

#### Testimony for Submission by

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To the Senate Subcommittee on Federal Financial Management, Government Information, and International Security of the Homeland Security and Government Affairs Committee

For the oversight hearing "Ensuring Early Diagnosis and Access to Treatment for HIV/AIDS: Can Federal Resources Be More Effectively Targeted?"

Wednesday, April 26, 2006, 2:30 p.m.

The Louisiana HIV/AIDS Program respectfully submits testimony for the record regarding the importance of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act and the CDC HIV/AIDS prevention program in assisting Louisiana to provide prevention, care, and treatment services to low-income persons living with HIV/AIDS and those at risk for contracting HIV/AIDS. I also serve on the Executive Committee of the National Alliance of State and Territorial AIDS Directors (NASTAD) and former chair of the organization. I am submitting this testimony on behalf of NASTAD as well. State AIDS directors appreciate the longstanding support of the United States Senate for the Ryan White CARE Act and domestic prevention programs that are of the utmost importance to Americans living with HIV/AIDS.

As the past chair of NASTAD, I would like to share with you some of the views of my fellow state AIDS directors, in addition to the state of Louisiana. I have limited my comments to those that address increasing access to prevention services provided by state health departments, including testing, and life-saving drugs provided by the AIDS Drug Assistance Program (ADAP) and.

The Louisiana HIV/AIDS Program administers Louisiana's HIV/AIDS prevention and care programs, which are funded by federal and funds. HIV infections have penetrated both metropolitan and rural communities in our state. Over 50 percent of Louisiana's AIDS cases are outside of our one Title I eligible metropolitan area (EMA), New Orleans. In 2004, the state of Louisiana had the eleventh highest number of AIDS cases reported and the fifth highest AIDS incidence rate in the nation. There are a total of 25,846 cumulative cases and 14,793 individuals living with HIV/AIDS in Louisiana as of March 31, 2006. In 2005, 967 new HIV/AIDS cases were detected in Louisiana. We have had approximately 11,198 Louisianans die as a result of having HIV/AIDS (as of the end of 2005). Of those living with HIV/AIDS, the vast majority are members of minority groups: 66 percent are Black, three percent are Latino and one percent are

444 North Capitol Street NW | Suite 339 | Washington, DC 20001-1512 Tel. (202) 434.8090 | Fax: (202) 434.8092 Asian American, Pacific Islander or Native American. Seventy-four percent of newly detected HIV cases were among African Americans. Women make up 28 percent of living HIV/AIDS cases compared to 77 percent for men.

In federal fiscal year 2006, Louisiana received \$18.9 million in Ryan White CARE Act funding for Titles I and II – including \$6 million for the Title II base, \$15 million for ADAP, and \$950,512 for our one emerging community – Baton Rouge. Louisiana's one Title I EMA, New Orleans, was funded at \$7.4 million. Louisiana received \$4.9 million for our HIV prevention cooperative agreement and \$1.6 million for our surveillance cooperative agreement with CDC. Governor Blanco and the Louisiana legislature have demonstrated a commitment to HIV/AIDS care and treatment by providing \$2.5 million in state funds for prevention and over \$9 million for treatment of people living with HIV, through the state's public hospital system, in spite of Louisiana's budget deficit.

# **Role of Public Health in HIV/AIDS**

State public health agencies serve an essential and unique role in the delivery of HIV/AIDS prevention, care and treatment programs. The agencies are entrusted through U.S. law as the "central authorities of the nation's public health system" and as such, bear the primary public sector responsibility for health. State public health responsibilities include: disease surveillance; epidemiology and prevention; provisions of primary health care services for the uninsured and indigent; and overall planning, coordination, administration, and fiscal management of public health services. As such, unlike other CARE Act grantees, states have on overall responsibility in coordinating HIV/AIDS services provided by the CARE Act and other federal programs in each state.

# **Importance of State Public Health Prevention Programs**

HIV prevention and surveillance programs are funded by the Centers for Disease Control and Prevention (CDC) under general authority provided by federal public health law. Since 1988, CDC has provided HIV prevention resources to 65 state, local, and territorial health departments to implement comprehensive HIV prevention programs in their jurisdictions. In FY2005, states, local, and territorial health departments received \$301 million for these efforts. States conduct the following efforts as part of their comprehensive HIV prevention programs:

- *Counseling, Testing, Partner Counseling, and Referral Services* aimed at ensuring that individuals and their partners learn their HIV serostatus, receive counseling on behavior change to avoid infection or prevent transmission, and obtain referrals for prevention and care services.
- *Health Education/Risk Reduction* provides support for, and technical assistance on, targeted education and outreach activities for individual, group, and community-level interventions and street and community outreach.
- *Community Planning* to ensure the participation of infected and affected communities in the development of effective HIV education and prevention interventions.
- *Capacity Building* to strengthen the delivery of effective prevention programs.
- Prevention Research and Program Evaluation to monitor progress, outcome and impact of the programs they support, as well as to assess needs and develop culturally appropriate services.

The President's FY2007 budget includes \$93 million, of which \$86 million is new funding, to increase testing in medical settings, make voluntary testing a routine part of medical care, and create new testing guidelines, models and best practices. According to the President, this initiative would facilitate the testing of more than three million additional Americans. The President's initiative would prioritize funding for regions with the highest numbers of new cases as well as focusing on incarcerated persons and injection drug users.

State AIDS directors support the President's request for \$86 million in new funding for domestic HIV prevention and believe this funding should be allocated via the prevention and surveillance cooperative agreements with state and local health departments. State and local health departments fund HIV testing in a variety of settings in their communities and are in the best position to maximize the potential of the President's testing initiative. However, testing alone will not prevent new infections. Funds must be increased to make up for three years of cuts which have hampered the ability of health departments to implement CDC's Advancing HIV Prevention Initiative.

# **Importance of Surveillance**

HIV/AIDS epidemiology, surveillance and seroprevalence activities provide data that are critical to targeting the delivery of HIV prevention, care and treatment services. State health agencies are uniquely positioned to conduct these activities because of the expertise, statutory authority, and confidentiality protections of existing public health disease surveillance and reporting systems. States conduct a variety of surveillance activities to track the HIV/AIDS epidemic. In FY2005, states, local, and territorial health departments received \$68 million for these efforts.

The five main types of surveillance are the following:

- *Core surveillance* is the primary source of population-based data on persons living with HIV and AIDS in the U.S.
- Incidence Surveillance provides reliable and scientifically valid estimates of the number of newly-acquired HIV infections though collection and testing of blood specimens from all newly reported HIV infections; calculation of population-based estimates for HIV incidence; and monitoring and tracking HIV strains for resistance to antiretroviral drugs.
- Behavioral Surveillance is a multi-year, CDC sponsored surveillance effort whose goal is to measure an extensive set of HIV risk behaviors and related risk factors among selected highrisk populations in 26 cities with the highest number of people living with HIV/AIDS (as of the end of 2000).
- *Morbidity Monitoring Project* (MMP) is a surveillance system under development that will be nationally representative of HIV-infected persons receiving medical care in the U.S. The system utilizes HIV care providers to collect necessary data.
- *Enhanced Perinatal Surveillance* monitors progress made in reducing perinatal HIV transmission.

Resources for surveillance are sorely needed as the federal government shifts prioritization from AIDS to HIV case reporting and funding for core surveillance has eroded significantly in recent years.

### **Integration of Prevention into Care Setting**

Federal agencies, health departments, and communities understand the growing importance of close linkages between HIV prevention and care services to ensure that individuals learn their HIV status and receive referrals to appropriate services. State AIDS directors support the delivery of HIV prevention services in primary care settings as the standard of care. Studies indicate that HIV-positive individuals take steps to protect their partners from infection, with 70 percent reporting reductions in risky behaviors.

Health departments use partner counseling and referral services (PCRS) as one tool to identify HIV-positive individuals and ensure their linkage to medical, support, and prevention services. Research has found PCRS to be a cost effective strategy for identifying HIV infected persons unaware of their serostatus. The CARE Act also allows Titles I and II to conduct early intervention services (EIS) such as counseling and testing, outreach and referral services, provided those programs are not duplicated with existing CDC programs. Previously, early intervention activities were only allowed among Title III and IV grantees. The 2000 CARE Act amendments also added grants to states for carrying out programs providing PCRS. While the CARE Act called for \$30 million to be appropriated in FY2001 for the new PCRS grants, no money has ever been provided to states through this grant mechanism.

Currently, all states and territories conduct PCRS as a requirement of their prevention cooperative agreement through the CDC. PCRS includes three basic elements: 1) Seeking the names of partners who may be at risk for infection (partner elicitation), 2) Locating partners and notifying them of their risk (partner notification), and 3) Providing HIV testing and risk reduction counseling to partners (partner counseling). PCRS is not limited to the time of initial diagnosis but is offered continuously to provide on-going support for positive persons related to serostatus disclosure and to ensure that both positive persons and their partners have access to prevention services. Partner notification, a key public health strategy to fight communicable disease, lies within the authority of health departments as part of their mission to protect public health.

State AIDS directors support the continuation of funding for PCRS through the CDC cooperative agreements with the states and six directly funded cities.

### **Importance of Testing**

The CDC is finalizing their "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings." State AIDS directors participated in the development of these guidelines, including attendance at two CDC consultations. We are supportive of these guidelines. CDC should work with health departments on the publication of an implementation guide for health departments. Many health departments are playing a central role in implementing and supporting routine screening in key health care settings (particularly emergency rooms, STD clinics, acute care clinics, etc.) within their jurisdictions. Experiences and recommendations from these programs would serve to facilitate expanding the number of health departments implementing and supporting testing in these settings.

Over the past several years, health departments have moved resources from settings with low HIV prevalence and low testing yields to target high prevalence settings where the majority of positive persons are found. These moves have met with resistance from local health departments

and community agencies, often in rural areas. Recent studies supporting the cost effectiveness of screening in very low prevalence settings has created confusion on the role of public health and has caused resistance to health department efforts to refocus funding. These recommendations will potentially create further confusion. Given limited funding, public health resources must be targeted toward settings where they will most likely identify the greatest number of positives. Third party payers must be encouraged to reimburse for testing for routinization of testing to be realized.

While many jurisdictions may have statutes or regulations with specific requirements for consent, provision of pre-test information and delivery of results, this does not mean these statutes and regulations pose a barrier to routine testing. Many jurisdictions have already implemented routine testing in these settings and proven their ability to work within their current statutes and regulations.

State AIDS programs are one of the largest implementers of HIV rapid testing programs. We have long supported the development and approval of rapid testing and worked collaboratively with Congress and the Administration to ensure rapid tests were considered for a CLIA waiver. In several jurisdictions and in certain settings, barriers to rapid testing exist. In addition, there are insufficient resources provided to states to fully implement their use.

## **Perinatal Prevention**

Perinatally acquired AIDS cases have decreased dramatically, due in large part to HIV testing among greater numbers of pregnant women and their subsequent treatment. In 2003, the CDC reported only 152 new cases of perinatally transmitted AIDS. This represents an 84 percent decline from a high of 954 new AIDS cases in 1992. Only three states account for over 50 percent of all new perinatal cases reported to the CDC. Twenty-two states reported no pediatric AIDS cases. Perinatal initiatives developed by state and local health departments have contributed to the significant decline in perinatally acquired AIDS cases from the peak in the early 1990s.

Louisiana had three cases reported in 2003. Louisiana requires written consent for HIV testing, which has not been a deterrent in testing pregnant women who are unaware of their statues. We treat each case of perinatal transmission as a sentinel event and follow-up to determine where the woman fell through the cracks in the health care system. We continue to find that the lack of access to prenatal care and fear of seeking care for non-citizens and substance using women remains the primary barrier to eliminating perinatal acquired infections.

The prevention of mother to child transmission is one of our greatest prevention successes. One way to further reduce cases is to provide hospitals serving the un- and underinsured with HIV rapid tests for use in the labor and delivery setting. This would require resources for the rapid test kits as well as training for hospital staff on counseling and administration of the screening test.

# Importance of the AIDS Drug Assistance Program

The state AIDS Drug Assistance Program is the largest component of the CARE Act. AIDS Drug Assistance Programs (ADAPs) provide HIV/AIDS-related prescription drugs to uninsured

and underinsured individuals living with HIV/AIDS in the 50 states, the District of Columbia, Puerto Rico, Guam, and the Virgin Islands. ADAPs began serving clients in 1987, when Congress first appropriated funds to help states purchase AZT. In 1990, ADAPs were incorporated under Title II of the newly enacted CARE Act. Federal funding for ADAPs is allocated by formula to states and territories. In FY2006, the federal ADAP earmark was \$798 million.

Since the advent of highly active antiretroviral therapy (HAART) in 1996, AIDS deaths have declined and the number of people living with HIV/AIDS has increased markedly. ADAPs have played a crucial role in making HAART more widely available. In a given year, ADAPs reach approximately 136,000 clients, or about 30 percent of people with HIV/AIDS estimated to be receiving care nationally.

ADAP has made an enormous difference in the lives of Louisianans infected with HIV/AIDS. The Louisiana ADAP has 26 drugs on the formulary and a fiscal eligibility of 200 percent of the Federal Poverty Level (FPL). In June 2005, the Louisiana ADAP spent \$955,331 for 4,609 prescriptions on behalf of 1,704 clients.

The services provided by ADAPs differ from state to state. Eligibility criteria and other services provided such as diagnostic resistance testing and hepatitis C treatments all differ between states. For example, in FY2005 formularies ranged from 19 FDA approved antiretrovirals (ARVs) to all FDA- approved HIV-related drugs. There is also a tremendous range in eligibility criteria. Eligibility criteria range from 125 percent of FPL in one state to 500 percent FPL in several states. Serving as a the final safety net prescription drug program, the variation between state ADAPs is further exacerbated by the variation in benefits and eligibility criteria of state Medicaid programs.

ADAPs are not entitlement programs; annual federal, and in most cases, state appropriations, determine how many clients ADAPs can serve and the level of services they can provide. In FY2005, state's were dependent on state contributions state contributions and pharmaceutical discounts and rebates to sustain their ADAP programs, as the increase in federal dollars for ADAPs was extremely limited. In FY2005, state contributions totaled \$253 million, drug rebates totaled \$196 million, Title II base funds contributed to ADAPs totaled \$23 million and Title I funds contributed to ADAPs totaled \$18 million.

States utilize two types of purchasing systems for mediations with 30 states purchasing drugs directly and 24 purchasing through a pharmacy network and then seek rebates. Louisiana is a direct purchase state. In recent years, HRSA and other agencies have suggested that states who are not currently purchasing through a direct purchase system should switch to such a purchasing method. Lower costs are often cited as a reason to do so. A recent study of California's ADAP found that after calculating mandatory *and* negotiated rebates, prices paid for HIV pharmaceuticals are comparable to those paid by states using direct purchase mechanisms. Direct purchase ADAPs often have additional administrative, dispensing and distribution costs that also must be considered in the total cost when comparing these two purchasing mechanisms. Additionally, there are many factors that states must consider to minimize access barriers when choosing a model for drug purchasing, including the size, geography and

demographics of the populations they are trying to serve. The state's existing health care and pharmacy infrastructure are also key considerations in the model chosen.

ADAPs receive the lowest prices in the country for antiretroviral therapies. In 2003, NASTAD established the ADAP Crisis Task Force to negotiate with the pharmaceutical industry on behalf of all ADAPs. Although the large states had the bargaining power, the Task Force felt it was critical that all ADAPs, large and small, had access to the same prices and discounts. The Task Force has agreements with all eight manufacturers of ARVs (Abbott, Boehringer-Ingelheim, BMS, GSK, Gilead, Merck, Pfizer, and Roche). As a result of this highly successful public-private partnership, the Task Force achieved supplemental discounts/rebates beyond those mandated by the 340B program and price freezes that have resulted in over \$300 million in savings over the past three years. The Task Force has also expanded negotiations to makers of therapies to treat opportunistic infections (OIs) and other high cost, highly utilized drugs.

## **Unexpended Expiring ADAP Funds**

While administering ADAP, some states periodically finish fiscal years with small amounts of unspent funds. These amounts, typically ranging from five or ten percent of overall awards, may be requested in the subsequent fiscal year to provide services during that fiscal year. The unspent funds typically result from delays in notice of grant awards from the federal government, timing of the receipt of rebate checks, or other unanticipated fluctuations in spending at the state level. Occasionally, the amount of unexpended funds reaches beyond ten percent of a grantee's overall award for reasons specific to the individual jurisdiction. Louisiana currently has no unexpended ADAP funds.

State AIDS director unanimously agree that expiring unexpended funds must be put back into the CARE Act rather than being returned to the Treasury, as is currently the case. States with excessive and chronic amounts of unobligated funds need immediate technical assistance from HRSA to address issues that hinder a state from spending their award.

Our ADAP proposal outlined below would redistribute unobligated funds from all Titles of the CARE Act back into the ADAP program. Although this would be considered one-time-only funding, it would allow states to provide life saving therapy to individuals in need for a year.

# **Impact of Medicare and Medicaid**

As the payer of last resort, the CARE Act is the safety net under other public programs such as Medicaid and Medicare. ADAPs provide services to persons on Medicaid with insufficient drug coverage, i.e., a limited number of prescriptions per month, and assist clients' cost-sharing to receive full Medicaid benefits. As Medicaid programs are altered from state to state, CARE Act programs must adapt to fill the gaps. The Medicare prescription drug benefit (Part D) added another coverage option for eligible individuals living with HIV/AIDS. ADAPs have been assisting clients enroll in Medicare prescription drug plans and implementing their policies to assist clients with filling any gaps of the Medicare drug benefit. The full financial impact of Medicare Part D on ADAPs will be unknown for sometime. However, it is estimated that ADAPs will save approximately \$53 million due during FY2006 as a result of Medicare Part D. This number is expected to rise to \$67 million in FY2007.

## **Challenges Facing ADAPs**

Ten years after the advent of highly active antiretroviral treatments, the lives of people living with HIV/AIDS have been greatly extended. Therefore, individuals may remain on ADAP for a lifetime. ADAPs across the country continue to encounter significant challenges in maintaining fiscal stability while adequately serving the growing number of uninsured and underinsured individuals living with HIV. These challenges are even more problematic in states with less expansive Medicaid programs and state ADAPs that are administered solely as a result of federal funding.

As of February 16, 2006, a total of 791 individuals were on ADAP waiting lists in nine states. Nine ADAPs have instituted capped enrollment and/or other cost-containment measures since April 1, 2005. Eight ADAPs anticipate the need to implement new or additional cost-containment measures during the current ADAP fiscal year ending March 31, 2007.

Congress and the President have shown strong support for ADAP. On June 23, 2004, President Bush announced immediate availability of \$20 million in one-time funding outside of ADAP to provide medications to individuals on ADAP waiting lists in 10 states (registered as of June 21, 2004). At maximum enrollment, the program served 1,487 individuals. As of February 16, 2006, four individuals were enrolled in the program, which is administered separate from ADAPs by BioScrip, Inc. The program is expected to end in the very near future as funding expires. Funds were not provided to continue the program and states have either enrolled these clients in their ADAP or into pharmaceutical patient assistance programs.

For individuals on waiting lists, states make every effort to ensure that clients are linked to pharmaceutical patient assistance programs. However with inadequate resources to even serve clients, it is difficult to accomplish this task as well. It is extremely challenging to engage in efforts to increase the number of people who are aware of their HIV status if the only thing you have to offer is a waiting list.

Although waiting lists are an indication of an ADAP in fiscal crisis, states use other mechanisms to restrict access to the program including reducing financial eligibility criteria, limiting the drugs that are available through the formulary setting monthly expenditure limits, or setting enrollment or medical criteria limits for access to new medications. Many states often pursue these options rather than instituting a waiting list. Solutions to tackle the ADAP crisis that only address waiting lists are insufficient and unfair to other states in need.

As the approximately 300,000 HIV positive individuals who know their status but are not in care seek treatment or are referred into care, a percentage of these individuals without private insurance or ineligible for Medicaid will seek medications through ADAP. And with the use of HIV rapid testing technology, the ability of states to identify HIV positive individuals will increase. Therefore, reauthorization must address the ability of states to increase access to ADAP, including states in chronic need.

### **Recommendations for Reauthorization**

First and foremost state AIDS directors want the CARE Act to recognize the role of the states in coordinating care and treatment services within the state. Currently, other grantees of the CARE

Act are not required to work with the state and HRSA provides little oversight of their activities to ensure that there is not duplication of services. We are seeking to increase accountability by requiring state and local care delivery coordination. There are proposals before Congress to eliminate the statewide component of the CARE Act and only provide states funds for cases outside of Title I EMAs. This will decrease effective state-wide coordination of services. States are responsible for the care of all citizens with HIV in their state and this responsibility should not be undermined. If the statewide component of the Title II base is eliminated, many statewide mandates would need to be eliminated due to lack of resources and participation of the other grantees in statewide processes. The infrastructure to continue providing vital care and treatment services would also be greatly compromised.

State AIDS directors have two proposals for reauthorization which are reflective of our vision for improved access to HIV care services in the nation: (1) to enhance the availability of ADAP resources and services for persons living with HIV/AIDS in need in all areas of the nation, and (2) to provide additional resources to states with chronically insufficient Title II base funds through a Title II base supplemental grant mechanism.

# Increase ADAP Stability

State AIDS directors believe a central goal of reauthorization legislation should be to increase states' ability to provide antiretroviral therapy treatment to people with HIV/AIDS. For the past five years, ADAP expenditures have grown by \$100 million each year. We support the inclusion of explicit and increasing authorization amounts for ADAP. While this does not ensure that the appropriators will follow suit, we are committed to working with Congress to secure increased funding for ADAP.

For FY2007, state AIDS directors seek an increase of \$197 million for ADAPs to maintain those currently enrolled, to meet the growing demand to enroll new clients, and to strengthen ADAPs to provide PHS recommended drugs. We recommend the establishment of a guaranteed minimum level of new funding to ADAP for use in providing access to HIV/AIDS drugs and care, and to direct a portion of this new funding to states with waiting lists, inadequate formularies and restrictive income eligibility criteria. State AIDS directors recommend that a minimum increase of \$60 million be provided annually to support ADAPs. While \$60 million does not represent the entire need, this guaranteed funding would enable states to provide treatments to low-income individuals, consistent with U.S. Public Health Service guidelines, while enabling them the flexibility to make formulary decisions based on the financial status of their ADAPs. It also recognizes the importance of state general revenue support of ADAPs. If the money is not appropriated, unexpended funds from all titles of the CARE Act should be used and, if necessary, an equal percentage tap on all CARE Act titles, excluding ADAP, should be taken to sustain ADAPs.

# ADAP Supplemental Grants for States in Need

State AIDS directors agree that ADAP Supplemental Grants need to be strengthened and a guaranteed source of funding secured. The ADAP Supplemental should no longer be limited to 3 percent of the ADAP appropriation. Rather, the ADAP Supplemental funding should include the amount appropriated in FY2006, plus 20 percent of the guaranteed \$60 million ADAP increase. We recommend that eligibility for the ADAP Supplemental be revised as the current

legislation limits awards only to those states with specific program restrictions in place as of January 2000. State ADAPs operate within a complex and dynamic financial environment; therefore restricting eligibility only to those states with restrictions in place as of January 2000 conflicts with the need to provide additional support for states that meet the definition of severe need today. Furthermore, such restrictions in eligibility do not allow for downturns in state and federal economies, rise in the cost of antiretroviral treatment, or other events that impact program solvency over time.

Accordingly, we recommend eligibility be based on: 1) Gross income eligibility criteria of less than 300 percent of FPL; or 2) Inadequate formulary – lack of coverage of any FDA-approved antiretroviral drugs or the PHS-recommended drugs for the treatment and prophylaxis of opportunistic infections for individuals with incomes less than 300 percent of FPL; or 3) Waiting lists of ADAP applicants with incomes less than 300 percent of FPL. A state would maintain eligibility throughout the authorization period and could become eligible for the supplemental at any time during the period.

In addition, state AIDS directors recommend repealing the overall Title II hold harmless provision (including base, ADAP earmark, ADAP supplemental grants, Emerging Communities, and Minority AIDS Initiative funding). This provision has resulted in the unintended loss of significant funds to the pool of available money for ADAP Supplemental grants to states in severe need.

# Elimination of ADAP Supplemental Match Requirement

The legislation requires that states secure \$1 in state funds for every \$4 in federal funds prior to submitting an application for the grant. Therefore, states that meet one of the eligibility requirements but lack the funds to meet the match have been unable to access the funds. This match requirement has resulted in a loss of funds to several state ADAPs that are in dire need of additional resources. We support the removal of the match requirement for the ADAP Supplemental only, with other state match and maintenance of effort requirements continuing in a reauthorized CARE Act.

# List of ADAP Core Medications

State AIDS directors recommend that states provide treatments to low-income individuals consistent with PHS guidelines which allow states the flexibility to make formulary decisions based on the financial status of their ADAPs. We oppose any additional formulary requirements without guaranteed federal funding to accompany them.

The significant range of drug access among states raises concern about disparities in access depending on where individuals live. State AIDS directors recognize the need to address such disparities and the importance of establishing a standard of care available to all ADAP clients regardless of residency. However, we are concerned that establishing a core formulary may actually reduce access by creating a formulary ceiling for states with more expansive formularies. For example, if a state with drugs available to treat HIV, OIs, hepatitis co-infection and treatment side effects faces budgetary challenges, the program may be forced to ramp down to offer only the core drugs as a means of cost-savings. Establishing a core formulary may send

a message to state legislators and appropriators that only the drugs defined in the core formulary are needed to provide comprehensive care to people living with HIV/AIDS.

In addition, requiring a core formulary for ADAPs may cause more fiscal strain for ADAPs with limited formularies. For example, in 2005 Louisiana's ADAP offered only the FDA-approved ARVs on its formulary due to budgetary constraints. If a core formulary were defined to include the PHS recommended drugs for prevention and treatment of OIs, it could potentially force this and other ADAPs, in the absence of additional funding, to reduce enrollment in order to allow access to these additional drugs. States with limited formularies would also be forced to put all their Title II base dollars into their ADAP in order to bring their ADAP up to the floor.

We believe, through an annual guaranteed level of funding for ADAP and the enhancement of the ADAP Supplemental Grants, states will provide access to therapies consistent with PHS guidelines including all antiretroviral medications and highly recommended "A1" OI drugs.

## Maximization of Funds for Treatment

State AIDS directors recognize the challenges that HRSA faces in administering the 340B Drug Discount Program as authorized under Section 602 of the Veterans' Health Care Act of 1992. We recommend that the Secretary, through HRSA, provide the Unit Rebate Amount (URA) generated by the Centers for Medicare and Medicaid Services on a quarterly basis with ADAPs utilizing the 340B rebate option in the same manner as it is shared with state Medicaid programs. This will allow ADAPs to determine whether they are receiving the appropriate prices and rebate amounts.

We recommend the CARE Act clarify that states that receive rebates from drug manufacturers resulting from the use of federal funds direct the rebate funds back into their ADAP program.

We also recommend that all CARE Act grantees be required to coordinate purchasing efforts with their respective state's ADAP in order to maximize purchasing power and extend the lowest possible price to all grantees. Coordination should occur unless the grantee is able to demonstrate that it can otherwise obtain lower prices for medications than those available through the state's ADAP.

# Technical Fix for Select Territories to Receive ADAP Funds

The HHS Office of Inspector General recently determined that American Samoa, the Marshall Islands, and the Northern Marianas Islands are ineligible to receive ADAP funds and therefore did not receive ADAP funding in FY2006. Although the amount of money is under \$10,000, these territories should be eligible to receive ADAP funds as they do from the Title II base. A technical correction is necessary to address this matter.

# Increase Capacity of States to Provide Care Services

State AIDS directors believe the current EC provision should be modified to address the disparity of funding between EMA and non-EMA states, and those states with 50% of their AIDS cases outside of the EMA. These areas are experiencing a severe lack of Title II base resources that fund critical primary care and support services. States with chronically insufficient Title II base funds have long wait times for primary care and struggle to meet the

needs of persons in smaller urban and rural areas that lack the density to secure Title I CARE Act resources. State AIDS directors propose new resources be directed to states with epidemics that are not highly concentrated enough to be eligible for Title I funding, through Title II base supplemental grants. Funds would be distributed to non-minimum award states without Title I EMAs and to the two states (Louisiana and Ohio) with Title I EMAs in which 50 percent or greater of their state's cases reside outside of their Title I EMA. The \$70 million for the Title II base in the President's budget should be appropriated and directed to these states via formula. If the additional funding recommended by the President is not appropriated, the \$10 million currently directed to emerging communities should be directed to these states.

State AIDS directors also recommend that minimum awards for states be boosted to \$500,000 to ensure a minimum level of infrastructure and capacity to deliver services is maintained. Minimum awards for territories with a significant numbers of cases should be increased to \$200,000 as well.

#### **Emergency Response**

The CARE Act and policies of other federal agencies, including CDC, should be altered to allow for flexibility as a result of a natural disaster, such as was experienced with Hurricanes Katrina and Rita. Currently, there is no flexibility to allow for emergency reimbursement of services provided when evacuating ADAP clients seek services in other states. In addition, flexibility on the part of HRSA is necessary. In the case of Louisiana, we continue to struggle to put a program back together and provide services to clients. Since Hurricane Katrina, HRSA and CDC have continued to seek continual administrative reports. The needs of the clients must be paramount over the needs of bureaucracy. In cases of an epic natural disaster, federal agencies should be provided the flexibility to waive administrative requirements as well as the financial match, maintenance of effort, and Women's Infant Children and Youth (WICY) requirements on states.

The Louisiana HIV/AIDS Program thanks the Chairman, Ranking Member and members of the Subcommittee for their thoughtful consideration of our recommendations to revise the CARE Act to increase equitable access to critical CARE Act funded services.