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NATIONAL ALLIANCE OF STATE  
& TERRITORIAL AIDS DIRECTORS

## WAITING LIST MANAGEMENT

ADAP TA Brief No.4

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# AIDS Drug Assistance Programs and Cost Containment Strategies: Waiting List Management

## INTRODUCTION

Part B of the Ryan White HIV/AIDS Treatment Modernization Act (Ryan White Program) established federally-funded, state-administered AIDS Drug Assistance Programs (ADAPs) to provide HIV medications for low-income, uninsured, and underinsured individuals living with HIV/AIDS in the United States. This is the fourth in a series of six ADAP technical assistance briefs focusing on cost containment strategies. Other topics include: *Eligibility Criteria, Formulary Management, Managing Prescription Utilization, Insurance Purchasing and Client Cost-Sharing.*

This TA brief focuses on ethical and effective management of waiting

lists, when demand for ADAP services outstrips available funding. The topics covered include:

- Background information about the need for, and use of, ADAP waiting lists, since 2002;
- Ethical issues that must be considered before initiating a waiting list;
- Two waiting list models that have been used by ADAPs; and,
- Strategies for managing a waiting list.

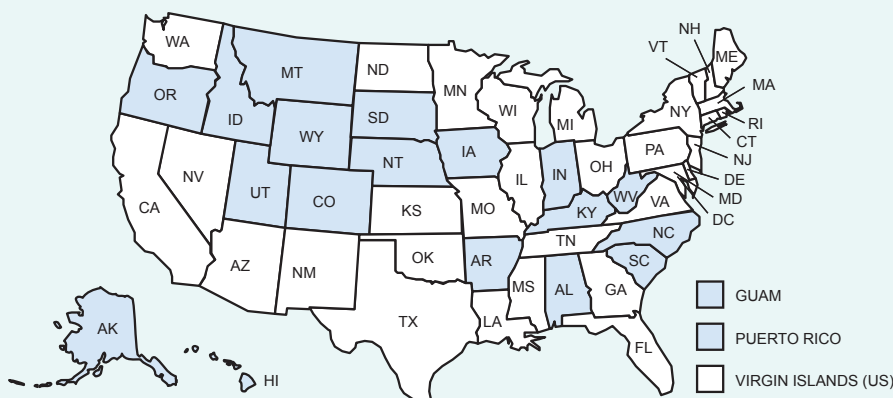
## BACKGROUND INFORMATION

Congress has “earmarked” Part B Ryan White Program funds for ADAP since 1996, starting with an appropriation of \$52 million and increasing to more than \$775 million in

2007, in response to growing demand for HIV/AIDS treatment. In some states, additional funding for ADAP may come from: other Part B ‘base’ grant funds; state-matching funds in jurisdictions with more than one percent of the HIV/AIDS cases nationwide reported for the two most recent years; state appropriations; contributions from other Ryan White programs; and drug manufacturers’ rebates.

Despite appropriations increases, steady growth in the number of eligible clients, combined with rising costs of complex HIV/AIDS treatments, sometimes results in states experiencing greater demand for ADAP services than available resources can cover. In these instances, some ADAPs have implemented waiting lists for program services and medications.

## ADAPs Reporting a Waiting List, since July 2002 (Cumulative)



Note: Shaded states have reported a waiting list at some point, since July 2002 (cumulative)

## What Is a Waiting List?

A waiting list is a mechanism used to limit access to the ADAP when funding is not available to provide medications to all eligible persons requesting enrollment in the state. The ADAP verifies overall eligibility for the program and places eligible individuals on a waiting list, as necessary, prioritized by a pre-determined criterion. The ADAP manages the waiting list to bring clients into the program as funding becomes available.

## PRESIDENTIAL ADAP INITIATIVE

In June 2004, President Bush announced the one-time availability of \$20 million for HIV-related drug therapies - “the Presidential ADAP Initiative” (PAI). The initiative targeted ten states with waiting lists at that time (AK, AL, CO, ID, IA, KY, MT, NC, SD, and WV). Enrollment in the initiative continued from October 2004 through September 2006, allowing 1,802 clients to receive medications through the initiative. Although the PAI initially expired in March 2006, HRSA received a no-cost extension to ensure all clients could transition successfully either to their state ADAP or to Patient Assistance Programs (PAPs). The PAI ended in September 2006 with all but one percent of funding expended. During the initiative, additional states (5) not eligible for it instituted waiting lists; and new waiting lists were begun in eight of the ten initiative states for individuals who were ineligible for enrollment in the PAI.

### Frequency of ADAP Waiting Lists

According to NASTAD’s bi-monthly *ADAP Watch* surveys conducted between July 2002 and September 2007:

- Twenty states reported having a waiting list in place at some point during that period.
- The number of people on waiting lists ranged from a low of 302 to a high of 1,738.

### ADAP WAITING LIST MODELS

If, after implementing all other *feasible* cost containment mechanisms (i.e. lowering FPL, reducing formulary, capping cost, etc.), demand for ADAP services continues to outpace available resources, a waiting list may become necessary. From an administrative perspective, creating and managing a waiting list is a challenging process.

Among the issues ADAPs face are:

- how to monitor the waiting list;
- how clients can access medications while on the waiting list;
- how new clients will be enrolled from the waiting list;
- what ethical principles will be used to develop policies and procedures for a waiting list; and,
- what other options are available to reduce or eliminate the need for waiting lists.

In order to address each of these issues in an efficient, equitable, and effective manner, the state should work closely with its ADAP Advisory Committee.

Before creating a waiting list, ADAPs should review models used by other states and their ‘lessons learned.’ Equally important, the ADAP must publish their policy to the community of clients, providers and case managers, and then ensure that these policies are administered consistently across the state.

### Ethical Considerations

General ethical considerations for public health, as well as HIV/AIDS treatment-specific guidelines, are relevant to guide the development of a fair access process to the state’s ADAP. While these considerations can conflict and will not apply to every situation, it is important to maintain a consistent and fair process for access to ADAP. There are important ethical principles to consider when developing a waiting list.<sup>1</sup>

It is also important to keep in mind that elements of the DHHS Guidelines For the Use of Antiretroviral Agents in HIV-I-Infected Adults and Adolescents have ethical as well as clinical implications for ADAPs and clinicians. For example, the Guidelines:

- Recognize that there are subgroups of patients or special populations where specific considerations are critical when selecting and monitoring antiretroviral treatment, in order to assure safe and effective treatment, including: patients with acute HIV infection, HIV-infected adolescents, injection drug users, women of child bearing potential and pregnant women, and those with hepatitis B or C, or tuberculosis co-infections;
- Recommend against complete antiretroviral cessation in late treatment failure as this has resulted in rapid progression to AIDS and death; and,
- In discussing when treatment should be initiated with asymptomatic patients, “...reaffirms the desirability of initiating therapy before the CD4 cell count falls below 200 cells/mm<sup>3</sup>,” while also pointing out that “...there are inconsistent data documenting added value in treating before the count falls below 350 cell/mm<sup>3</sup>, but some clinicians opt to consider treatment in patients with CD4 count >350 cell/mm<sup>3</sup> and HIV RNA >100,000 copies/ml”. A review of the literature on this issue can be seen in the “When to Treat: Indications for Antiretroviral Therapy” section.<sup>2</sup>

### First-come, First-served Model

An ADAP waiting list using a first-come, first-served model is generally structured to place any individual applying to ADAP on the waiting list in order of receipt of a completed enrollment application and eligibility confirmation. The ADAP may choose to require that all applications be completed through a case manager. This requirement ensures that each applicant has the opportunity to work with a case manager to access HIV medications through other mechanisms such as Pharmaceutical Assistance Programs (PAPs) while on the waiting list.

**A**labama does not currently have a waiting list, however, their previous experience has prepared them should circumstances develop that warrant reinstating one. In this event only new clients who have proper documentation submitted at the time of their application for ADAP, and who are found to be eligible for enrollment, will be placed on any future ADAP waiting list. Clients will be moved to active ADAP on a first-come, first-served basis. If after review by the ADAP staff, documentation is missing, the client's application is returned to their provider, unprocessed, requesting required documentation.

Alabama's current biannual (twice a year) recertification policy states that all clients must have biannual recertification completed to remain on the program, whether on active ADAP or on a waiting list (if applicable). All clients must sign a client certification statement agreeing to provide required information twice a year to remain enrolled in ADAP.

### Additional Access Model

An ADAP waiting list model based on patient criteria beyond 'first come, first served' is generally structured by prioritizing particular medical or patient criteria. Within each priority group in the hierarchy, applicants may then be placed on a first-come, first-served basis.

Hierarchical criteria are typically established by the state based on recommendations from its ADAP Advisory Committee, which should include HIV/AIDS medical provider specialists, other service providers, pharmacists, and consumers. Examples of waiting list hierarchical criteria include the following<sup>3</sup>:

- Pregnant women (risk of vertical transmission);
- An individual who is already on an antiretroviral treatment regimen as documented by their physician;
- An individual with tuberculosis co-infection;
- Treatment naïve patients who meet PHS criteria for initiation of treatment;
- An individual with an ADAP designated viral load and/or CD4 count; and
- Other eligible applicants not meeting the above criteria.

### ADAP WAITING LIST MANAGEMENT

Managing an ADAP waiting list is also of crucial importance and has ethical dimensions as well. Patients on waiting lists should be provided with clear and understandable information about:

- Why his/her access to drugs through

ADAP is being denied, and the options and alternatives that are available;

- The objective and standardized waiting list criteria that has been established with the guidance of health experts; and
- The approximate length of time one can expect to remain on the waiting list before access to drugs becomes available.

The ADAP may find it useful to require ADAP applicants on the waiting list to work with their case manager to access HIV/AIDS prescriptions through PAPs or other medication assistance or insurance program options. Keep in mind that PAPs may require people to apply often, sometimes as frequently as every month, and separate applications must be sent to the manufacturer of

**N**orth Carolina does not have a waiting list at this time. During the time periods in which a waiting list was in effect, the state ADAP continually provided information to clinicians, case managers, clinic/ASO staff and others about pharmaceutical manufacturers' Patient Assistance Programs (PAPs). Most of those in North Carolina that were responsible for assisting people living with HIV/AIDS with their medications were already familiar with PAPs, since, during that time period, the financial eligibility criterion for the state's ADAP was the lowest in the nation ( $\leq 125$  percent FPL). This meant that those working with people living with HIV/AIDS in North Carolina were already accessing PAPs on behalf of large numbers of HIV positive individuals with incomes that did not meet the North Carolina ADAP eligibility requirements. An analysis done at one point during a "waiting list period" revealed that the vast majority of individuals on the ADAP waiting list were, in fact, receiving essential HIV and related medications through PAPs, clinical trials, or Medicaid coverage.

Should a waiting list become necessary again, the North Carolina ADAP will use hierarchical criteria, as recommended by its HIV Clinical/Medications Advisory Committee. In November 2007, North Carolina increased its financial eligibility requirement to 250 percent FPL. With the permission to increase the program's financial eligibility criterion, the General Assembly imposed a requirement that if a waiting list were to be reinstated, the program was to give priority to those that would have qualified under the old criterion ( $\leq 125$  percent FPL). Therefore, should the need occur to reinstitute a waiting list, the North Carolina ADAP would be obligated to manage the process with a blend of both sets of requirements; by first selecting those who are at or below 125 percent FPL, and then applying the hierarchical criteria to that group of individuals.

each prescribed medication needed. For someone on a multiple drug regimen, this process can be quite time-consuming and cumbersome. For individuals with special needs the process can be completely overwhelming.

In order to effectively monitor the status of ADAP applicants on the waiting list, case managers may be responsible for providing a monthly update to the ADAP on the status of their clients' access to medications and any changes in the applicants' eligibility status. All monthly updates should be documented on a waiting list log.

When an ADAP slot becomes available, the eligibility status of the person next-in-line on the waiting list should be confirmed prior to moving that person from the waiting list to active enrollment in ADAP. Once confirmed, the ADAP should notify the applicant, the case manager, and the appropriate ADAP pharmacy or pharmacy benefits manager.

The ADAP should employ an objective, fair process that will provide legitimacy to the decisions made. A fair process should include:

- Being public and transparent about why, what, and how;
- Having an appropriate and ethical rationale for the ADAP waiting list model and process;
- Appropriate stakeholders' involvement in developing and implementing the process; and,
- A revisions and appeals mechanism.

## WAITING LIST MANAGEMENT CHECKLIST:

When considering making any changes, ADAPs should:

- Determine if they are economically feasible and administratively manageable for the ADAP in light of current staff capacity and internal administrative processes.
- Train case managers on how to maintain a client on the waiting list and how to enroll clients on PAPs and other medication access programs.
- Educate clients and case managers about the waiting list, including how long a client can anticipate being on a waiting list and other options for receiving medications.
- Anticipate problems with client participation on the waiting list that may occur with implementation and develop procedures to respond rapidly to address unintended consequences.
- Be familiar with state legislation and administrative regulations that may impact the ability to make changes in ADAP or establish a waiting list.
- Follow the internal state agency process for review and approval of changes to the ADAP.
- Communicate to the community about why and when the ADAP will introduce a waiting list.
- Consult other ADAPs that have investigated and/or adopted a waiting list to find out how they approached it, the results and lessons learned.
- Communicate with your HRSA

Project Officer and NASTAD when the state is considering implementing a waiting list, when and if significant challenges arise, and when any changes are actually implemented.

## RESOURCES

- National Alliance of State and Territorial AIDS Directors (NASTAD) – [www.NASTAD.org](http://www.NASTAD.org)
- HRSA HIV/AIDS Bureau – [www.hrsa.gov](http://www.hrsa.gov)
- HRSA 340B Prime Vendor Program – [www.340bpvp.com/public/](http://www.340bpvp.com/public/)
- HRSA Target Center – Technical Assistance for the Ryan White Community - <http://careacttarget.org/>
- Kaiser Family Foundation – [www.kff.org/hiv/aids/us.cfm](http://www.kff.org/hiv/aids/us.cfm)
- Office of Pharmacy Affairs – [www.hrsa.gov/opa](http://www.hrsa.gov/opa)
- Pharmacy Services Support Center – <http://pssc.aphanet.org>
- ADAP listserv sponsored by NASTAD – [NASTADTA@NASTAD.org](mailto:NASTADTA@NASTAD.org)
- Kaiser Family Foundation and National Alliance of State and Territorial AIDS Directors, *National ADAP Monitoring Project Annual Report*. April 2007.
- Ryan White HIV/AIDS Treatment Modernization Act, Pub. L. No 109-415, (2006).
- Current treatment guidelines – <http://aidsinfo.nih.gov>
- Comprehensive information on ARVs and OI medications – [www.aidsmeds.com](http://www.aidsmeds.com)

## Endnotes

1. Ruth Klain. Ethics and Equity in Access to HIV Treatment – 3 by 5 Initiative. Consultation Document Prepared for the WHO and UNAIDS, Geneva, Jan 26-27 2004. Paper can be downloaded at: <http://www.who.int/ethics/en/background-macklin.pdf>
2. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC), “Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.” October 2006. Available at: <http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf>
3. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC), “Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents.” October 2006. Available at: <http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf>

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