



Proposal to Strengthen the Ryan White CARE Act Title II AIDS Drug Assistance Program

The AIDS Drug Assistance Program (ADAP), a component of Title II of the Ryan White CARE Act, provides FDA-approved medications to people living with HIV/AIDS who have limited or no prescription drug coverage. ADAP funds may also be used to purchase health insurance for eligible clients or to pay for services that enhance access, adherence, and monitoring of drug treatments. It serves approximately 30 percent of those living with HIV/AIDS who are receiving care in the United States.

During the past five years, ADAP has not received the funding necessary to match the rise in drug prices, enrollment, and utilization. This funding gap has led to significant barriers for many states in providing access to treatment for those in need. Several state ADAPs have been forced to implement one or more cost-containment strategies, including reducing the formulary, narrowing medical eligibility requirements, increasing cost-sharing, limiting per capita expenditures, and/or establishing waiting lists.

Anti-HIV drugs taken correctly and in combination save lives, increase quality of life and allow many people living with HIV/AIDS to remain productive members of their communities. Delaying onset to AIDS reduces morbidity, mortality, and costs to the public. ADAPs should be able to provide a basic level of service to all people living with HIV/AIDS who have no other source of access to medications. To that end, the CAEAR Coalition supports full funding for ADAP and advocates for the lowest possible prices for drugs distributed by state ADAPs.

The CAEAR Coalition also believes that reauthorization of the Ryan White CARE Act provides an opportunity to make some structural changes that would provide meaningful assistance to states that are struggling to provide treatment to those in need, without causing significant harm to other states.

Update ADAP Formula Allocations

Currently, the ADAP formula is based on estimated living AIDS cases. In the time since the development of the formula in 1990, the Centers for Disease Control and Prevention (CDC) has established data sets that allow for more accurate counting of living AIDS cases. Therefore, the ADAP allocation formula should be updated and changed to use actual living AIDS cases, adjusted by CDC for reporting delays.

CAEAR Coalition further recommends that the Secretary of Health and Human Services implement the recommendations in the 2003 IOM report *Measuring What Matters: Allocation, Planning and Quality Assessment for the Ryan White CARE Act* to direct the CDC to establish a process to be completed no later than December 2006, by which state and other eligible area HIV data from name- and non-name-based reporting systems is accurately merged to produce a national HIV/AIDS data set inclusive of all reported living HIV cases. This data set would be used for formula distribution for the first Fiscal Year subsequent to a determination by the Secretary that the HIV/AIDS data set is complete.

Should the Secretary determine the HIV/AIDS data set to be complete by December 2006, then, beginning in Fiscal Year 2007, ADAP formula awards should be determined by the number of persons living with HIV/AIDS adjusted for reporting delays.

Hold Harmless Provisions for ADAP/Title II

CAEAR Coalition supports protection period provisions to minimize shifts of funding from previous years under their formula grants.

CAEAR Coalition supports the protection period provisions recommended by the National Alliance of State and Territorial AIDS Directors:

- Revise the stand-alone Title II base and ADAP earmark hold harmless provision to reflect a 1.5% loss each year (based on FY 2005 funding levels) with a maximum possible loss of 7.5% over a five-year period, or 92.5%.

Ensure that ADAP and other CARE Act Programs Receive the Lowest Possible Drug Prices

Recent negotiations between State AIDS Directors and certain pharmaceutical manufacturers have resulted in price reductions and freezes for a number of medications on ADAP formularies. Reauthorization of the CARE Act provides an opportunity to ensure that ADAPs and all CARE Act programs that provide treatment for people with HIV/AIDS receive the lowest possible price paid by the federal government, thus allowing these programs to maximize their funds.

CAEAR Coalition recommends that the Federal Ceiling Price (FCP) be extended to include all CARE Act funded medication programs, including ADAP. FCP is the maximum price for drugs that may be sold to the Veterans' Administration, the Department of Defense, Public Health Service, and the Coast Guard.

Strengthen and Expand the ADAP Supplemental Treatment Drug Grants

Title II ADAP Supplemental Treatment Drug Grants are available to help assist states that are most challenged in providing AIDS drugs to their citizens. Currently, 3% of ADAP appropriations are set aside for this supplemental fund. States are eligible to apply for these funds if they meet one of four criteria:

- Financial eligibility restriction to 200 percent of Federal Poverty Level (FPL) or below, or
- Medical eligibility restrictions, or
- Limited formulary composition for antiretroviral medications, or
- Limited formulary composition for the treatment of opportunistic infections (fewer than 10 medications).

In addition to meeting one of the four criteria, states must also match the supplemental award with one state dollar for every four federal dollars.

The CAEAR Coalition believes that this fund is an effective mechanism to address the severe need among many state ADAPs. However, while these grants have been able to help some states in need, the ADAP supplemental fund needs to expand and strengthen in order to assist more states and provide more additional monies to those states.

To that end, the CAEAR Coalition recommends that ADAP Supplemental funds no longer be restricted to 3% of the ADAP appropriations. Instead, the supplemental pool should start at 4.5% of the FY 2007 ADAP earmark, and increase by 1% the second year and 0.5% over the remaining years of the reauthorized CARE Act, ending at 7% in the final year. This gradual increase would ensure more supplemental funding available to states in need with minimal harm to those states that do not qualify for such funds.

CAEAR Coalition also agrees with the following proposals specific to ADAP Supplemental Grants offered by the National Alliance of State and Territorial AIDS Directors (NASTAD) in its reauthorization recommendations:

The state match requirement for ADAP Supplemental Treatment Drug Grants should be eliminated. This requirement has been reported as the most common barrier for states to overcome. Many of the states with severe ADAP needs have them because they are unable to contribute adequately to the program. While CAEAR Coalition believes that state contributions are necessary to the success of the Ryan White CARE Act, this particular barrier should be removed, allowing more states with need to access supplemental funding.

Eligibility for ADAP supplemental funds should be expanded to allow for participation among additional states that have established limits to treatment access but don't meet current eligibility standards. States should meet one of the following three criteria during the FY 2006 to FY 2011 five-year authorization period:

1. Gross income eligibility criteria of less than 300% of FPL (currently 200% FPL); or
2. Inadequate formulary, defined as lack of coverage of any FDA-approved antiretroviral drugs or the PHS-recommended drugs for the treatment and prophylaxis of opportunistic infections for ADAP participants with incomes less than 300% of FPL; or
3. Waiting lists of ADAP applicants with incomes less than 300% of FPL (currently not on the list of eligibility requirements).

State eligibility for supplemental funds will continue throughout the CARE Act authorization period after eligibility has been established.

HRSA, in consultation with Title II and ADAP stakeholders, should develop a needs-based distribution methodology for ADAP supplemental funds that may include a competitive process. The distribution process should consider states' ADAP status in each year and the funds necessary to improve the states' status relative to the three criteria listed above.

Unfunded Mandates Won't Alleviate the ADAP Crisis

Because ADAP is a discretionary program, it is impossible to apply entitlement-style standards without a guarantee of sufficient funds to implement them. The CAEAR Coalition believes that

while the goal of reaching parity among state ADAPs is a worthy one, establishing a mandatory core formula, eligibility requirements, or other across-the-board standards without ensuring adequate funding is unreasonable and results in an unfunded entitlement mandate. Furthermore, the CAEAR Coalition believes that states could interpret a core formulary as a ceiling, and not a floor, resulting in reduced efforts among some states to provide supplemental funding for a more comprehensive list of available drugs. Finally, the CAEAR Coalition is concerned that, should a core formulary be mandated, there will be attempts to shift funding from states that have contributed well to their ADAPs and are therefore able to deliver a comprehensive care to states that are unable (or unwilling) to provide the core formulary.

Shifting Funds from Other Titles Is the Wrong Approach

The CAEAR Coalition understands that people with HIV/AIDS need access to comprehensive services to manage their HIV disease and strive for healthy, productive lives. Taking medications does not happen in a vacuum; one needs primary care services to prescribe and monitor drug therapy. In addition, many people with HIV/AIDS need mental health, substance abuse, and vital support services to help create a stable environment in which to be able to adhere to drug regimens and health care visits. Therefore, CAEAR Coalition strongly opposes any proposal to shift monies from other Titles of the Ryan White CARE Act to fund ADAP. Such an action would result in a further decrease in the capacity of CARE Act programs to provide crucial care and support services, thus significantly reducing the ability of ADAPs to adequately serve people with HIV/AIDS.

Eliminating the 80/20 Title II Provision Will Harm Some State ADAPs

Currently, the distribution of CARE Act Title II base (non-ADAP) funds is based on a formula that allocates 80% of the funds based on all estimated living cases in the states and 20% on the estimated living AIDS cases in the state that are outside of the state's CARE Act Title I EMAs. Some have called for the elimination of this "80/20" provision, meaning the allocation of all Title II base funds would be calculated solely on the estimated living AIDS cases in the state that are also located outside of the Title I EMAs.

CAEAR Coalition opposes the elimination of this provision for a number of reasons. From an ADAP perspective, this elimination could result in an unintended consequence of harming many state ADAPs.

Eighteen states would lose more than \$76 million in Title II base funding, even though they have more people living with HIV/AIDS than ever before. Many of these states supplement their ADAP funding with a portion of their Title II base funds, allowing them to provide treatment access to those in need. By losing a significant portion of their Title II base, they will be forced to choose between reducing ADAP services, thus adding to the nation's ADAP crisis, or reducing basic HIV care services offered through Title II. In addition, a severe reduction in Title II funding could result in less funding for states to maintain the structure and staffing to run a strong and efficient ADAP. Weakening some state ADAPs to provide funding for others is not an effective way to address the ADAP crisis.

To see all CAEAR Coalition documents related to Ryan White CARE Act reauthorization, visit www.caear.org.