Recommendations to Guide the 2005 Reauthorization of the Ryan White CARE Act

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The National Alliance of State and Territorial AIDS Directors (NASTAD) represents the nation's chief state health agency staff who have programmatic responsibility for administering AIDS health care, prevention, education and supportive service programs funded by state and federal governments.

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Executive Summary

The National Alliance of State and Territorial AIDS Directors (NASTAD) strongly supports the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act – a critical component in the nation's HIV/AIDS prevention, education, and treatment efforts. The CARE Act is a federal-state partnership to provide comprehensive care and treatment to low income, uninsured and underinsured people living with HIV/AIDS.

State and territorial HIV/AIDS programs administer the Title II programs of the CARE Act, including the state AIDS Drug Assistance Program (ADAP). Title II provides funds to all states, the District of Columbia, Puerto Rico, the Virgin Islands and U.S. Territories to improve the quality, availability and organization of care services for people living with HIV.

Title II is designed to assure that people living with HIV have access to quality HIV care, regardless of whether they live in rural, suburban or urban areas. $1.1 billion in federal funds were appropriated to Title II in FY2005, including $797 million in dedicated funds for ADAP. In 2004, over 136,000 individuals received ADAP services.

There continue to be low-income persons living with HIV/AIDS that are unable to access Title II services due to funding limitations of the program. NASTAD supports full funding for the CARE Act to ensure that all low-income HIV-positive individuals have access to primary care, life-saving therapy, and support services that are essential to keeping persons in care and adherent to their treatment regimen. NASTAD supports the inclusion of an authorizing level for Title II that addresses these unmet needs, at a minimum of $1.4 billion for FY2006.

NASTAD has extensively examined the effectiveness of the CARE Act over the past two years. Further, NASTAD has developed five structural and financing proposals and 30 issue-specific profiles, which inform this position paper.

NASTAD supports the existing structure of the law. NASTAD has two major financing proposals to provide additional resources to states in need – one through the ADAP Supplemental Grants and one through the Title II Base Emerging Communities Supplemental Grants.

NASTAD has identified six major themes that should frame the 2005 CARE Act Reauthorization. They include: strengthening state program capacity; maintaining program infrastructure; CARE Act simplification and flexibility; enhancing state's ability to coordinate HIV/AIDS health systems; CARE Act mandates; and CARE Act accountability.

The number of people living with HIV/AIDS is growing, therefore, increasing the number of individuals expected to be served by CARE Act programs. The epidemic continues to grow disproportionately among people of color, women and young people. State AIDS directors believe that we need to reexamine our programs and our approaches to ensure that the CARE Act provides funding in an equitable manner to assure that individuals throughout the United States, regardless of state or jurisdiction of residence, have access to comprehensive HIV/AIDS health and medical care of the highest quality.

Recommendations to Guide Reauthorization of the CARE Act

Overview

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act has had a tremendous impact on the lives of people with HIV/AIDS throughout the nation, improving the availability and quality of health care services for these individuals and their families. As the largest federal program for people living with HIV/AIDS, the CARE Act is an essential source of support for HIV/AIDS care and treatment services. As NASTAD's *Principles for Reauthorization* state, assuring that all persons with HIV/AIDS, regardless of geographic location, have equal access to appropriate and high-quality HIV/AIDS services is our highest priority.

Disparities in the availability of resources affect the accessibility and quality of HIV services, both within and between states. NASTAD recognizes that the structure of the Ryan White CARE Act contributes to the challenges faced by some states in effectively addressing the needs of persons living with HIV/AIDS. In many states, the current structure is a contributing factor to funding disparities that affects availability, accessibility and quality of services, both within and between states, as well as the coordination of HIV care and the efficient delivery of essential services. While the Ryan White CARE Act cannot be viewed as the sole mechanism for equalizing these inherent differences, the current structure of the CARE Act leaves many states struggling with the delivery and coordination of HIV services, while trying to meet legislative mandates to provide for the public health of citizens within their respective jurisdictions.

NASTAD recognizes that alternative proposals for serving persons living with HIV/AIDS have been developed, including the Institute of Medicine's report *Securing the Legacy of Ryan White.* This report attempts to respond to these challenges. These proposals are worthy of and warrant further study, consideration and discussion.

At this time, NASTAD recommends retaining the current structure of the CARE Act. It does so while establishing the following two goals which are reflective of NASTAD's vision for improved 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 address inequities in per-capita overall CARE Act funding among states.

NASTAD strongly supports further discussion and study of the structure of the CARE Act, and reserves the right to make recommendations regarding changing the structure of the Act in pursuit of improved HIV care services for all persons living with HIV disease. The Ryan White CARE Act must strive to provide funding in an equitable manner to assure that individuals throughout the United States, regardless of state or jurisdiction of residence, have access to comprehensive HIV health and medical care of the highest quality.

Recommendations to Guide Reauthorization of the CARE Act

Principles for Reauthorization

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act was originally signed into law on August 18, 1990 as a federal program designed to improve the quality and availability of care for persons with HIV/AIDS and their families. The Act was subsequently amended and reauthorized in 1996 and again in 2000. The current Act is scheduled to expire and requires reauthorization at the end of September 2005. The CARE Act reaches over 500,000 individuals each year, making it the federal government's largest program specifically for people living with HIV disease.

Like many health problems, HIV disease disproportionately strikes people in poverty, racial/ethnic populations, and others who are underserved by healthcare and prevention systems. CARE Act funded programs are the "payer of last resort." They fill gaps in care not covered by other resources. The most likely users of CARE Act services include low income, uninsured or underinsured individuals who have no other source of healthcare. In order to fill these gaps in care while maximizing limited available CARE Act resources, states are entrusted with ensuring collaboration among other CARE Act grantees and programs within the state to reduce duplication of services. States are the only CARE Act grantees that have this legal responsibility within the United States public health system to ensure the delivery of effective public health programs in their respective jurisdictions. The role of states, therefore, is unique among CARE Act grantees and must be affirmed in CARE Act legislation to reflect this responsibility.

Scheduled reauthorization of the CARE Act presents NASTAD and its member states and jurisdictions a timely opportunity to re-evaluate the extent to which the goals and objectives of the CARE Act continue to be met. The goal in 2005, as it was in 1990, is to assure all persons living with HIV/AIDS equitable access to state-of-the-art care and treatment by eliminating barriers to care imposed by income, age, race, ethnicity, place of residence, or gender and sexual orientation. The epidemic today can be characterized somewhat differently than the epidemic 20 years ago. Today's infected population is more likely to include persons of color, women, and youth. The U.S. Centers for Disease Control and Prevention (CDC) estimates that over 40,000 new HIV infections occur each year; of these new infections, over half are among persons from communities of color, about 70% are among men and 30% are among women. Between 1985 and 2003, the proportion of adult/adolescents AIDS cases reported in the U.S. among women increased from 8-27%. Furthermore, in February of 2005, 592 persons were on waiting lists for the AIDS Drug Assistance Program (ADAP), a figure which will likely continue to increase as funding levels fall behind demand and need for the program. Those in need should not have to wait for medical care or medications. Access to medications, as well as to other essential health care and supportive services, varies from one state to another throughout the nation.

Ongoing principles for CARE Act programs include:

- Assuring that all persons with HIV/AIDS have access to appropriate and high-quality health, medical care, and other related and required support services.
- Coordinating CARE Act services with other health care delivery systems, thus ensuring that available resources are expended in a manner such that efficiency, effectiveness, and

accountability are optimized, both within the CARE Act and across other delivery systems.
- Revising care systems as needed to meet emerging needs.
- Evaluating the impact of CARE Act funds and making improvements as needed.

These principles must guide current reevaluation in light of the changes noted. Evaluation is particularly pertinent in the face of fiscal constraints in states throughout the nation that relate to medical assistance programs and the ability of the states to provide care and services for populations at risk. For those who have no other source of or access to health care, the role and responsibility of CARE Act programs is paramount.

NASTAD proposes that the CARE Act be evaluated in a manner that seeks to achieve the following goals and objectives through subsequent proposals for change:

- Assure equitable access to state of the art care and treatment for all persons with HIV/AIDS.
- Assure that all individuals, regardless of income, racial or ethnic group, age, gender and sexual orientation, or place of residence have equitable access to care.
- Ensure that the role of the states is emphasized, and is meaningful and enforceable. As the only CARE Act grantees that have legal authority within the United States public health system to ensure the delivery of effective and coordinated public health programs in their respective jurisdictions, the role of states is important and unique to other grantees.
- Ensure coordination of all publicly financed health and medical care programs, including CARE Act programs, Medicare, Medicaid, Veterans Administration programs, State Children's Health Insurance Programs (SCHIP) and state Pharmacy Assistance Programs, as well as other federal, state and local programs.
- Maximize simplicity, minimize administrative requirements, and maintain maximum state flexibility in program design and implementation.
- Ensure little to no disruption in service delivery or major changes to infrastructure that impact service delivery.
- Emphasize the federal government's role and responsibility in assuring equitable access to care while incorporating, where possible, mechanisms to maximize utilization of state resources.

These goals and ongoing principles have guided the direction for all reauthorization analyses and NASTAD's subsequent program recommendations.

Recommendations to Guide Reauthorization of the CARE Act

Summary of Recommendations

Theme 1: Strengthening State Program Capacity

1) Enhance the availability of ADAP resources for persons in need living with HIV/AIDS in all areas of the nation by potentially tapping all titles of the CARE Act and revisions to the ADAP Supplemental Treatment Drug Grants.

2) Address inequities in per-capita CARE Act funding among states by revising the Title II base Emerging Communities Supplemental Grants to provide additional Title II resources to states in need.

3) Reduce Title I eligibility to 1,500 estimated living AIDS cases during the previous five years.

4) Increase the minimum Title II award to $500,000 and provide Guam with a minimum award of $200,000 by eliminating the provision that stipulates a minimum award for states with fewer than 90 estimated living AIDS cases.

5) Use of HIV Cases in Title II Formula Awards:
   a. Include living HIV cases, in addition to living AIDS cases, in the Title II base and ADAP earmark formulas phased-in over a 10-year period.
   b. Include CDC-certified HIV case data from all states in the formula, regardless of the type of reporting system, that meet reasonable data quality and completeness standards.
   c. Require CDC to get input from stakeholders, including states, when developing the methodology to estimate HIV cases for states with immature data systems.
   d. Oppose any legislative mandate requiring states to shift from a code-based to a name-base HIV reporting system.

6) Revise the drug purchasing options available to CARE Act drug assistance entities:
   a. Extend the Federal Ceiling Price to all CARE Act funded medication programs, including ADAPs.
   b. Share the Unit Rebate Amount generated by CMS on a quarterly basis with ADAPs utilizing the 340B rebate option in the same manner as it is shared with state Medicaid programs.
   c. Require all CARE Act grantees with pharmacy assistance programs to coordinate purchasing efforts within states.
   d. Establish a Center for Medicare and Medicaid Services (CMS)/Health Resources and Services Administration (HRSA) Work Group to oversee and implement policies that affect both the Medicaid Rebate and the 340B programs.

7) Increase authorizing levels for all components of the CARE Act, including the Title II base and ADAP earmark.

Theme 2: Maintaining Program Infrastructure

8) Maintain flexibility to allow CARE Act funds to be used in the provision of services, both medical and support, based on locally determined needs within each state.

9) Revise Title II hold harmless provisions:
    a. Revise the stand-alone Title II base and ADAP earmark hold harmless provision to reflect a 1.5% loss each year (based on FY2005 funding levels) with a maximum possible loss of 7.5% over a five-year period, or 92.5%.
    b. Repeal the overall Title II hold harmless provision.

10) Minority AIDS Initiative (MAI):
    a. Authorize the Title II portion of the MAI.
    b. Provide additional resources to states to enhance outreach and education efforts in linking minority populations to services.
    c. Distribute Title II MAI funds to the 30 states with the highest percentage of persons of color to avoid states receiving awards that are too small to be effective.

11) HIV/HCV and HIV/HBV Co-infection:
    a. Maintain flexibility for all CARE Act grantees in the use of CARE Act resources to address HIV/HCV and HIV/HBV co-infection.
    b. Require AIDS Education and Training Centers (AETCs) to collaborate with the CDC's Prevention Training Centers to ensure that HIV care providers are adequately trained in prevention and treatment of viral hepatitis as approximately one-third of individuals with HIV are co-infected with HCV and 6-10% are co-infected with HBV.
    c. Instruct HRSA to develop an agency-wide strategic plan, including the identification of necessary resources, for addressing HIV/HCV and HIV/HBV co-infection and HCV mono-infection.

12) AIDS Education and Training Centers:
    a. Prioritize AETC funding for HIV specific training to primary care providers.
    b. Require AETCs to enter into Memorandums of Agreement with state AIDS programs that specify how both entities will collaborate.
    c. Include a service commitment in an HIV-specific clinic, community health center or minority health center as one requirement of the loan forgiveness/scholarship program for health care providers.

Theme 3: CARE Act Simplification and Flexibility

13) Reduce the administrative burden placed upon states.
    a. Make CARE Act Title I and Title II planning, application and grant cycles concurrent.
    b. Keep "Off-year" reporting requirements of the biennial application process to a minimum.
    c. Reduce or keep to a minimum unfunded mandates for activities such as determining unmet need, quality management, comprehensive planning and Statewide Coordinated Statement of Need (SCSN).
    d. Provide additional funding for time-intensive requirements, such as determination of unmet need.
    e. Eliminate many of the unnecessary reporting requirements placed upon Title II grantees.

14) Continue State Match and Maintenance of Effort Requirements:
    a. Maintain flexibility of allowable costs for state match and maintenance of effort requirements.
    b. Eliminate match requirement for ADAP Supplemental Treatment Grant awards.

15) Eliminate the Women, Infant, Children and Youth (WICY) proportional spending requirement from Titles I and II.

16) Unmet Need:
    a. Eliminate the legislative requirement to quantify unmet need to identify the number of persons who know their status and are not in care.
    b. Short of elimination, maintain flexibility in methodologies for determining unmet need as well as data sources used to estimate need.
    c. Provide funding to states for the resource intensive process of determining unmet need.

17) Revise the quality management requirements of the CARE Act.
    a. Maintain states' flexibility to choose the quality management strategies that work effectively in their jurisdiction.
    b. Account for costs associated with quality management activities separately from administrative costs, as quality management is an integral part of service delivery.
    c. Require HRSA to provide states with technical assistance to develop quality management systems for support services.
    d. Provide funding to states to develop and maintain effective quality management strategies.

18) Prevention and Care Integration:
    a. Provide states with more flexibility for incorporation of Early Intervention Services and Prevention for Positives programs into CARE Act programs.
    b. Recognize HIV prevention as a standard of care for persons living with HIV/AIDS.
    c. Encourage and provide technical assistance to providers to adopt standards based on incorporating HIV prevention into the medical care of persons living with HIV/AIDS.

Theme 4: Enhancing State's Ability to Coordinate HIV/AID Health Systems

19) Revise coordination and planning requirements of the CARE Act.
    a. Eliminate the Statewide Coordinated Statement of Need requirement in the CARE Act.
    b. Require HRSA to consult with each state and other grantees within a jurisdiction prior to approving new grants.
    c. Require documentation of collaborative efforts with the state in grant applications or progress reports for all CARE Act grantees, including AETCs and dental reimbursement programs.
    d. Eliminate the administrative requirement to submit a separate Comprehensive Plan from the Title II grant application.
    e. Provide states with maximum flexibility to determine the appropriate mechanism and timing of coordination efforts among the various CARE Act programs.

20) Revise the payer of last resort requirement in the CARE Act.
    a. Provide explicit allowance for the CARE Act programs to wrap-around Medicaid and Medicare to help support payment of co-pays and other out- of-pocket expenses that provide necessary health care services to persons living with HIV/AIDS.
    b. Enable states the flexibility to serve clients who have coverage for services through other payers that are also covered under the CARE Act if the services covered elsewhere are difficult to access (e.g., location of services is too far to enable the client access to the services).
    c. Require Medicaid and Medicare to provide eligibility data to ADAPs to ensure the payer of last resort requirements are met.
    d. Require Medicaid to reimburse states through a Medicaid Administrative Reimbursement process for staff time devoted to Medicaid coordination activities.
    e. List the programs that are included with respect to the payer of last resort provision, including those of the Veterans' Administration, Medicaid, Medicare, Indian Health Services (IHS), State Children's Health Insurance Programs, and other federal, state and local programs, including other pharmacy benefits programs.

21) Revise the Title III provision of the CARE Act.
    a. Prioritize new planning or Title III grants to underserved states that do not have access to Title I funding, and as a secondary priority, underserved areas of states outside of existing Eligible Metropolitan Areas (EMAs).
    b. Require HRSA to consult with each state and other grantees within a particular jurisdiction prior to determining new Title III projects within a particular area.
    c. Strengthen and enforce the provision of HIV services provided by community health centers that receive federal, but not CARE Act, support.
    d. Require HRSA to allow representatives from states in monitoring visits at Title III agencies and provide copies of subsequent reports to the states upon request.

Theme 5: CARE Act Mandates

22) Oppose a mandated set of core services that are more limited than current law, or percentage set-asides for specific services, or limitations on the amount of funding that can be allocated for an eligible service.

23) Oppose establishment of an ADAP core formulary requirement, a nationwide Federal Poverty Level eligibility standard or other mandates regarding the operation of ADAP programs.

24) Oppose any new mandates on consumer or provider participation in Title II consortia and/or ADAP advisory committee, or planning body makeup and/or process.

25) Oppose any legislative mandate that redirects or withholds funds from states, through the Title II base award, based upon a state's passage of a mandatory newborn testing law or regulation.

26) Oppose any legislative mandate requiring states to switch from an "opt-in" to an "opt-out" approach for testing pregnant women.

27) Fund perinatal prevention activities through CDC and not redirection of CARE Act funding.

28) Fund partner notification and referral services through CDC and not redirection of CARE Act funding.

29) Oppose any legislative mandate requiring state health departments to report clients to the criminal justice system.

30) Oppose any legislative mandate, including percentage set-asides, that require CARE Act grantees to incorporate abstinence-only education messages into CARE Act funded programs.
    a. Support comprehensive sexual education programs funded through CDC and other funding streams.

Theme 6: CARE Act Accountability

31) Support existing accountability processes through which states monitor their subgrantees.
    a. Oppose any legislative mandates prescribing a one-size-fits-all set of standard for states in monitoring their subgrantees.
    b. Require HRSA's Office of Performance Review to simplify additional requests to states for performance reviews of subgrantees.

32) Require HRSA to give a comprehensive accounting of their administrative tap on the CARE Act to Congress annually.

33) Require HRSA to provide CARE Act grantees and Congress with a comprehensive accounting of how CARE Act funded research is being translated into practice.

34) Exempt the CARE Act from HHS's evaluation tap.

THEME 1: STRENGTHENING STATE PROGRAM CAPACITY

NASTAD's two major recommendations focus on improving HIV care services in the nation by strengthening states' program capacity by: (1) Enhancing the availability of ADAP resources and services for persons living with HIV/AIDS in need in all areas of the nation; (2) Addressing inequities in per-capita CARE Act funding among states. Other recommendations designed to strength state program capacity focus on: changes to minimum grant awards; use of HIV cases in Title II funding awards; 340B Program Pricing and coordinated purchasing of medications in ADAP; and expanded authorized funding levels for the title of the CARE Act.

AIDS Drug Assistance Program (ADAP) Funding and Supplemental Grants

ADAPs nationally require significant annual increases in appropriations from the CARE Act to meet increasing expenditures driven by growth in enrollment, utilization, and rising drug prices. Annual appropriations for ADAPs have not kept pace with the rate of expenditure increases during the FY2000 to FY2005 authorization period of the CARE Act, resulting in barriers to accessing essential HIV/AIDS drugs.

Therefore, NASTAD recommends 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. NASTAD recommends that a minimum increase of $60 million be provided annually to support ADAPs. If the annual appropriation increase for the ADAP earmark is less than $60 million, NASTAD recommends that an amount necessary to ensure a minimum increase of $60 million be provided through an equal percentage tap on all other CARE Act titles (excluding ADAP). If the appropriated increase to ADAP is equal to or exceeds $60 million, NASTAD recommends that there be no tap in that year.

Furthermore, NASTAD recommends that 80% of annual ADAP increases be directed to the Title II ADAP earmark to support the provision of treatments under Section 2616. Additionally, NASTAD recommends these funds be distributed through a formula based on each state's proportion of the country's estimated living AIDS cases. NASTAD also recommends incorporating living HIV cases into the distribution formula as detailed on page 15 of this document.

NASTAD also recommends that 20% of annual ADAP increases be directed to the Title II ADAP Supplemental Treatment Drug Grants.[1] NASTAD recommends that ADAP supplemental funds no longer be limited to 3% of the ADAP appropriation. Rather, the ADAP supplemental pot would include the amount allocated to this category for FY2005, plus the 20% portion of the guaranteed annual ADAP increase during the five-year CARE Act authorization period. NASTAD also recommends that the state match requirement for the ADAP Supplemental Treatment Drug Grants be eliminated.

[1] Public Law 106-345: Section 2618(I)(ii).

NASTAD recommends that eligibility for ADAP supplemental funds be based on a state meeting any one of the following three criteria during the FY2006 to FY2011 five-year authorization period. State eligibility for supplemental funds will continue throughout the CARE Act authorization period after eligibility has been established.

(1) Gross income eligibility criteria of less than 300% of FPL.
(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 ADAP participants with incomes less than 300% of FPL.
(3) Waiting lists of ADAP applicants with incomes less than 300% of FPL.

NASTAD recommends that HRSA, in consultation with Title II and ADAP stakeholders, 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.

RECOMMENDATION # 1 – (Legislative) Enhance the availability of ADAP resources for persons in need living with HIV/AIDS in all areas of the nation by potentially tapping all titles of the CARE Act and revising the ADAP Supplemental Treatment Drug Grants.

Title II Emerging Communities Supplemental Grants[2]

While there is a critical need to enhance the availability of ADAP resources in states and territories, there is also a need to provide states with additional Title II base resources for primary care and support services. NASTAD has conducted data analysis to determine the states and territories per AIDS case allocation.[3] States without Eligible Metropolitan Areas (EMAs) (19) comprise the vast majority of states with a per AIDS case rate below the national average (30). NASTAD recommends modifying the current Title II Emerging Communities (EC) supplemental grants into grants to states to supplement their Title II base funding. States would use the additional monies for activities allowed under the Title II base authorization and HRSA guidance and direct resources to the communities where cases within their states reside. This proposal maintains the original intent of the Emerging Communities provision from the 2000 reauthorization, directing resources to states with epidemics that are not highly concentrated enough to be eligible for Title I funding.

Specifically, NASTAD recommends redefining the current provision to target additional funding to states that have a CARE Act per capita funding level below the national average by redirecting funds to states without Title I EMAs that do not receive minimum award funding and to those states with Title I EMAs in which 50% or greater of their state's cases reside outside of their Title I EMA(s). In addition, NASTAD recommends reducing Title I eligibility to 1,500 estimated living AIDS cases during the previous five years.

NASTAD recommends that funding under this provision be authorized at $35 million and allocated by formula among applicant states. For states without Title I EMAs the funding should be allocated based on the number of estimated living AIDS cases in a state. For eligible states with Title I EMAs the funding should be allocated based on the number of estimated living AIDS cases residing

[2] Public Law 106-345: Section 2620.
[3] The state per AIDS case rate was determined by totaling a states Title I, II, III IV, and Part F (excluding Emerging Communities and SPNS) and dividing by a state's estimated living AIDS cases.

outside of the Title I EMA(s). Applicant states and territories would receive an allocation equal to the product of: 1) the number of non-EMA estimated living AIDS cases in a state divided by the total number of cases eligible for the provision and 2) the amount appropriated for the provision.

RECOMMENDATION #2 - (Legislative) Address inequities in per-capita CARE Act funding among states by revising the Title II base Emerging Communities Supplemental Grants to provide additional Title II resources to states in need.

RECOMMENDATION #3 - (Legislative) Reduce Title I eligibility to 1,500 estimated living AIDS cases during the previous five years.

Minimum Grant Awards[4]

The CARE Act provides minimum Title II base awards to states with either less than 90 estimated living AIDS cases ($200,000) or more than 90 estimated living AIDS cases ($500,000). Territories receive a minimum Title II base award of $50,000.

RECOMMENDATION #4 – (Legislative) Increase the minimum Title II award to $500,000 and provide Guam with a minimum award of $200,000 by eliminating the requirement that stipulates a minimum award for states with fewer than 90 estimated living AIDS cases. *This will allow North Dakota and Wyoming, as well as Guam, the ability to enhance their system capacity.*

Use of HIV Cases in Title II Formula Awards[5]

The November 2003 Institute of Medicine (IOM) report "*Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White Care Act*" concluded that the reporting of HIV cases is not yet complete and accurate enough nationwide to be used in CARE Act allocation formulas. Of 56 states, territories and the District of Columbia, all have now implemented some type of HIV reporting.

Forty-three jurisdictions have name-based reporting. The remaining 13 jurisdictions utilize a code or name-to-code system for reporting HIV cases. Several jurisdictions have only recently implemented HIV reporting and therefore their HIV data is not yet considered "mature" enough to be reliable. CDC has not accepted HIV case report data from the 13 jurisdictions that collect and report HIV case data using codes or name-to-code systems, determining that these systems do not meet national performance and evaluative standards.

NASTAD believes the use of HIV cases in addition to AIDS cases in CARE Act allocation formulas is preferable and more closely reflects the epidemic than living AIDS cases. In order to accomplish this, HIV surveillance and reporting systems must be strengthened. The IOM study recommends that HRSA continue to use estimated living AIDS cases for at least the next four years, in order to give states more time to improve HIV reporting or develop alternative strategies to case reporting.

[4] Public Law 106-345: Section 2618(a)(I)(A) and (B).
[5] Public Law 106-345: Section 2618(a)(I)(D).

- ***RECOMMENDATION #5a - (Legislative) Include living HIV cases, in addition to living AIDS cases, in the Title II base and ADAP earmark formulas, phased-in over a 10-year period.***

- ***RECOMMENDATION #5b - (Legislative) Include CDC-certified HIV case data from <u>all</u> states, regardless of the type of reporting system, that meet reasonable data quality and completeness standards.***

- ***RECOMMENDATION #5c - (Legislative) Require CDC to get input from stakeholders, including states, when developing the methodology to estimate HIV cases for states with immature data systems.***

- ***RECOMMENDATION #5d - (Legislative) Oppose any legislative mandate requiring states to shift from a code-based to a name-base HIV reporting system.***

340B Program Pricing and Coordinated Purchasing of Medications in ADAP

The 340B Drug Discount Program is authorized under Section 602 of the Veterans' Health Care Act of 1992. This federal program allows specific Public Health Service (PHS) grantees, referred to as "covered entities," to access the same discounts as Medicaid programs, not to exceed a statutorily set ceiling price. Participation in the 340B Program is not mandatory, but rather is strongly encouraged by HRSA. In August 2003, HRSA reported that 50 of the 57 ADAPs that received funding in FY2003 participate in the 340B program. If ADAPs do not purchase under the 340B program, they are required to demonstrate that they are receiving the lowest possible prices on medications (examples of other purchasing arrangements include coordinated purchasing with a university or hospital-based pharmacy program or through the state's Medicaid program).

A March 2003 Office of the Inspector General report (A-06-01-00060) revealed that five manufacturers overcharged 340B covered entities $6.1 million for sales occurring during the one-year period ending September 1999. The overcharge occurred because of miscalculation of Best Price, which in turn affected the Medicaid Rebate calculation and ultimately the 340B ceiling price. Because the Medicaid Rebate and 340B discount price are so interrelated and the data used to calculate these prices are not available to the public, it is critical that the oversight by both CMS and HRSA's Office of Pharmacy Affairs (OPA) is as efficient and effective as possible. Both agencies are responsible for administering programs that provide life-saving care and treatment to our country's most vulnerable individuals.

In order to expand access to medications in states with limited eligibility or formulary coverage and to fill gaps that exist in ADAP coverage (e.g., waiting times between enrollment into ADAP and actual approval and subsequent obtaining of medications), some CARE Act grantees under Titles I and III of the CARE Act have established and now administer local Pharmacy Assistance Programs (PAPs). HRSA requires these grantees administering PAPs to demonstrate in their annual applications that they are purchasing medications at the lowest possible price. While participation in the 340B program among ADAPs is documented, data are not available concerning the number of other CARE Act grantees with established local PAPs that participate in the 340B program.

RECOMMENDATION #6 –Revise the drug purchasing options available to CARE Act drug purchasing entities.

- ***RECOMMENDATION #6a- (Legislative) Extend the Federal Ceiling Price (FCP)[6] to all CARE Act funded medication programs, including ADAPs.*** *By doing so, annually-appropriated federal and state funds for drug purchasing can be maximized, therefore expanding access and improving program efficiency.*

- ***RECOMMENDATION #6b - (Legislative) Share the Unit Rebate Amount (URA) generated by CMS 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 ensure adequate accountability for accurate reconciliation of rebates.*

- ***RECOMMENDATION #6c - (Legislative) Require all CARE Act grantees with PAPs to coordinate purchasing efforts within states.*** *If the FCP is not extended to all CARE Act funded medication programs, NASTAD recommends 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.*

- ***RECOMMENDATION #6d – (Administrative) Establish a CMS/HRSA Work Group to oversee and implement policies that affect both the Medicaid Rebate and the 340B programs.*** *NASTAD believes there needs to be better communication and coordination between CMS and HRSA. A CMS/HRSA Work Group would serve as the repository for statutorily defined discounts like the Medicaid Rebate and the 340B ceiling price. In addition, this Work Group could coordinate current and future efforts to recover overcharges by pharmaceutical manufacturers who fail to give Best Price and AMP to the administrators of the Medicaid and 340B programs as required by law.*

Authorized Funding Levels

The IOM Report, "*Public Financing and Delivery of HIV/AIDS: Securing the Legacy of Ryan White,*" estimates that 233,000 HIV positive Americans do not have consistent access to Highly Active Anti-retroviral Therapy (HAART). Low-income persons living with HIV/AIDS continue to be unable to access Title II services due to funding limitations of the program. NASTAD supports full funding for the CARE Act to ensure that the needs of all low-income HIV-positive individuals have access to primary care, life-saving therapy, and support services that are essential to keeping persons in care and adherent to their treatment regimen. NASTAD supports the inclusion of an authorizing level for Title II[7] that addresses these unmet needs, at a minimum of $1.4 billion in FY2006, with increasing amounts through FY2011.

RECOMMENDATION #7 – (Legislative) Increase authorizing levels for all components of the CARE Act, including the Title II base and ADAP earmark.

[6] The Federal Ceiling Price (FCP) is the maximum price for drugs that may be sold to the Veteran's Administration (VA), the Department of Defense (DOD), Public Health Service (PHS), and Coast Guard.
[7] Public Law 106-345: Section 2677(b).

THEME 2: MAINTAINING PROGRAM INFRASTRUCTURE

NASTAD's recommendations to maintain program infrastructure focus on: supportive services, hold harmless provisions within Title II, communities of color, hepatitis/HIV co-infection, and AIDS Education and Training Centers.

Supportive Services Within the CARE Act

The CARE Act re-enforces the importance of both medical and supportive services in providing comprehensive care and treatment to people living with HIV/AIDS. As defined in Section 2612b of the CARE Act, support services may include case management, transportation assistance, benefits counseling, housing referrals and supportive services for women, children and families. The CARE Act states that support services must "facilitate or enhance the delivery, continuity, or benefits of health services."[8]

The patchwork nature of funding for HIV-related services makes supportive services all the more important. Many individuals need the assistance of a case manager to sort through the various private and public programs through which they might be receiving care. The supportive services provided through the CARE Act are essential to ensuring access to and retention in appropriate care and treatment.

RECOMMENDATION #8 - (Legislative) Maintain flexibility to allow CARE Act funds to be used in the provision of services, both medical and support, based on locally determined needs within each state.

Hold Harmless Provisions within Title II of the CARE Act

The CARE Act currently has two provisions that ensure Title II jurisdictions will receive a level of funding similar or equal to previous years under their formula grants. These provisions are typically referred to as "hold harmless" provisions and apply to Title II base grants and the ADAP earmark, as well as the overall Title II award (including base, ADAP earmark, ADAP supplemental grants, Emerging Communities, and Minority AIDS Initiative funding).

Hold harmless provisions limit shifts in Title II base and ADAP earmark funding that otherwise could help address funding disparities that exist from state to state. However, with limited funding, as well as two consecutive years of cuts to the Title II base, these disparities cannot be corrected via major shifts in Title II resources without impacting existing services in jurisdictions that would lose funding.

RECOMMENDATION #9 – Revise Title II hold harmless provisions.

- ***RECOMMENDATION #9a - (Legislative) Revise the standalone Title II base and ADAP earmark hold harmless provision[9] to reflect a 1.5% loss each year (based on FY2005 funding levels) with a maximum possible loss of 7.5% over a five-year period, or 92.5%.*** *This would continue to apply to the Title II base and the ADAP earmark.*

[8] Public Law 106-345: Section 2604(b)(1)(B).
[9] Public Law 106-345: Section 2618(H)(i).

- ***RECOMMENDATION #9b - (Legislative) Repeal the overall Title II hold harmless provision[10].*** *The provision has resulted in losses to the pool of available money for critical ADAP Supplemental grants.*

Communities of Color

Since 1999, Minority AIDS Initiative (MAI) funds have been earmarked to expand or improve CARE Act medical and support-service capacity in communities of color. Under Title II of the CARE Act, MAI funds are used to support education and outreach services specifically targeting racial and ethnic minority populations impacted by HIV. NASTAD believes that these funds, while inadequately funded and distributed within Title II at $7 million, are valuable in helping states link underserved minority populations to critical care and treatment services, including ADAP, and other publicly funded HIV care and treatment programs. While NASTAD supports these education and outreach services, states should have the flexibility to utilize these funds for other care and treatment and support services that target racial and ethnic minority populations impacted by HIV -- including the provision of medications through ADAP when resources are scarce.

RECOMMENDATION #10a - (Legislative) Authorizing the Title II portion of the Minority AIDS Initiative.

RECOMMENDATION #10b – (Legislative) Provide additional resources to states to enhance outreach and education efforts in linking minority populations to services.

RECOMMENDATION #10C – (Administrative) Distribute Title II MAI funds to the 30 states with the highest percentage of persons of color to avoid states receiving awards that are too small to be effective.

HIV/HCV and HIV/HBV Co-infection

Increasingly, state public health HIV/AIDS programs are assuming responsibility for viral hepatitis prevention and care activities, due to its similarities with HIV/AIDS in disease transmission and populations affected. In recent years, enhanced hepatitis outreach and awareness efforts have resulted in many persons living with HIV/AIDS learning of their co-infection with hepatitis B (HBV) or hepatitis C (HCV). It is estimated that one-third of persons living with HIV are co-infected with HCV and that 6-10% of persons with HIV are infected with hepatitis B virus (HBV). [11] The risk of hepatitis-related cirrhosis and other liver-related complications is higher in those who are co-infected with HIV and HCV.

State public health programs and CARE Act grantees remain challenged with how to effectively manage and respond to HIV/HCV and HIV/HBV co-infection. CARE Act resources can be used for HCV and HBV treatments for individuals who are also HIV-infected. Inadequate funding of ADAPs, however, has limited access to HCV treatments for co-infected individuals, and state Medicaid restrictions threaten access to HCV treatments for many others. CARE Act resources can be used for hepatitis A and B vaccines as well as HBV treatments.

[10] Public Law 106-345: Section 2618(I)(ii)(IV).
[11] CDC. *Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-related Chronic Disease*. MMWR 1998; 47(No. RR-19):1-39.

- ***RECOMMENDATION #11a – (Legislative) Maintain flexibility for all CARE Act grantees in the use of CARE Act resources to address HIV/HCV and HIV/HBV co-infection.*** *Providers funded by all titles of the CARE Act must have the flexibility to adequately and appropriately treat their co-infected clients by addressing, to the extent determined possible by the capacity and resources of the provider agency/program, both their HIV and HCV/HBV diseases.*

- ***RECOMMENDATION #11b – (Legislative) Require AIDS Education and Training Centers (AETCs) to collaborate with CDC's Prevention Training Centers to ensure that HIV care providers are adequately trained in prevention and treatment of viral hepatitis as approximately one-third of individuals with HIV are co-infected with HCV and 6-10% are co-infected with HBV.*** *Without increasing provider knowledge and skills of HCV co-infection, many clinicians will remain uneducated and their HIV patients who are at risk of or infected with HCV will remain undiagnosed or uninformed.*

- ***RECOMMENDATION #11c – (Administrative) Instruct HRSA to develop an agency-wide strategic plan, including the identification of necessary resources, for addressing HIV/HCV and HIV/HBV co-infection and HCV mono-infection.***

AIDS Education and Training Centers (AETCs)[12]

The AETCs' goal is to "increase the number of health care providers who are educated and motivated to counsel, diagnose, treat and medically manage individuals with HIV infection and to help prevent high risk behaviors that lead to HIV transmission."[13] In this time of diminishing resources, programs that provide direct benefit to individuals living with HIV should be given priority within the AETC programs, as is already the case in the remainder of the CARE Act. This includes well trained and culturally competent providers. Research has shown that that HIV-positive African Americans under the care of a white physician delayed effective treatment almost four months longer than their counterparts with African-American physicians.[14]

An historical lack of coordination continues to shadow the regional AETCs. State AIDS Directors repeatedly struggle with duplicative training programs, difficulty accessing AETC provider trainings and inconsistent competence of the regional AETC training staff. These deficits undermine the existing vigorous statewide care continuums as well as reduce the likelihood that AETCs reach their program goals.

RECOMMENDATION #12a – (Legislative) Prioritize AETC funding for HIV-specific training to primary care providers. *Significant attention should be given to assisting white primary care providers to effectively serve patients of color.*

RECOMMENDATION #12b - (Administrative) Require AETCs to develop and enact Memorandums of Agreement (MOA) with State AIDS Directors that specify how both entities will collaborate. *Overall coordination prevents duplication of training services and ensures a consistent statewide dissemination of information.*

[12] Public Law 106-345: Section 2692.
[13] http://www.hab.hrsa.gov/history.htm.
[14] King, et al. "Does Racial Concordance Between HIV-Positive Patients and Their Physicians Affect the Time to Receipt of Protease Inhibitors?" Journal of General Internal Medicine, November 3, 1004.

RECOMMENDATION #12c – (Administrative) Include a service commitment in an HIV specific clinic, community health center or minority health center as one requirement of the loan forgiveness/scholarship program for health care providers. *Loan forgiveness programs exist at both the federal and state levels. More attention should be given to making HIV programs a priority. Patients of color continue to face barriers to access when seeking HIV/AIDS services, and increasing the number of health care providers of color may aid in improving the accessibility of HIV/AIDS resources for minority communities.*

THEME 3: CARE ACT SIMPLIFICATION AND FLEXIBILITY

NASTAD's recommendations to simplify and provide flexibility within the CARE Act focus on: reducing unfunded mandates, streamlining the application and reporting requirements, state match and maintenance of effort, WICY set-aside reporting requirements, unmet need, quality management, and prevention-care integration flexibility.

CARE Act Simplification

The CARE Act has a large number of requirements, including determination of unmet need, quality management, the Statewide Coordinated Statement of Need (SCSN), and comprehensive planning. Many of these requirements are unfunded mandates that place additional administrative burden on states. These mandates compel state health departments to engage in costly and time-consuming processes in order to fulfill the requirements of each mandate. For example, the requirement for states to develop a separate comprehensive plan is an unfunded mandate that is duplicative of other planning processes. This reporting requirement should be eliminated and the required information be requested as part of the Title II grant application.

Throughout a funding cycle, HRSA requires that progress reports and additional information be submitted. While state and local health departments recognize the importance of these reporting requirements, only necessary information should be collected. Often time, the elements are repetitive of the Title II grant application and/or the information is available through other sources. In addition, there are situations where data collected by states is not utilized, reported, or analyzed by HRSA.

RECOMMENDATION #13 – Reduce the administrative burden placed upon states.

- ***RECOMMENDATION #13a - (Legislative) Make CARE Act Title I and Title II planning, application and grant cycles concurrent***. *This would improve collaboration and planning across Title I and Title II CARE Act grantees. It would also help to eliminate redundancies in planning, funding, and delivering HIV care services across jurisdictions.*

- ***RECOMMENDATION #13b - (Administrative) Keep "Off-year" reporting requirements of the biennial application process to a minimum***. *This will allow states to focus on longer-term planning and the delivery of services to eligible clients. Reports should also be limited to quantitative data and a brief summary of new accomplishments and barriers.*

- ***RECOMMENDATION #13c – (Administrative) Reduce or keep to a minimum unfunded mandates for activities such as determining unmet need, quality management, comprehensive planning and SCSN.*** *Eliminating many of these legislative requirements or only requiring information once during a funding period would ensure that state and local health departments are able to allocate their financial and human resources in the most effective manner.*

- ***RECOMMENDATION #13d - (Administrative) Provide additional funding for time-intensive requirements, such as determination of unmet need****. This would allow health departments to ensure that they were complying in the most accurate and responsible way possible. Many of the unfunded mandates are time consuming for health department staff. These mandates use resources and staff time that might be more effectively used in another capacity. However, these mandates should not come before the provision of medical care and treatment to clients.*

- ***RECOMMENDATION #13e - (Administrative) Eliminate many of the unnecessary reporting requirements placed upon Title II grantees****. This would allow states to focus on providing vital services to HIV-positive individuals.*

State Match and Maintenance of Effort

The CARE Act contains two provisions designed to assure state funding support for HIV care and treatment programs. To prevent federal funds from offsetting specific HIV-related budget reductions at the state level and to encourage increased state contributions to HIV care services, Title II contains a state funding match[15] and maintenance of funds assurance[16] requirement. The current economic situation has forced state governments to reduce funding for many state programs, including HIV/AIDS services. With the state match and maintenance of effort provisions, Title II programs confronting state budget cuts face the possibility of losing federal funds through the withholding or reduction of Title II CARE Act funding. This further penalizes already fiscally strapped states and may restrict access to care and critical, life-saving services.

Additionally, Title II administrators lack the authority to ensure maintenance of effort assurances are met. In determining maintenance of effort requirements, expenditures from numerous state agencies are aggregated to calculate the overall amount of state expenditures for HIV-related services. Title II administrators often have little to no control over other departments' budgets or expenses from year to year.

Because of a 1:4 state match requirement for ADAP Supplemental grant awards, some eligible states have been unable to access this targeted program designed to increase access to care in states with ADAP restrictions. This match requirement has resulted in a loss of funds to several state ADAP programs that are in dire need of additional resources.

RECOMMENDATION #14 – (Legislative) Continue state match and maintenance of effort requirements for states.

RECOMMENDATION #14a - (Legislative) Maintain flexibility of allowable costs for state match and maintenance of effort requirements. *NASTAD continues to support the flexibility of states to determine allowable, appropriate expenditures in meeting these mandates.*

[15] Public Law 106-345: Section 2617(d).
[16] Public Law 106-345: Section 2617(b)(6)(E)

RECOMMENDATION #14b – (Legislative) Eliminate match requirement for ADAP Supplemental Treatment Grant awards.

Women, Infants, Children and Youth (WICY) Funding Set-aside

In the 1996 reauthorization of the CARE Act, Congress added language to Sections 2604 (4) and 2611 (b) to assure adequate proportional funding for the aggregate population of infants, children, and women with AIDS. In the CARE Act Amendments of 2000, Congress included additional requirements on proportional spending. The law obligates grantees to spend a percentage of their Title II grant on services for each priority population of women, infants, children, and a newly added group, youth (WICY) that is consistent with the percentage of each WICY population among persons living with AIDS within the grantee's jurisdiction.

The WICY provision is the only population-specific requirement in Titles I and II of the CARE Act. States and EMAs should have the flexibility to address the disproportionate impact of HIV on underserved populations by directing funding based on epidemiology, assessments of need, and existing resources supporting services for those populations. Title I and Title II are charged with the responsibility of ensuring services for all clients, not just WICY clients; however, the ability of states and EMAs to direct funding based on need is inhibited by funding set-asides that require the expenditure of a legislatively established percentage of dollars for specific populations. In addition, the burdensome requirements resulting from the WICY provision are not consistent with the legislative directive related to administrative simplification.[17]

RECOMMENDATION #15 - (Legislative) Eliminate the WICY proportional spending requirement from Titles I and II.

Unmet Need

As required by the CARE Act, states for the first time in FY2005 must assess unmet service needs in their jurisdiction and determine the estimated number of individuals who know their HIV positive status but are not receiving primary medical care.[18] The CARE Act requires states to assess the needs of individuals not in care, to allocate resources based, in part, on this assessment, and to develop strategies to identify individuals not in care and "encourage" them to utilize services. States were first asked to describe the quantitative and/or qualitative methodologies they employ to assess individuals not in care in their annual CARE Act applications for FY2004. In 2003, HRSA announced that all states would be expected to use a methodology developed by the University of California at San Francisco in order to determine unmet need. No additional funding has been provided to jurisdictions to produce an unmet need assessment.

States have reported that quantitative and qualitative efforts to document unmet need are complex, challenging and prohibitive in many jurisdictions. Given the overwhelming difficulties that states have confronted in an effort to collect, analyze, and report data and related information on unmet need associated with persons not in care, and without sufficient resources to support such efforts, states are not well served by legislative mandates that require estimating unmet need. In addition, the data cannot be considered complete or comparable within and across jurisdictions; therefore, the

[17] HRSA developed a 20-page guidance to states to comply with one line of statute.
[18] Public Law 106-345: Section 2617(b)(3).

data will not be meaningful and cannot be used at the federal level to support accurate estimates of unmet need. Neither the federal government nor Congress are well-served by this legislative mandate.

RECOMMENDATION #16 –Revise the provision requiring states to quantify unmet need.

- ***RECOMMENDATION #16a – (Legislative) Eliminate the legislative requirement to quantify unmet need to identify the number of persons who know their status and are not in care.*** *Eliminating this requirement will not diminish the importance of conducting outreach to link persons with HIV to care, especially given CDC's Advancing HIV Prevention (AHP) initiative intended to identify and encourage entry into care of all persons living with HIV.*

- ***RECOMMENDATION #16b – (Administrative) Short of elimination, maintain flexibility in methodologies of determining unmet need as well as data sources used to estimate need.*** *However, it should be noted that providing this flexibility may pose difficulties for comparing data across jurisdictions.*

- ***RECOMMENDATION #16c – (Administrative) Provide funding to states for the resource intensive process of determining unmet need.***

Quality Management

Under the CARE Act, states and EMAs are required to establish a quality management program to assess the extent to which HIV health services provided to persons living with HIV/AIDS are consistent with the most recent Public Health Service (PHS) guidelines.[19] HRSA's policies also mandate that all quality management activities conducted by the states ensure that strategies for improvements to quality medical care include vital health-related support services and that demographic, clinical, and health care utilization data are used to monitor the spectrum of HIV-related illnesses and trends in the local epidemic.

A 2004 Institute of Medicine (IOM) report[20] found that current quality management efforts are not guided by a common conceptual framework and measures are often not standardized. The report suggests developing a standardized set of measures and recommends that the Department of Health and Human Services "provide additional resources to HRSA and CDC to develop infrastructure for monitoring quality at the patient, clinic, and population levels." The report also found that Congress should "enhance flexibility in the administrative caps at the grantee level to promote infrastructure development."

RECOMMENDATION #17 – Revise the quality management requirements of the CARE Act.

- ***RECOMMENDATION #17a – (Legislative) Maintain states' flexibility to choose the quality management strategies that work most effectively in their jurisdiction****. Quality management programs are often costly and time-consuming. It is imperative that states not be required to replace their established quality management programs with a federally mandated process.*

[19] Public Law 106-345: Sections 2604(c) and 2612(d).
[20] "*Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act*." Institute of Medicine, November 7, 2004.

States recognize the value and necessity of appropriate quality management programs and many jurisdictions have already developed model programs that may be utilized across states.

- ***RECOMMENDATION #17b – (Legislative) Account for costs associated with quality management activities separately from administrative costs, as quality management is an integral part of service delivery.*** *In order for states to provide effective quality management programs, they must be allowed flexibility in spending. Enhanced flexibility in the administrative caps would allow states to better direct their quality management activities to ensure the greatest level of accuracy and accountability. Additional funds have not been provided for quality management, so in order to establish these programs, many states diverted funds from services to develop quality management programs. Additional funding must be provided for states to continue to establish quality management programs.*

- ***RECOMMENDATION #17c – (Administrative) Require HRSA to provide states with technical assistance to develop quality management programs for support services.***

- ***RECOMMENDATION #17d – (Administrative) Provide funding to states to develop and maintain effective quality management strategies.*** *HRSA must provide additional technical assistance support to state health departments and their staff on assessing quality management. States are interested in ensuring that the information they collect is reliable and detailed enough to provide their programs and HRSA with quality measures. To do this, states need increased technical assistance to work through the complicated process of measuring quality and responding with appropriate changes to enhance quality of services.*

Prevention and Care Integration

The delivery of HIV prevention services in the primary care setting is increasingly considered the standard of care for persons living with HIV. In July 2003, CDC, HRSA, the National Institutes of Health, and the HIV Medicine Association of the Infectious Disease Society of America released the guidelines *Incorporating HIV Prevention into the Medical Care of Persons Living with HIV.* The guidelines present clear recommendations for clinicians regarding screening patients for risk, incorporating behavioral interventions into practice, referring patients to appropriate prevention services, and working with partners through partner counseling and referral services (PCRS). The care setting often presents a missed opportunity for the inclusion of HIV prevention services.

The CARE Act allows grantees to utilize Title I and II dollars on prevention, or Early Intervention Services (EIS), including risk reduction counseling and HIV testing, and Prevention for Positives programs. This allowance, however, is restrictive to most grantees who find it difficult to meet the payer of last resort requirements in order to utilize CARE Act funding for these programs.

RECOMMENDATION #18a – (Legislative) Provide states with more flexibility for incorporation of Early Intervention Services and Prevention for Positives programs into CARE Act programs.

RECOMMENDATION #18b – (Administrative) Recognize HIV prevention as a standard of care for persons living with HIV/AIDS.

RECOMMENDATION #18c – (Administrative) Encourage and provide technical assistance to providers to adopt standards based on incorporating HIV prevention into the medical care of persons living with HIV/AIDS.

THEME 4: ENHANCING STATE'S ABILITY TO COORDINATE HIV/AIDS HEALTH SYSTEMS

NASTAD's recommendations to enhance the ability of states to coordinate HIV/AIDS health systems focus on: SCSN and comprehensive planning, payer of last resort, and Title III grants.

Statewide Coordinated Statement of Need, Comprehensive Planning, and the Role of the States in Coordinating Services

The Statewide Coordinated Statement of Need (SCSN) and comprehensive planning processes are designed to achieve a goal of collaboration; however, they have become burdensome and duplicative. No additional funding has been provided for states to facilitate these efforts.

The CARE Act requires that each state periodically convene a meeting of persons living with HIV/AIDS, representatives of grantees under each title of the CARE Act, providers, and public agency representatives for the purpose of developing the SCSN.[21] States are the only grantees under the CARE Act with the requirement to convene such a meeting, although all other titles are required to demonstrate in their applications consistency with the SCSN in their particular state.

RECOMMENDATION #19 – Revise coordination and planning requirements of the CARE Act.

- ***RECOMMENDATION #19a – (Legislative) Eliminate the SCSN requirement in the CARE Act.*** *This requirement is duplicative of other requirements associated with the annual state application (which includes a comprehensive plan), public advisory and participatory planning requirements associated with the annual application, and Title I planning council and Title II consortia needs assessment and planning activities.*

- ***RECOMMENDATION #19b – (Legislative) Require HRSA to consult with each state and other grantees within a particular jurisdiction prior to approving new grants.*** *This requirement would improve state and grantee efforts to reduce duplication and allow new resources to be targeted to severe need jurisdictions (those with inadequate Title II base services or ADAPs that have inadequate formularies, low income eligibility levels, or other criteria, including presence of waiting lists). New projects should be consistent with the above collaborative planning processes and not duplicate existing programs, regardless of which title or other program is providing services.*

- ***RECOMMENDATION #19c – (Legislative) Require documentation of collaborative efforts with the state in grant applications or progress reports for all CARE Act grantees, including AETCs and dental reimbursement programs.*** *As part of each Title II application, the state will*

[21] Public Law 106-345: Section 2617(b)(5).

continue to report on the progress of the state's CARE Act grantee collaborative efforts and, where appropriate, document the participation of other grantees.

- ***RECOMMENDATION #19d – (Administrative) Eliminate the administrative requirement to submit a separate Comprehensive Plan from the Title II grant application.*** *The current requirement is duplicative and unnecessary.*

- ***RECOMMENDATION #19e – (Administrative) Provide states with maximum flexibility to determine the appropriate mechanism and timing of coordination efforts among the various CARE Act programs.*** *The elimination of the SCSN does not eliminate the responsibility of all CARE Act grantees to actively participate in ongoing collaborative efforts within each state to ensure, to the greatest extent possible, access to coordinated client services across the state and reduced duplication of services. At its discretion, the Title II grantee in each state would be responsible for convening, planning, coordinating, and facilitating such efforts, with the assistance and input of the other grantees. Where a grantee's service area crosses over more than one state, the grantee should be required to participate in the collaborative process of each state in which they serve clients. New and/or additional funding should be provided to states in order to facilitate this process.*

Payer of Last Resort

The CARE Act requires that CARE Act funds not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, under any state compensation program, under an insurance policy, or under any federal, state or local health benefits program. [22] This provision of the CARE Act is widely known and referred to as the "payer of last resort." While this is clearly understood with respect to most programs, HRSA's HIV/AIDS Bureau has generally been unable to clearly articulate a policy regarding payer of last resort. Some state Medicaid programs have also been unwilling to provide client eligibility data to ADAPs, making it difficult for ADAPs to fully comply with the payer of last resort provision.

RECOMMENDATION #20 – Revise the payer of last resort requirement in the CARE Act.

- ***RECOMMENDATION #20a – (Legislative) Provide explicit allowance within the CARE Act to wrap-around Medicaid and Medicare to help support payment of co-pays and other out-of-pocket expenses that provide necessary health care services to persons living with HIV/AIDS.***

- ***RECOMMENDATION #20b – (Legislative) Enable states the flexibility to serve clients who have coverage for services through other payers that are also covered under the CARE Act if the services covered elsewhere are difficult to access (e.g., location of services is too far to enable the client access to the services).***

- ***RECOMMENDATION #20c – (Legislative) Require Medicaid and Medicare to provide eligibility data to ADAPs to ensure the payer of last resort requirements are met.***

[22] Public Law 106-345: Section 2617(b)(6)(F)(i and ii).

- ***RECOMMENDATION #20d – (Legislative) Require Medicaid to reimburse states through a Medicaid Administrative Reimbursement process for staff time devoted to Medicaid coordination activities.***

- ***RECOMMENDATION #20e – (Administrative) List the programs that are included with respect to the payer of last resort provision, including those of the Veterans' Administration, Medicaid, Medicare, Indian Health Services (IHS), State Children's Health Insurance Programs, and other federal, state and local programs, including other pharmacy benefits programs.***

Title III Grants

The CARE Act includes language[23] giving priority for new Title III grants to "rural areas" and "underserved" areas. Of the programs funded under Title III during FY2003, approximately 44% were in urban areas, 36% were in rural areas and 19% were in mixed rural and urban areas. Of the grantees funded since 2000, 79% were rural and 21% were urban. It does appear that HRSA has responded appropriately to the CARE Act language regarding a preference for making new Title III awards in rural areas, however, it is unclear whether or not these Title III programs were within or near Title I EMAs.

RECOMMENDATION #21 – Revise the Title III provision of the CARE Act.

- ***RECOMMENDATION #21a – (Legislative) Prioritize new planning or Title III grants to underserved states that do not have access to Title I funding and as a secondary priority, underserved areas of states outside of existing Eligible Metropolitan Areas (EMAs).***

- ***RECOMMENDATION #21b - (Legislative) Require HRSA to consult with each state and other grantees within a particular jurisdiction prior to determining new Title III projects within a particular area***. *This requirement would help to reduce duplication and allow new resources to be targeted to severe need jurisdictions (those with inadequate Title II base services or ADAPs that have inadequate formularies, low income eligibility levels, or other criteria, including presence of waiting lists). New projects should be required to coordinate services with the state, consistent with collaborative planning processes, and not duplicate existing programs, regardless of which title or other program is providing services.*

- ***RECOMMENDATION #21c - (Administrative) Strengthen and enforce the provision of HIV services provided by community health centers that receive federal, but not CARE Act, support.*** *In challenging fiscal times, it becomes increasingly important to maximize all resources available to provide services for persons living with HIV/AIDS.*

- ***RECOMMENDATION #21d - (Administrative) Require HRSA to allow representatives from states in monitoring visits at Title III agencies and provide copies of subsequent reports to the states upon request.*** *This requirement would increase collaboration between grantees and reduce duplication of services.*

[23] Public Law 106-345: Section 2653(d)(1) and (2)

THEME 5: CARE ACT MANDATES

In general, NASTAD strongly opposes any legislative mandate that requires states to pass legislation or enact regulations in order to receive their Title II funding award or any portion thereof. This would include withholding state awards until states pass mandatory newborn testing, if the status of the mother is unknown; requiring states to switch from an "opt-in" to an "opt-out" approach for testing pregnant women; requiring states to shift from code-based to name-based HIV reporting; and requiring state health departments to turn over clients to the criminal justice system.

NASTAD strongly opposes mandatory set-asides for specific populations or types of services. This would include the existing Women, Infants, Children and Youth set-aside, as well as, any other specific population. The CARE Act should not include a mandated set of services that is more limited than current law; percentage set-asides for specific services, such as hepatitis C or nutrition services; or limitations on the amount of funding than can be allocated for an eligible service.

The CARE Act has a large number of mandates, including determination of unmet need, quality management, the SCSN, and comprehensive planning all of which are unfunded mandates that place additional administrative burden on states. These mandates compel state health departments to engage in costly and time-consuming processes in order to fulfill the requirements of each mandate. NASTAD supports the elimination of unfunded mandates that would then allow state health departments to allocate their financial and human resources toward critical HIV/AIDS services. NASTAD strongly opposes any new unfunded mandates, whether they are legislative or administrative. This would include new client level data reporting requirements without the provision of appropriate resources to carry out the activity.

NASTAD's recommendations regarding CARE Act mandates focus on: Core set of medical services, ADAP core formulary considerations, participatory planning, partner counseling and referral services, and abstinence/prevention education.

Core Set of Medical Services

Due to funding disparities, lack of sufficient resources available for the CARE Act, and the availability of services through other public health payers, CARE Act services differ within and between states. NASTAD recognizes the importance of providing a common standard of care available to all CARE Act clients regardless of residency. At the same time, establishing a set of core medical services is troubling for several reasons. First, establishing a set of core medical services undermines the importance of support services in maintaining a person in care and adherent to their drug regimen. Second, establishing a core will establish a ceiling not a floor whereby resources will be allocated only for this newly defined set of services, ignoring the necessity of support and other vital services. Furthermore, the needs of people living with HIV/AIDS has shifted since the beginning of the epidemic and will continue to do so. Mandating a core set of services could make it difficult to meet the changing needs of individuals living with HIV/AIDS. Third, establishing of core set of services could lead to a redistribution of dollars. Many people living with HIV/AIDS could find themselves without access to services they had previously received. Fourth, establishing a core set of services ignores the complex payer mix existing in states that have non-CARE Act providers providing much of the core.

RECOMMENDATION #22 – (Legislative) Oppose a mandated set of core services that are more limited than current law, or percentage set-asides for specific services, or limitations on the amount of funding that can be allocated for an eligible service.

ADAP Core Formulary

Medications available on ADAP formularies vary by state. For example, in FY2003, drugs available on state formularies ranged from the 18 FDA-approved antiretrovirals (ARVs) to approximately 400 drugs to treat HIV and related conditions. This significant range of drug availability raises concern about formulary differences among the states and variations in services depending on where individuals live.

NASTAD recognizes the need to address such disparities and the importance of establishing a standard of care available to all ADAP clients regardless of residency. However, there is also the concern that establishing a core formulary may actually reduce access by creating a formulary ceiling for states with more expansive formularies. States that make large general revenue contributions to their ADAPs will have no incentive to do so if a floor is set.

In addition, requiring a core formulary for ADAPs may cause more fiscal strain for ADAPs with lean formularies. If a core formulary were defined to include the PHS recommended drugs for prevention and treatment of opportunistic infections (OIs), this may force these and other ADAPs, in the absence of additional funding, to reduce enrollment in order to allow access to these additional drugs. These states will also be forced to put all their Title II base dollars into their ADAP in order to bring their ADAP up to the floor.

RECOMMENDATION #23 – (Legislative) Oppose establishment of an ADAP core formulary requirement, a nationwide Federal Poverty Level eligibility standard, or other mandates regarding the operation of ADAP programs. *NASTAD, through its position to redesign the ADAP Supplemental Grant Awards, believes states will provide access to therapies consistent with Public Health Service (PHS) guidelines (either through ADAP or through other sources), including all antiretroviral medications and recommended "A1" drugs to treat OIs.*

Participatory Planning

Persons living with HIV/AIDS play an essential role in planning and implementing CARE Act programs to successfully serve target populations. While the CARE Act mandates that HIV-positive individuals make up 33% of Title I Planning Councils, states have the flexibility to determine the composition of Title II consortia and ADAP advisory committees to best fit individual community needs.

States have been successful in meeting program requirements without mandates for consumer or provider participation in Title II and ADAP planning bodies. Such mandates place additional administrative burden on states by requiring them to engage in costly and time-consuming processes in order to fulfill them. Scare CARE Act resources should be prioritized for services, not to create more planning infrastructure.

RECOMMENDATION #24 – (Legislative) Oppose any new mandates on consumer or provider participation in Title II consortia and/or ADAP advisory committees or planning body makeup

and/or processes. *States are committed to participatory planning but must have the flexibility to determine the makeup and functions of consortia and/or ADAP advisory committees.*

Federal Grants to Reduce Perinatal Transmission of HIV

Perinatally acquired AIDS cases have decreased dramatically due, in large part, to HIV testing and subsequent treatment 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% decline from a high of 954 new AIDS cases in 1992. Only three states account for over 50% of all new perinatal cases reported to the CDC - New York (48), Florida (20), and California (14). 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.

In 1996, Congress authorized through Section 2625 of the CARE Act $10 million for grants to support counseling, testing, and outreach to pregnant women and infants. Priority in funding was given to states with the highest prevalence of perinatal transmission cases. In 2000, Congress authorized an additional $20 million in new funds for grants supporting counseling, testing, outreach and treatment of pregnant women and infants. One of the goals of the CARE Act Amendments of 2000 was to provide a financial incentive to states to adopt laws or regulations that mandate the testing of newborns if their mother's HIV status is unknown at the time of delivery. No state has adopted such a law since the federal legislation was enacted. Currently, New York and Connecticut are the only states with such laws. Congress has yet to provide resources for these grants.

RECOMMENDATION #25 – (Legislative) Oppose any legislative mandate that redirects or withholds funds from states, through the Title II base award, based upon a state's passage of a mandatory newborn testing law or regulation.

RECOMMENDATION #26 – (Legislative) Oppose any legislative mandate requiring states to switch from an "opt-in" to an "opt-out" approach for testing pregnant women.

RECOMMENDATION #27 – (Legislative) Fund perinatal prevention activities through CDC and not redirection of CARE Act funding.

Partner Counseling and Referral Services (PCRS)

Health departments use partner counseling and referral services 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 allows Titles I and II to conduct early intervention services (EIS), including risk reduction counseling and testing. 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. [24] While the CARE Act authorized $30 million for the PCRS grants, no money has ever been provided to states through this grant mechanism.

[24] Public Law 106-345: Section 2631(a).

Currently, all states and territories conduct PCRS as a requirement of their prevention cooperative agreement with the Centers for Disease Control and Prevention. 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 HIV-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.

These grants were never funded and are duplicative of what states are already doing in the area of PCRS. The CARE Act is designed to provide care and treatment to people living with HIV and as such, does not include PCRS in its primary focus. PCRS should continue to be funded primarily by CDC cooperative agreements with state health departments. Funding PCRS through the CARE Act diverts resources away from care and treatment services.

RECOMMENDATION #28 –Fund partner notification and referral services through CDC and not redirection of CARE Act funding.

RECOMMENDATION #29 – (Legislative) Oppose any legislative mandate requiring state health departments to report clients to the criminal justice system.

Abstinence Prevention Education in CARE Act Services

The CARE Act was designed to assure comprehensive health and support services to individuals living with HIV/AIDS. Federal agencies, health departments and community-based organizations understand the importance of close linkages between HIV prevention and care services to ensure that individuals learn of their HIV status and receive referrals to appropriate services. There is a movement toward mandating abstinence within some federal programs. One-third of all U.S. global bilateral prevention funds must go towards abstinence-until-marriage programs. Abstinence-only programs do not provide information about contraception, safe sex or disease prevention methods. Furthermore, abstinence-only-until-marriage messages have no meaning for gay and lesbian people, for whom marriage is illegal in most parts of the country.

RECOMMENDATION #30 – (Legislative) Oppose any legislative mandate, including percentage set-asides, that require CARE Act grantees to incorporate abstinence-only education messages into CARE Act funded programs and other funding streams.

- ***RECOMMENDATION #30a –Support comprehensive sexual education programs funded through CDC.***

THEME 6: CARE ACT ACCOUNTABILITY

NASTAD's recommendations to address CARE Act accountability focus on: accountability of HRSA and CARE Act grantees and the HRSA administrative tap.

Accountability of HRSA and CARE Act Grantees

States and territories, as Title II grantees, are monitored in a rigorous manner by HRSA. States and territories are required to provide program budget and fiscal reports and detailed contractor/provider budget packages each year. Grantees must also provide HRSA with a budget package for each Title II subgrantee with whom they contract. This package provides HRSA with a detailed explanation of the intent of the contract, the services to be offered and the dollars provided. States must also offer a detailed explanation of their subgrantee monitoring process. In addition, all CARE Act grantees are required to submit a CARE Act Data Report (CADR) annually. The CADR collects information on all clients that have received at least one CARE Act service. Data collected include: information on co-morbid conditions; prescribed medications; type of service provided; characteristics of clients; and information related to pregnant clients and the services they receive. In addition, ADAPs currently provide monthly reports on client utilization and also quarterly pricing reports.

States have processes to monitor the organization with which they subcontract to provide services to individuals living with HIV/AIDS. The majority of states have a process that includes both fiscal monitoring and program monitoring. States must also ensure that subgrantees have quality management programs in place, which help the subgrantee and the state identify problems that may impact health status outcomes. While HRSA does not mandate the process by which states must monitor their subgrantees, states are required to provide extensive detail about their various monitoring programs.

Since the enactment of CARE Act in 1990, the Office of the Inspector General (OIG) within the Department of Health and Human Services has audited HRSA's HIV/AIDS Bureau and CARE Act grantees at least 25 times to ensure accountability in the usage of CARE Act resources. The OIG routinely audits Title II grantees and their subgrantees for compliance with operating procedures, as well as conducting inspections and evaluations of the programs. Findings from these audits often result in more restrictive subgrantee monitoring programs, many of which place additional burdens on state health departments.

HRSA has recently consolidated its grants management offices, relocating most Title II monitoring responsibilities from regional offices to the national headquarters, and created the Office of Performance Review (OPR). In response to OIG reports, HRSA has indicated that HAB and the OPR will comprehensively review each of HRSA's grantees. NASTAD supports accountability of all CARE Act programs and grantees and believes that the current system of audits and evaluations upholds this.

RECOMMENDATION #31 – (Legislative) Support existing accountability processes through which states monitor their subgrantees.

- ***RECOMMENDATION #31a – (Legislative) Oppose any legislative mandates prescribing a one-size-fits-all set of standards for states in monitoring their subgrantees.*** *Any new standards for grantees' monitoring of subgrantees should reflect that a common protocol does not fit all grantees. Any new standards should be constructed administratively in consultation with states and territories.*

- ***RECOMMENDATION #31b – (Administrative) – Require HRSA's Office of Performance Review to simplify additional requests to states for performance reviews of subgrantees.*** *NASTAD recognizes the importance of grantee monitoring. However, much of the information needed to assess accountability and other programmatic goals can be found in the data already required by HRSA.*

HRSA Administrative and SPNS Tap Accountability

HRSA takes an administrative tap on the funds appropriated by Congress. All titles of the CARE Act are subject to the administrative tap. The ADAP earmark in Title II is exempt from an administrative tap and thus the tap is taken entirely from the Title II base. In the three most recent fiscal years, HRSA has taken between 3% and 3.6% off the Title II base appropriation for the administrative tap.

NASTAD appreciates that much of these funds pay for salaries and overhead for HAB. State AIDS directors believe these funds should be used to ensure that HAB has a knowledgeable staff that can provide in-depth technical assistance to states to enhance and improve their programs. NASTAD is increasingly concerned that much of this technical assistance has been outsourced and that comprehensive knowledge of state programs does not reside within HAB.

Special Projects of National Significance (SPNS)[25] is funded through a percentage tap on Title I, Title II base, Title II and Title IV of the CARE Act – up to $25 million. SPNS support the development of innovative HIV/AIDS service delivery models that have potential for replication in other jurisdictions. In recent years, the SPNS tap has been funded through an evaluation tap taken by HHS through authority in Section 241 of the PHS Act. For FY2005, that tap is 2.4% of the entire CARE Act or $49 million, out of which SPNS receives $25 million, with the other $24 million going to fill gaps in other PHS programs.

RECOMMENDATION #32 – (Legislative) Require HRSA to give a comprehensive accounting of the administrative tap to Congress on an annual basis.

RECOMMENDATION #33 – (Legislative) Require HRSA to provide CARE Act grantees and Congress with a comprehensive accounting of how CARE Act funded SPNS research is being translated into practice.

RECOMMENDATION #34 – (Legislative) Exempt the CARE Act from the HHS evaluation tap.

[25] Public Law 106-345: Section 2691.

Appendix A

NASTAD Ryan White CARE Act Fact Sheet

Ryan White Comprehensive AIDS Resources Emergency Act

The Ryan White CARE Act (RWCA) was enacted in 1990 in response to the growing number of HIV-positive individuals living in the U.S. The RWCA programs, administered by the Health Resources and Services Administration (HRSA), provide primary health care, pharmaceutical treatments, and support services for low-income people with HIV/AIDS. The RWCA provides services to over 500,000 HIV-positive individuals in all 50 states, the District of Columbia, Puerto Rico and the U.S. territories. The RWCA has been reauthorized and amended twice, in 1996 and 2000, and is up for reauthorization in September 2005. RWCA programs are funded at $2 billion in FY2005.

Need for RWCA Services

An estimated 950,000 people are living with HIV disease in the U.S. and at the end of 2002 over 384,906 of those people were living with AIDS. The RWCA is a social safety net program, designed to be the payer of last resort for HIV services. Some HIV-positive individuals rely on the RWCA to provide their entire medical and support services. However, even individuals who have private insurance often use the CARE Act to provide one or two of their services. RWCA funded clinics and support service organizations are much more likely than other HIV/AIDS care organizations to serve HIV-infected individuals who are poor (80% of users with annual incomes less than 300% of the federal poverty level or the FPL) and people of color (69%).[26]

HIV-related care is prohibitively expensive for most HIV-positive individuals. Estimates for a year of HIV treatment are approximately $14,000. These costs more than double to $34,000 when an individual progresses to a full-blown AIDS diagnosis.[27] The RWCA expressly acts to alleviate some of the financial burdens placed on HIV-positive individuals and their families.

Unmet Need and Ethnic/Racial Disparities

Between 180,000 and 240,000 people living with HIV are unaware of their positive status. Furthermore, over 300,000 individuals living with HIV are not receiving HIV-related care. While ethnic and racial minorities make up just over 25% of the U.S. population, they represent 70% of all new AIDS cases, 69% of the estimated number of persons living with AIDS, and 69% of the estimated new HIV infections annually.[28, 29] Being part of a minority group is also associated with less frequent and irregular outpatient care. Several studies have shown increased emergency room visits and hospitalizations and fewer outpatient care visits by minority patients with HIV than white

[26] Health Resources and Services Administration, "The AIDS Epidemic and the Ryan White CARE Act: Past Progress, Future Challenges," U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau, 2002.
[27] "Cost of treating patient with AIDS double that of one with HIV," *Agence France Presse*, July 10, 2002
[28] Centers for Disease Control and Prevention, *HIV/AIDS Surveillance Report*, 2002 Vol. 14.
[29] Centers for Disease Control and Prevention, *HIV/AIDS Update, A Glance at the Epidimic,"* (n.d.).

patients with HIV.[30] Other studies show that many African Americans and Latinos received care less often, required hospitalization more frequently, and had less access to HIV/AIDS drugs than their white counterparts. Individuals lacking health insurance faced the same problems.[31] Members of minority groups are also disproportionately uninsured or underinsured. Approximately 85% of African Americans with HIV do not have private insurance and therefore are more likely to depend on the public sector for medical care.[32] Poor people living with HIV/AIDS depend tremendously on programs funded through the RWCA and other public providers of medical care such as Medicaid.

Ryan White CARE Act Federal Funding Streams

Title I

Title I provides funding for health care and supportive services to eligible metropolitan areas (EMAs) that report at least 2,000 AIDS cases during the previous five years and have a population of at least 500,000. There are 51 EMAs in 21 states, Puerto Rico, and the District of Columbia.

The Title I allocation is divided into two components:

- Fifty percent of allocations are awarded in formula grants based on the estimated number of people living with AIDS in the EMA over the most recent 10-year period; and
- Fifty percent of allocations are awarded in competitive supplemental grants based on demonstration of severe need and other criteria.

Minority AIDS Initiative (MAI)

Congress established the MAI in FY1999 as the result of the advocacy of the Congressional Black Caucus to address the disproportionate impact of HIV/AIDS among African Americans. In FY2000, Congress expanded the MAI to address the growing needs caused by the epidemic of other ethnic and racial minorities. The MAI was designed to focus special attention on solving a growing public health problem as well as to develop and improve the capacity of minority community-based organizations (CBOs) to more effectively serve their communities.

Title I receives MAI funds to expand medical and supportive service capacity in communities of color and expand peer treatment education that is both culturally and linguistically appropriate to individuals living with HIV/AIDS. The funds are allocated using the established Title I planning council processes to allow each EMA to respond to locally-determined needs.

Title II

Title II provides funding to states and territories to improve the quality, availability, and organization of health care and support services for individuals and families with HIV disease, and provides access to pharmaceuticals through the AIDS Drug Assistance Program (ADAP).

[30] Cunningham, W.E., L.E. Markson, R.M Andersen, et al., "Prevalence and predictors of highly active antiretroviral therapy use in persons with HIV infection in the US," Journal of Acquired Immunodeficiency Syndrome, 25.2 (2002):115-123.

[31] Shapiro, M. et al, "Variations in the Care of HIV-Infected Adults in the United States: Results from the HIV Cost and Services Utilization Study," Journal of the American Medical Association, 281.24 (June 23, 1999).

[32] Bozzette, A., S.H. Berry, N. Duan et al., "The care of HIV-infected adults in the United States: HIV Cost and Services Utilization Study Consortium," New England Journal of Medicine, 339.26 (1998): 1897-1904.

Title II Base
HRSA distributes base Title II funding to all 50 states, the District of Columbia and the eight territories (Puerto Rico, Guam, the Virgin Islands, American Samoa, Marshall Islands, North Mariana Islands, Republic of Palau, and the Federal States of Micronesia) using a formula based on each jurisdiction's non-EMA estimated living AIDS cases over the most recent 10-year period. Estimated living AIDS cases residing within an EMA are also included in the formula, but receive less money per case due to the existence of Title I. States with fewer than 90 living cases receive a minimum Title II base grant of $200,000, and states with over 90 living AIDS cases receive a minimum of $500,000. U.S. territories receive a minimum of $50,000. States with more than 1% of total AIDS cases reported in the United States during the previous two years must contribute a match with their own resources.

ADAP Earmark
The state AIDS Drug Assistance Program provides medications to low-income individuals with HIV disease, who have limited or no coverage from private insurance or Medicaid, in all 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, the Marshall Islands, American Samoa and the Northern Marianas Islands. ADAP earmark awards are based on a formula using each jurisdiction's estimated living AIDS cases (EMA and non-EMA) over the most recent 10-year period.

ADAP Supplemental
Three percent of the ADAP earmark funds are set aside for grants to states with severe need that meet one of the following criteria: financial eligibility at or below 200% FPL, medical eligibility restrictions, limited formulary composition for antiretroviral medications, or limited formulary composition for the treatment of opportunistic infections. These funds are distributed to eligible states using the same living AIDS cases formula that determines state ADAP awards. States are required to provide a $1 match for each $4 of federal ADAP supplemental funding.

Emerging Communities
Title II also provides supplemental grants to states to support HIV services in emerging communities (EC)—cities reporting between 500 and 1,999 estimated living AIDS cases in the most recent five years. Title II directs $10 million or 50% of new Title II base funding, whichever is greater, to emerging communities. The greater of 25% of EC funding or $5 million is allocated for tier one (1,000 to 1,999) EC awards, and the greater of 25% of EC base funding or $5 million is allocated for tier two (500-999) EC awards. The formula used may cause the number of ECs to change from year to year. For instance, in FY2001 there were 39 ECs, in FY2002 35 ECs, in FY2003 33 ECs, in FY2004 29 ECs, and in FY2005 28 ECs.

MAI
Title II receives funding via the MAI to increase minority participation in ADAPs and other HIV-related services. HRSA distributes the MAI awards by an estimated living AIDS case formula based on disease burden in minority populations.

Title III
Title III provides direct grants to over 425 community-based primary health clinics and public health providers in 49 states, Puerto Rico, the District of Columbia, the Virgin Islands, and the Federated States of Micronesia, and it is an important means for targeting HIV-related medical services to underserved communities of color and in rural areas. Title III services include HIV

counseling and testing, medical evaluation and referral and outpatient clinical care. HRSA distributes Title III funds through competitive grants directed to service providers.

Early Intervention and Capacity Building Grants
Title III provides support directly to community-based providers for early intervention and primary care services for people with HIV/AIDS. Title III also provides funds for capacity building grants to help organizations develop, enhance or expand quality HIV/AIDS primary care services.

Planning Grants
Title III also funds planning grants, which help communities plan activities that will lead to a comprehensive continuum of outpatient HIV primary care services.

MAI
Title III MAI funds are distributed through both Early Intervention and Planning grants to health care providers with a history of serving communities of color to enhance their early intervention services capacity.

Title IV

Title IV provides access to comprehensive family-centered care for children, youth, women, and their families with or at risk for HIV, and access to research of potential clinical benefits. HRSA provides services to this population in 35 states, the District of Columbia, Puerto Rico, and the Virgin Islands.

HRSA administers Title IV funds through a competitive grant application process and directly funds 89 programs in three-year cycles, including 16 youth-focused programs. Title IV grantees include community and faith-based organizations, medical schools, children's hospitals, and state and community health departments.

MAI
Title IV MAI funds are distributed to Title IV grantees to deliver comprehensive, culturally competent and linguistically appropriate HIV care and support services to minority women, infants, and youth.

Part F: HIV/AIDS Education and Training Centers (AETCs)

AETCs support training for health care providers to counsel, diagnose, treat, and manage individuals with HIV infection and to help prevent high-risk behaviors that lead to infection. The AETC program consists of 10 regional programs and four national centers with a nationwide network of over 70 training sites serving all 50 states, Puerto Rico, the District of Columbia, and the six U.S. Pacific Jurisdictions. HRSA awards AETC funds through competitive bids.

MAI
AETCs receive funding via the MAI to increase the training capacity of centers to expand the number of community-based minority health care professionals with treatment expertise and knowledge about the most appropriate standards of HIV/AIDS-related treatments and medical care as developed by the U.S. Public Health Service.

Part F: Dental Reimbursement Program

This program provides support to 66 dental schools, postdoctoral dental education programs, and dental hygiene programs for care provided to persons with HIV/AIDS. HRSA reimburses these programs for the costs of providing oral health care to people with HIV/AIDS.

Special Projects of National Significance (SPNS)

SPNS support the development of innovative HIV/AIDS service delivery models that have potential for replication in other jurisdictions. The SPNS program is the research and development component of the CARE Act. SPNS is funded through a percentage tap on Title I, Title II base, Title III and Title IV of the CARE Act—up to $25 million.

Community-Based Dental Partnership Program (CBDPP)

The CBDPP funds eligible dental schools, postdoctoral dental education programs, and dental hygiene programs to increase access to oral health care for unserved and underserved rural and urban HIV positive populations. CBDPP funds support 12 eligible entities in 11 states.

Appendix B

Directory of State and Territorial AIDS Directors

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Appendix C

Title II Historical Funding Chart

State	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY2002	FY2003	FY2004
AL	$2,756,823	$4,167,971	$5,110,076	$7,294,833	$8,223,550	$10,100,107	$11,005,960	$10,867,008	$12,142,447
AK	$288,443	$362,917	$444,562	$593,491	$644,658	$863,456	$898,686	$926,023	$974,705
AZ	$2,260,259	$3,496,214	$4,553,503	$6,281,940	$7,876,550	$9,267,392	$10,130,689	$11,255,601	$11,648,614
AR	$1,369,814	$2,050,008	$2,505,494	$3,313,331	$3,729,267	$3,970,060	$4,397,016	$4,933,831	$4,933,831
CA	$36,282,354	$57,920,029	$73,677,524	$95,937,546	$106,594,028	$108,968,671	$115,580,982	$118,274,998	$121,425,527
CO	$2,509,154	$3,734,969	$4,614,053	$5,755,742	$6,501,977	$7,384,159	$7,988,712	$7,447,255	$8,420,061
CT	$3,651,778	$6,120,430	$8,267,209	$11,422,933	$12,473,062	$13,071,734	$13,873,014	$14,915,598	$15,175,723
DE	$1,259,006	$1,942,410	$2,429,055	$3,065,717	$3,444,082	$3,952,853	$4,549,172	$5,129,211	$5,340,795
DC	$3,332,588	$5,490,772	$7,719,573	$11,009,761	$12,208,813	$13,851,117	$15,492,398	$16,875,124	$18,323,488
FL	$25,220,349	$41,314,996	$53,845,136	$73,482,287	$84,151,932	$90,768,728	$99,913,339	$108,800,440	$111,668,948
GA	$7,394,151	$12,340,139	$16,211,799	$21,473,723	$24,609,445	$29,063,413	$31,581,983	$32,523,811	$36,143,569
HI	$1,180,678	$1,701,733	$1,933,618	$2,425,061	$2,714,578	$2,973,119	$2,879,231	$3,134,711	$3,298,130
ID	$285,657	$362,917	$444,562	$581,700	$637,862	$946,929	$977,028	$940,179	$1,019,352
IL	$7,260,236	$12,033,969	$15,478,545	$21,516,441	$23,741,440	$26,962,344	$29,041,633	$32,061,756	$34,870,568
IN	$2,762,555	$4,301,051	$5,362,040	$7,161,199	$7,813,244	$8,888,172	$9,607,370	$10,080,837	$11,402,950
IA	$613,264	$917,406	$1,104,116	$1,450,320	$1,597,254	$1,684,688	$1,886,371	$2,046,335	$2,067,375
KS	$1,050,840	$1,565,364	$1,888,481	$2,407,272	$2,680,639	$2,856,155	$2,993,080	$3,061,160	$3,061,160
KY	$1,344,978	$2,078,323	$2,882,026	$4,075,831	$4,679,465	$5,757,688	$6,377,776	$6,566,479	$7,170,005
LA	$4,080,447	$6,969,329	$9,199,630	$13,072,061	$14,659,595	$16,282,740	$19,462,270	$19,165,624	$22,953,426
ME	$536,845	$719,201	$806,854	$970,811	$1,053,098	$1,165,524	$1,222,848	$1,291,963	$1,333,909
MD	$6,521,685	$10,948,524	$14,847,982	$20,672,553	$23,625,388	$25,567,961	$28,539,346	$33,236,307	$34,509,971
MA	$4,836,051	$7,528,256	$9,780,533	$12,626,775	$15,135,145	$17,849,167	$19,027,859	$20,165,312	$20,190,874
MI	$3,897,084	$5,814,246	$7,690,514	$10,452,742	$11,836,551	$12,389,033	$13,817,447	$14,902,329	$15,455,849
MN	$1,249,617	$1,878,085	$2,365,346	$2,995,477	$3,429,038	$3,583,168	$3,930,918	$4,041,505	$4,059,707
MS	$1,868,450	$2,760,714	$3,623,766	$4,995,545	$5,940,732	$7,005,955	$7,994,828	$8,927,096	$9,454,950
MO	$3,131,126	$4,586,448	$5,952,010	$7,811,393	$8,842,764	$9,100,570	$10,041,335	$10,231,106	$10,250,137
MT	$129,912	$201,037	$375,524	$477,324	$493,995	$766,328	$784,249	$798,932	$847,196
NE	$506,277	$733,358	$931,421	$1,206,634	$1,363,635	$1,556,845	$1,752,274	$1,735,366	$1,887,660
NV	$2,049,946	$3,001,392	$3,898,380	$4,647,952	$4,962,828	$5,341,517	$5,768,265	$6,248,392	$6,456,309
NH	$332,092	$529,197	$651,190	$861,790	$927,722	$1,137,986	$1,170,914	$1,225,589	$1,257,028
NJ	$13,135,111	$21,380,789	$28,345,926	$37,702,846	$40,762,441	$43,471,413	$45,652,579	$47,117,129	$47,641,537
NM	$882,641	$1,183,568	$1,687,316	$2,476,155	$2,684,197	$2,842,890	$3,042,298	$3,338,463	$3,338,463

State	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY2002	FY2003	FY2004
NY	$38,324,520	$64,354,160	$87,884,362	$127,095,837	$138,462,204	$147,829,027	$153,793,751	$166,416,534	$169,263,213
NC	$4,810,589	$7,053,271	$8,657,402	$11,672,934	$13,337,097	$16,397,641	$17,948,397	$18,905,269	$22,655,805
ND	$107,243	$124,390	$145,189	$175,060	$183,474	$287,207	$288,717	$292,543	$292,543
OH	$4,668,106	$7,316,497	$8,953,866	$11,834,654	$12,862,596	$13,812,449	$14,653,307	$15,732,171	$16,762,266
OK	$1,656,387	$2,282,191	$2,890,518	$3,902,893	$4,285,048	$5,081,993	$5,890,896	$5,923,857	$6,343,022
OR	$1,684,631	$2,749,308	$3,438,455	$4,333,257	$4,722,939	$4,836,281	$5,266,094	$5,719,559	$5,902,627
PA	$7,991,467	$12,944,947	$1,693,781	$23,632,455	$26,896,745	$29,471,755	$32,266,464	$37,124,991	$33,759,339
RI	$1,083,242	$1,548,831	$1,843,025	$2,354,312	$2,574,101	$2,814,801	$2,981,815	$3,104,681	$3,189,276
SC	$4,516,376	$6,622,883	$8,161,966	$10,934,388	$13,250,895	$16,641,780	$18,086,947	$18,549,396	$20,705,328
SD	$112,536	$138,843	$161,507	$205,084	$233,352	$338,771	$372,293	$391,032	$705,706
TN	$3,757,915	$5,736,623	$7,230,546	$9,818,153	$11,468,392	$14,706,935	$16,464,366	$21,178,234	$21,178,234
TX	$16,132,517	$25,697,515	$35,149,403	$50,244,224	$56,932,045	$66,476,848	$70,384,189	$68,629,133	$76,009,370
UT	$810,043	$1,251,524	$1,542,931	$2,083,114	$2,426,761	$2,788,914	$3,111,672	$3,235,191	$3,235,191
VT	$279,529	$342,140	$404,394	$488,047	$510,156	$787,721	$838,895	$883,059	$883,059
VA	$5,365,718	$8,116,678	$10,452,242	$13,099,292	$14,845,195	$18,847,843	$20,770,666	$20,375,565	$22,525,348
WA	$3,154,250	$4,898,005	$6,404,980	$8,333,780	$9,019,810	$9,311,929	$10,243,929	$10,986,852	$11,121,586
WV	$446,290	$740,356	$937,140	$1,422,541	$1,462,626	$1,705,633	$1,856,487	$1,943,767	$2,175,400
WI	$1,840,433	$2,579,528	$3,054,537	$3,812,983	$4,242,502	$4,918,809	$5,290,698	$5,183,308	$5,588,912
WY	$113,650	$137,940	$169,038	$196,506	$205,536	$329,954	$340,041	$350,383	$360,347
GU	$4,970	$11,608	$11,052	$19,652	$38,809	$116,169	$118,503	$132,268	$135,839
PR	$9,376,181	$12,920,475	$16,793,353	$23,401,013	$25,647,632	$26,646,201	$28,814,408	$30,748,881	$33,759,339
VI	$197,360	$191,525	$222,610	$624,935	$667,110	$833,928	$772,935	$976,601	$1,048,657
AS						$50,000	$50,000	$52,314	$52,314
MI						$50,000	$51,323	$52,314	$52,314
North Mar						$50,000	$51,323	$54,627	$54,627
RP						$50,000	$50,000	$50,000	$50,000
FSM						$50,000	$50,000	$50,000	$50,000
TOTAL	**$250,414,164**	**$397,895,000**	**$504,830,061**	**$709,904,300**	**$794,314,000**	**$874,624,471**	**$942,189,986**	**$999,308,000**	**$1,051,141,061**

Appendix D

FY2004 Title II Funding Awards

State/Territory	Base	AIDS Drug Assistance Program	Minority AIDS Initiative	Emerging Communities	Tota
Alabama	$4,042,811	$7,829,548	$77,828	$192,260	$12,142,447
Alaska	500,000	472,602	2,103	0	974,705
Arizona	3,201,547	8,392,903	54,164	0	11,648,614
Arkansas	1,785,169	3,116,716	31,946	0	4,933,831
California	31,236,233	89,623,465	565,829	0	121,425,527
Colorado	2,117,525	6,268,355	34,181	0	8,420,061
Connecticut	3,779,591	11,315,018	81,114	0	15,175,723
Delaware	1,848,490	3,202,722	39,177	250,406	5,340,795
District of Columbia	4,305,124	13,842,594	175,770	0	18,323,488
Florida	29,860,865	80,386,630	893,442	528,011	111,668,948
Georgia	9,408,492	26,474,249	260,828	0	36,143,569
Hawaii	1,203,101	2,084,512	10,517	0	3,298,130
Idaho	500,000	518,826	526	0	1,019,352
Illinois	8,837,193	25,746,254	287,121	0	34,870,568
Indiana	3,768,825	6,529,924	47,196	1,057,005	11,402,950
Iowa	753,765	1,305,985	7,625	0	2,067,375
Kansas	1,007,120	2,045,495	8,545	0	3,061,160
Kentucky	2,358,712	4,568,023	22,875	220,395	7,170,005
Louisiana	6,211,002	15,458,640	192,072	1,091,712	22,953,426
Maine	500,000	833,383	526	0	1,333,909
Maryland	8,446,358	25,746,254	317,359	0	34,509,971
Massachusetts	5,223,382	14,684,416	99,257	183,819	20,190,874
Michigan	4,335,555	11,002,763	117,531	0	15,455,849
Minnesota	1,026,762	3,010,727	22,218	0	4,059,707
Mississippi	3,345,060	5,795,703	88,477	225,710	9,454,950
Missouri	2,783,489	7,409,723	56,925	0	10,250,137
Montana	500,000	346,670	526	0	847,196
Nebraska	639,300	1,238,106	10,254	0	1,887,660
Nevada	1,684,896	4,738,678	32,735	0	6,456,309
New Hampshire	500,000	755,319	1,709	0	1,257,028
New Jersey	12,302,631	34,877,598	279,365	181,943	47,641,537
New Mexico	1,195,795	2,127,024	15,644	0	3,338,463
New York	42,659,431	124,956,784	1,252,475	394,523	169,263,213

North Carolina	7,403,985	14,345,524	197,593	708,703	22,655,805
North Dakota	200,000	92,543	0	0	292,543
Ohio	5,448,305	10,909,930	67,968	336,063	16,762,266
Oklahoma	2,054,284	4,074,872	23,795	190,071	6,343,322
Oregon	1,664,149	4,225,989	12,489	0	5,902,627
Pennsylvania	10,779,206	27,090,216	258,856	188,196	38,316,474
Puerto Rico	8,238,917	25,259,725	260,697	0	33,759,339
Rhode Island	1,103,249	1,911,506	14,461	160,060	3,189,276
South Carolina	6,774,143	13,119,209	164,858	647,118	20,705,328
South Dakota	500,000	204,654	1,052	0	705,706
Tennessee	6,185,987	12,018,438	122,526	2,851,283	21,178,234
Texas	19,125,106	56,415,194	469,070	0	76,009,370
Utah	1,074,024	1,980,565	7,099	173,503	3,235,191
Vermont	500,000	382,007	1,052	0	883,059
Virginia	5,929,341	16,206,221	145,007	244,779	22,525,348
Washington	3,118,978	7,966,718	35,890	0	11,121,586
West Virginia	713,239	1,457,428	4,733	0	2,175,400
Wisconsin	1,831,726	3,553,982	28,791	174,440	5,588,912
Wyoming	200,000	160,347	0	0	360,347
American Samoa	50,000	2,314	0	0	52,314
Federated States of Micronesia	50,000	0	0	0	50,000
Guam	50,000	94,332	1,446	0	145,778
Marshall Islands	50,000	2,314	0	0	52,314
Northern Marianas	50,000	4,627	0	0	54,627
Republic of Palau	50,000	0	0	0	50,000
Virgin Islands	353,137	687,763	7,757	0	1,048,657
Total	**$285,366,000**	**$728,030,284**	**$6,913,000**	**$10,000,000**	**$1,051,141,061**