community strategy meetings.

#### Minnesota

Minnesota is attempting to enroll as many people as possible in private insurance plans by using Title I funds (in partnership with the new Title I planning council) to purchase insurance for all uninsured people currently on the Drug Program. The program has also added recommended prescribing guidelines to its formulary and has asked doctors to help control costs through prudent prescribing practices. Increased database capacity is expected to be able to track utilization more closely.

### **Efforts to Control and Monitor Costs**

In light of the increased demands and heightened scrutiny placed upon the administration of ADAP programs, many states are in the process of re-evaluating how they provide access to HIV/AIDS therapies. In addition to the areas outlined above for sustaining coverage of medications for clients, many states are looking closely at ways to ensure that their resources are stretched as far as possible. Among the ideas are:

- establishing direct purchasing of drugs to take advantage of Public Health Service (PHS) discount pricing;
- aggressively negotiating rebates from drug manufacturers and reduced costs from contract pharmacies and wholesalers;
- establishing point-of-sale pharmacy tracking systems;
- monitoring client eligibility through improved screening and client recertification processes;
- improving coordination of benefits with state Medicaid agencies; and
- improving or establishing linkages with Ryan White Title I areas.

Among the specific ways states are re-evaluating their programs to ensure strong fiscal monitoring and control include these examples:

#### Alabama

Alabama is developing a redesigned drug assistance program by establishing a pharmacy specifically for the purchase of drugs for eligible HIV/AIDS patients. This will allow purchase at discounted Public Health Service prices. The program expects that savings in drug costs and administrative costs will allow coverage of protease inhibitors. Alabama will add all three protease inhibitors currently available to its formulary, but will reimburse for only one per participant.

#### California

The state's Office of AIDS has taken the following steps to control and monitor costs:

- 1. A position has been added to the State Department of Health Services Budget and Investigation's office to focus on local ADAP providers. The emphasis of their efforts will be on the adequacy of local eligibility screening.
- 2. Limitations on combination therapy has been instituted to allow no more than two nucleoside analogs and one protease inhibitor prescribed at any one time to clients.
- 3. An analyst position has been added to the Office of AIDS to increase the program's ability to provide oversight and technical assistance on eligibility and screening requirements.
- 4. Dissemination of information to all providers regarding successful local efforts to control costs (e.g., requiring applicants to demonstrate ineligibility for Medi-Cal).

#### Florida

To control and monitor expenditures and demand, the state is:

1. Creating a new database for the ADAP program to more efficiently administer the program.

- 2. Closely examining expenditures by month.
- 3. Utilizing PHS pricing to get most drugs with available funding.
- 4. Examining the possibility of accessing drugs for prices better than PHS.
- 5. Closely monitoring and enforcing ADAP eligibility requirements.
- 6. Closely reviewing applicants for possible Medicaid eligibility and referring as appropriate.

#### Hawaii

The STD/AIDS Prevention Branch is a covered entity under the Veteran's Health Care Act of 1992. As a result, HDAP has been able to procure all drugs on the formulary, with the exception of Crixivan, at the PHS price. The state has also negotiated a price below AWP for Crixivan. Should there be changes which affect PHS pricing, the program would be severely impacted.

In addition to the above, HDAP has controlled costs by limiting the kinds of drugs available through the program for the treatment of HIV infection, prophylaxis and treatment of OIs, treatment of hematologic abnormalities, and very limited medications for wasting. Also, patients are restricted to a single protease inhibitor and two anti-retrovirals or no more than triple combination therapy against HIV. Monitoring has increased with the advent of protease inhibitors, with tighter controls to insure that all drug utilization is followed carefully. In the past, pharmacies had been required to report quarterly; they are now required to report monthly.

#### Illinois

The state is:

- 1. Developing a system to monitor use of combination therapy for compliance with FDA approvals.
- 2. Developing guidelines regarding costs of various alternative treatments (i.e., antifungals) to encourage use of least costly alternative.
- 3. Developing a system to monitor for appropriate use of prophylactic therapies.

#### Michigan

HAPIS (HIV AIDS Prevention and Intervention Section) routinely checks clients' eligibility for Medicare, private insurance and other programs before authorizing eligibility. HAPIS reviews Medicaid client information system to assess Medicaid eligibility prior to paying any claim. The program has hired a consultant to put a system in place to expand the existing computer system which monitors specific drug utilization per unit of time. This system also monitors combination therapy utilization.

#### **New Hampshire**

To control and monitor expenditures, the program has: established a waiting list for protease inhibitors; put medical guidelines in place; monitors Medicaid eligibility monthly; provides funding for insurance coverage for eligible clients; receives drug rebates.

#### **New York**

New York State reduced its ADAP formulary on 1/1/96. The reduction in covered drugs has helped to offset increased costs of combination anti-retroviral therapy.

An electronic point of sale system (POS) provides real time utilization data to monitor utilization and costs and develop projections of future costs. The POS system is also being used for drug utilization review and limiting anti-retroviral therapy to three drug combinations.

#### Ohio

The HIV Drug Advisory Committee has become more active in several areas: they now meet quarterly to discuss formulary and programmatic decisions; a physician handbook has been written to provide all prescribers clinical guidance in providing clients with optimal, yet cost containing drug therapy. The committee has volunteered to provide consultation to doctors who have expensive prescribing patterns. Members have agreed to perform drug utilization reviews, and formulary decisions have been made to provide alternatives to drugs that currently have high expenditures.

Prior authorization procedures have been developed to contain the costs being expended for fluconazole. Monthly expenditure reviews are performed to identify cost trends and to locate errors in billing. A clearer program application has been developed to assist Ohio in referring clients who are eligible for other programs to the appropriate resources, saving ADAP resources.

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