



The Title II Community  
AIDS National Network  
1775 "T" Street, NW  
Washington, DC 20009

Phone: (202) 588-1775

Fax: (202) 588-8868

Web: [www.tiicann.org](http://www.tiicann.org)

Email: [weaids@tiicann.org](mailto:weaids@tiicann.org)

*Christopher D. Phipps, Esq. Counsel*  
*Herbert W. Perry CPA/EA*  
*Founder – Chair, Emeritus*

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*(26/3/05)*



# TITLE II COMMUNITY AIDS NATIONAL NETWORK: RYAN WHITE CARE ACT REAUTHORIZATION POSITION PAPER

May 21 2005

**The Ryan White CARE Act, Title II, Community AIDS National Network, Inc.**

**A 501(c)(3) Policy & Program Information Exchange & Support Organization for AIDS/HIV Education, Advocacy, Support & Action.**

## Executive Summary

The Title II Community AIDS National Network (TIICANN) is a national leader in education, advocacy, and collaboration to achieve equitable access to a comprehensive and accountable system of care and services, creating a voice for all people living with HIV/AIDS, their families, and their communities.

We strongly recommend that any discussion on reauthorizing the Ryan White Care Act (CARE Act) be premised on the findings and recommendations of the Institute of Medicine (IOM) Report, *The Public Financing and Delivery of HIV/AIDS Care*. This groundbreaking report was one of two ordered by the Department of Health and Human Services (HHS) in preparation for reauthorizing the CARE Act in 2005. Disturbingly, despite the convincing rationale supporting the need for a new and more effective delivery vehicle for HIV/AIDS medical care in the United States, the report was summarily dismissed by HHS.

The most significant finding of the IOM was that no health delivery system could be reconfigured to meet the very specific demands of HIV/AIDS care: **"The CARE Act was not designed nor can it be reconfigured to provide the HIV standard of care across discretionarily funded jurisdictions."** Neither Medicare nor Medicaid is capable of providing this care since patients must be disabled to be enrolled. How can these programs provide a standard of care whose primary goal is to prevent disability in the first instance? Private health insurance, unless substantially reconfigured, is also an increasingly unreliable source of care. Currently private insurance only covers about 20% of people living with HIV/AIDS, a proportion that has remained relatively flat over many years.

If none of these mechanisms can provide the care that nearly every expert agrees is required to maximize the benefits of a standard of care established in 1996 with the introduction of combination antiretroviral therapy (ART), what are the remaining options? First, a current program could be amended. The IOM makes a strong case that this will be inefficient and could be impossible. Second, maintain the status quo. This is patently unacceptable. As a society we can not afford to allow patients to continue to become sick and die needlessly when cost-effective means are available to prevent this outcome. In discussing an earlier proposal to amend Medicaid requirements to provide comprehensive HIV/AIDS care, the Director of the Health Care Financing Administration (now Centers for Medicare and Medicaid Service or CMS) stated that it was not the policy of the United States Government to permit patients to suffer needless morbidity and mortality to save money. We call on this Administration to either recommit to this principle or to openly state a change in position.

If the policy of the United States government has changed, and we are now obligated to inadequate management of the U.S epidemic, then certain changes are required.

First, TIICANN strongly supports strengthening the CARE Act by making it a more equitable funding source for all people living with HIV/AIDS in the United States.

Second, we support including the Early Treatment of HIV Act (ETHA) as an amendment to the reauthorized CARE Act.

Even if a new entitlement program conforming to the IOM program is established, however, the CARE Act will still be necessary to provide the adhesive that assures that people living with HIV have unimpeded access to the full range of social and support services they need, not just to stay alive, but to live full, rewarding, and productive lives. During implementation of the entitlement program outlined above, an advisory group made up of consumers, CARE Act providers, medical care providers, representatives of state HIV/AIDS departments (all to be nominated and selected by communities of their peers), and appropriate Health Resources Services Administration (HRSA) and HHS personnel should be named to plan and to coordinate:

1. Transition issues, including assurance that historically-funded CARE Act programs are included as grantees in the Centers of Excellence matrix; and
2. The continuation of CARE Act services until there is an assurance that such services are readily available to CARE Act consumers through the new program.

## **The Ryan White CARE Act must be amended to be more equitable**

Currently, a minimum of thirty states fall below equity in per capita CARE Act funding. These states receive fewer dollars per person with AIDS than other states and, thus, are forced to restrict necessary services. Steps are required during this third reauthorization process to address this problem.

Our goals in the following recommendations are:

1. To maximize services and minimize administrative costs and
2. To equalize services available to consumers in states without Title I funding.

### Specific proposals

#### 1. Title I

- a. Title I eligibility should be reopened, and eligibility should be expanded to cities with up to 1,500 countable AIDS cases. All eligible cities should be funded according to appropriate formulas, but before the application of Title I hold harmless provisions.

#### 2. Title II AIDS Drug Assistance Program (ADAP)

- a. Title II ADAP Supplemental Treatment Drug Grants should be funded at 50% of annual ADAP increases until either the implementation of the primary care system recommended in this paper is complete or until all states are able to provide:
  - i. ADAP services to all consumers who are HIV-positive, insufficiently insured, and earn up to 350% - *at a minimum* - of the federal poverty level.
  - ii. State formularies include **all** Food and Drug Administration (FDA) approved antiretrovirals and all drugs recommended in PHS Guidelines for the Treatment and Prevention of Opportunistic Infections.
- b. All rebates or discounts collected under Title II ADAP programs, which must be allocated back to the ADAP programs to which they are credited.
- c. Title II ADAP Base Funding must be increased by at least \$120 million per year for the term of this reauthorization or until the implementation of the primary care system recommended in this paper is completed, whichever occurs first. If \$120 million is not appropriated by Congress, the difference between the yearly appropriation and \$120 million shall be made up by a proportional tap on the funding of all non-ADAP Titles.
- d. ADAP Needs Assessment: HRSA should be required within one year of the passage of a reauthorized CARE Act to develop and verify a reliable ADAP pharmacoeconomic forecasting model, the findings of which must be presented to Congress with or before the President's presentation of his budget to Congress.

3. Title II Emerging Communities: This funding is critical to those states that use these funds to ensure access to a wide array of otherwise restricted services including primary medical, dental care, case management, etc. We recommend that this funding become a permanent part of a qualifying state's Title II base allocation in order to assure that services are not disrupted.

4. Title III: Title III funding should be prioritized for grantees in states that receive no Title I funding.

## PROVIDING UNIFORM ACCESS TO THE STANDARD OF CARE FOR HIV REQUIRES A NEW ENTITLEMENT

In 2004 the Institute of Medicine (IOM), in response to a request from the Health Resources Services Administration (HRSA), released *Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White*. The recommendations in the report centered on the development of a new entitlement to basic health care for all uninsured and underinsured people living with HIV/AIDS in the United States. After a brief flurry of interest, HRSA, on behalf of the Bush Administration, dismissed the report, stating publicly that the IOM had exceeded its authority in suggesting the creation of a new entitlement. The Title II Community AIDS National Network (TIICANN) strongly supports the findings and recommendations of the IOM report. Extensive data clearly demonstrates that the delivery of coordinated HIV medical care is efficient, effective, and relatively inexpensive in comparison to the systems presently available.

As the IOM report concluded:

*"The current financing and delivery system for publicly financed HIV care is complex and undermines the significant advances made in the development of new technologies to treat HIV/AIDS, such as highly active antiretroviral therapy (HAART). Many individuals experience delays in treatment access or are provided only limited options for specific drugs or important laboratory monitoring. As a result, each year there are missed opportunities to reduce mortality, morbidity and disability among individuals with HIV infection. It is not uncommon for patients to receive care for the first time with advanced disease stages. The fact that about 40,000 new AIDS diagnoses and 16,000 deaths occur each year further indicates that our current system is failing to ensure adequate health care for persons living with HIV infection. A similar number of new HIV infections each year indicate that the threat to the public's health from HIV continues."<sup>1</sup>*

The shortcomings of the present system of care are an inevitable outcome of attempting to deliver access to primary care for a potentially deadly chronic disease; the standard of care for HIV disease is constantly evolving, and primary care and medications must reach an ever growing number of patients through fragile, discretionarily funded programs, such as the CARE Act, Medicaid, Medicare, the Veterans Administration, etc.. The IOM cites three primary reasons that an entitlement program is required in order to maximize the opportunities that advances in the HIV standard of care have offered:

*"First, although current public financing strategies for HIV care have provided care to, and extended the lives of many low-income individuals, significant disparities remain in assuring access to the standard of care for HIV across geographic and demographic populations. As a result, many individuals have no access or limited access to the standard of care for HIV.*

*Second, certain characteristics of the system (e.g. fragmentation of coverage, multiple funding sources with different eligibility requirements, and significant variations in the type of HIV services offered), do not allow for comprehensive and sustained access to quality HIV care. In many respects, this system, conceived in the early epidemic, is inadequate to meet current needs.*

*Third, the current federal-state partnership for financing HIV care is unresponsive to the fact that HIV/AIDS is a national epidemic with consequences that spill across state borders."<sup>2</sup>*

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<sup>1</sup> IOM, *Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White*. May 2004

<sup>2</sup> Ibid

In short, a *standard* of care can **not** be equitably or efficiently provided through dozens of unequal and uncoordinated federal, state, and municipal programs. Despite the barriers and fragmentation of the current system, dramatic achievements have been produced. However, these achievements are not likely to be improved upon or even maintained unless a more coherent system is implemented with a capacity to absorb significant numbers of HIV-positive individuals not presently in HAART into a consistent system of care throughout the United States.

National data collected in 2003 led the Centers for Disease Control (CDC) to conclude that there should be approximately 480,000 HIV-positive Americans between the ages of 15 and 49 receiving antiretroviral therapy according to current treatment guidelines. Instead only 268,000 of those people were actually receiving treatment. The conclusion is that at least 212,000 more HIV-positive patients should be accessing HIV treatment, but are not. This number does not include the estimated 470,000 people whom the CDC estimates do not know their HIV status. Perhaps this lack of treatment explains why, fifteen years after the general availability of HAART, a large number of patients first learn that they are HIV-positive when they are hospitalized with an AIDS-defining condition.

This data makes it impossible to conclude that medical care, as it is presently being delivered, is adequate for most people living with HIV. If the system proposed here were available, anyone, upon being tested, could be assured that they would receive the appropriate standard of care. Without that assurance, what reason do we have to believe that the CDC estimates will change?

This situation is forcing a number of at risk individuals, many uninsured or inadequately insured, most of whom are African American or Latino, to perform a personal calculus in which they must decide if they would rather not be informed, placing themselves at the mercy of a medical system that may - or may not - be willing to take care of them. It is probable that many have already taken the equation to their own ends and decided that they would rather not know their HIV status. As a result tens of thousands of HIV-positive Americans will wait until they are sick enough not to have a choice in accessing treatment. By this point they may have spread their infection. They will also probably require expensive hospitalization or, at minimum, expensive care for one or more opportunistic infections. They might die and, even if they don't, they will present an expensive and complicated challenge for medical providers. Add up these expenses, and even if you ignore the unnecessary pain, suffering, and deaths that are an inevitable byproduct of this process, the resources that have been dedicated to caring for one individual could have provided care for many at an earlier stage of HIV disease.

The new system, to be effective, must:

- Ensure that low-income, HIV-infected individuals have access to an early, appropriate, and comprehensive set of medical and ancillary services that meet the federally defined standard of care. Eligibility must be set at a nationally uniform standard that ensures that low-income HIV patients at, or under, **at least** 350 percent of the federal poverty level (FPL) have coverage for recommended services regardless of where they reside. Spend down provisions for those over that threshold and who have extensive medical costs should also be included so that the uninsured or underinsured with higher incomes may participate through a sliding premium scale;
- Promote the delivery of high-quality services and a benefits package that meets the standard of care for HIV/AIDS and is uniform for all eligible patients;

- Facilitate the provision of services, with a minimum of administrative costs (for payers and providers) and a minimum of duplication of effort. Reimbursement rates must be adequate to enable providers to furnish services commensurate with the standard of care; and
- Be premised on a new financing mechanism with accountability controls that is capable of supporting eligibility, benefits, and provider payments that meet the standard of care, that is stable over time, and that inherently includes sufficient secure data to accurately measure results, health outcomes, and cost effectiveness.

The following benefits must be guaranteed to eligible enrollees:

- Primary care and prevention services: Under the Centers of Excellence model, experienced HIV primary care would encourage the best possible outcomes. Primary care should include physician and related health professional visits, hospital care, laboratory services, dental care, and such other services as may be determined by the Centers of Excellence model to provide comprehensive care to their patients. Voluminous data support the contention that HIV-positive patients with access to "expert" care have significantly longer life expectancies than those who do not. In addition only by assuring access to experienced medical care and a reliable system of provider reimbursement will programs such as the CDC's *Advancing HIV Prevention Initiative* (prevention for HIV-positives) have any real chance to succeed. If such care is reimbursed and providers are attached in a Centers of Excellence model, current disincentives by non-experienced providers to counsel and provide HIV testing will also be removed.
- HAART, opportunistic infection treatments, and prophylaxis and treatments for side effects: HAART and HIV-related medications are the center of reductions in death rates and dramatically lower rates of disease progression since 1996. The combination of access to drugs supported by experienced medical care will lead to significant improvement in both the patient's health and the public health.
- HIV case management: Expert case management provides a relatively inexpensive means of coordinating health care services, especially for populations with little or no experience in negotiating complex systems. Case management also permits coordination of healthcare with other required services, such as transportation, housing, and nutrition, which may not be provided under this benefit.
- Obstetric and gynecological services: If provided uniformly and in the context of primary care, these services have the capacity to eliminate perinatal transmission in the United States while guarding and improving women's health.
- Mental health and substance abuse services: According to the Johns Hopkins School of Public Health, up to 70 percent of patients with recent HIV diagnoses have mental health and/or substance abuse problems. Treating these underlying conditions leads to significantly better outcomes at a relatively low per-patient cost.
- Centers of Excellence (COE): The IOM proposes and TIICANN strongly supports providing all services through Centers of Excellence in HIV/AIDS Care. As numerous pilot projects have demonstrated, the principle of disease management embodied in the COE model provides the best possible care at the lowest possible cost with experienced medical providers leading the decisions on the costs benefit relationship between services offered, outcomes, and outlays. In addition a COE structure would make effective use of the expert

systems of care built through Ryan White CARE Act funding over the last fifteen years (see below).

The cost of deploying such a system is small compared to the proven benefits it would afford. A summary of these benefits must include:

- Preventing disability saves lives. According to the CDC, since the introduction of highly active antiretroviral therapy in 1996, deaths from AIDS in the US have dropped by over 70%. According to 2004 data by the RAND Corporation, *if early intervention were made universally available, death rates could drop by a further 66%*.<sup>3</sup>
- Providing early intervention saves money. Recent data from a study of the California ADAP program showed that while ADAP costs for an HIV-positive patient were \$28,100 a year, costs for an AIDS patient with at least one opportunistic infection were \$63,051 a year without hospitalizations. If one hospitalization is added, costs increase to \$106,102.<sup>4</sup> Cost differentials, especially in terms of costs per life year saved, are likely to be even more impressive under the system outlined here.
- Early intervention reduces new HIV infections. Data released last year in the journal *AIDS* showed that infectivity dropped by 60% with the introduction of HAART.<sup>5</sup> This data was confirmed by the National Institutes of Health in a study that showed infectivity dropped by 53% after introduction of HAART.<sup>6</sup> More uniform access to a full standard of care that provides the capacity to merge HIV prevention with primary medical care will lead to even more dramatic reductions in new HIV infections.

## THE RYAN WHITE CARE ACT MUST BE MAINTAINED

Of crucial note is the fact that the recommendations set out in this paper are in no way intended to compromise either the necessity for or the proven successes of the Ryan White CARE Act. Regardless of the development of an HIV primary care delivery system, the CARE Act will remain an essential tool. The CARE Act was never designed to provide basic medical care and, because it is formula driven and funded with discretionary resources, reconstruction of the CARE Act to do so would be impossible.

We strongly support strengthening the Ryan White CARE Act to do what it does best: provide the adhesive that assures that people living with HIV have unimpeded access to the full range of social and support services they need, not just to stay alive, but to live full, rewarding, and productive lives. Without national access to primary care, however, the utility of the CARE Act will become further and further compromised at a time when data indicate that many more existing HIV-positive patients should be in active treatment and that many more will be infected, and/or discovered in the coming five-year reauthorization period..

<sup>3</sup> Bhattacharya, J., Goldman, D., & Sood, N. (2004). The link between public and private insurance and HIV-related mortality. *Journal of Health Economics*, 22, 1105-1122. Abstract available at <http://www.taepusa.org/studies&reports.htm>.

<sup>4</sup> <http://www.atdn.org/nycase.pdf>

<sup>5</sup> Porco, T.C., Martin, J.N., et al. (2004). Decline in HIV infectivity following the introduction of highly active antiretroviral treatment. *AIDS*, Jan 2, 18(1), 81-88. Abstract at <http://www.taepusa.org/studies&reports.htm>

<sup>6</sup> Fang, C., Hsu, H., Twu, S., et al. (2004). Decreased HIV transmission after a policy of providing free access to highly active antiretroviral therapy in Taiwan. *Journal of Infectious Diseases*, 190, 879-885. Abstract at <http://www.taepusa.org/studies&reports.htm>

Specifically even if the new entitlement were immediately authorized, the process of implementation could easily take years. During that time, **all services provided by the CARE Act must be maintained.**

For these purposes an advisory group made up of consumers, CARE Act providers, medical care providers, representatives of state HIV/AIDS departments (all to be nominated and selected by communities of their peers), and appropriate HRSA and HHS personnel should be named within 60 days of authorizing legislation to plan and coordinate:

1. Transition issues, including assurance that historically-funded CARE Act programs are included as grantees in the Centers of Excellence matrix and
2. That no CARE Act services are discontinued until there is an assurance that such services are readily available to CARE Act consumers through the new program.

#### **STRENGTHENING THE RYAN WHITE CARE ACT:**

Our goals in the following recommendations are:

1. To maximize services and minimize administrative costs and
2. To begin to equalize services available to consumers in states without Title I funding.

Therefore, any changes to the Ryan White CARE Act through this reauthorization process must:

- a) **Limit Harm:** Changes to the CARE Act must ensure, to the greatest degree possible, that these changes limit actual harm, to health or to quality of life, to those served by the CARE Act or to communities and their members affected by or at risk for HIV infection. This recommendation should *not* be interpreted as a requirement that any specific provider or group of providers be held harmless in the process of reorganizing funding streams capable of providing nationwide access to the core services outlined below.
- b) **Reduce Data Collection and Management:** Little of the data collected by CARE Act grantees utilizing CARE Act funds has proven useful in any context except CARE Act administration. When these potentially rich sources of data have been analyzed by non-federal reviewers, however, reports and articles have been produced which have had a dramatic impact. For example, *The ADAP Monitoring Report*, produced annually by the National Alliance of State and Territorial AIDS Directors, the Kaiser Family Foundation, and the AIDS Treatment Data Network from data supplied by Title II ADAP Directors, provides one of the most comprehensive analyses available of any federal program. We suggest, therefore, that grantees be asked by the federal government to produce only data required for actual program administration. Program analyses utilizing patient level data are most efficiently provided using outside funding and impartial reviewers.
- c) **Eliminate Unfunded Mandates:** With repeated reauthorizations, the CARE Act has become a vehicle for policy initiatives that have little to do with the efficient and cost effective provision of key services to people living with HIV. In many cases these initiatives have incurred program and administrative costs that would have been better utilized by providing direct services, while the goals of such initiatives would have been better served had their requirements been imposed on more appropriate federal or state entities. Prevention initiatives, for example, are more efficiently administered by the CDC and related state authorities. No provision should be included or maintained in a reauthorized CARE Act unless it directly relates to: 1) the provision of key services or 2) the minimum necessary administration to assure the efficient provision of those services. In addition when administrative burdens are placed on grantees, they must be funded sufficiently to meet their



stated purposes. If they are not adequately funded, then the result is garbled data funded with resources that could be used most efficiently to provide services.

- d) Maximize Substantive Participation by Consumers of CARE Act Services: A reauthorized CARE Act must ensure that consumers maintain and expand their substantive participation in all policy, prioritization, funding, and planning functions carried out under the CARE Act mandates.

## **Specific Proposals**

### **1. Title I**

- a. Title I eligibility should be reopened and eligibility should be expanded to cities with up to 1,500 countable AIDS cases. All eligible cities should be funded according to appropriate formulas but before the application of Title I hold harmless provisions. This change is required to begin equalizing the services available currently only to people living with HIV in states that receive Title I funding. While we understand that such a change may cause disruption to historically-funded Title I grantees, we believe that the creation of the entitlement program at the center of these recommendations will minimize the practical impact of these changes. In any case the inequity between key services available to clients in Title I funded versus non-Title I funded areas has become insupportable and must be addressed.

### **2. Title II ADAP**

- a. Title II ADAP Supplemental Treatment Drug Grants should be funded at 50% of annual ADAP increases until either the implementation of the primary care system recommended in this paper is complete or until all states are able to provide:
- i. ADAP services to all consumers who are HIV-positive, insufficiently insured, and earn up to 350% - *at a minimum* - of the federal poverty level;
  - ii. State formularies include **all** FDA approved antiretrovirals and all drugs recommended in PHS Guidelines for the Treatment and Prevention of Opportunistic Infections;
- b. All rebates or discounts collected under Title II ADAP programs must be allocated back to the ADAP programs to which they are credited and not diverted to other federal, state, or municipal services;
- c. Title II ADAP Funding must be increased by at least \$120 million per year for the term of this reauthorization or until the implementation of the primary care system recommended in this paper is completed, whichever occurs first. If \$120 million is not appropriated by Congress, the difference between the yearly appropriation and \$120 million shall be made up by a proportional tap on the funding of all non-ADAP Titles. Note that this amount is sufficient only to maintain services at the current levels. This funding will not be necessary when the entitlement outlined above is implemented.
- d. ADAP Needs Assessment: HRSA should be required within one year of the passage of a reauthorized CARE Act to develop and to verify a reliable pharmacoeconomic model that:
- i. Accurately predicts ADAP need by state and income level (e.g., <350% of FPL, or >350% of FPL) and presents the total federal need;

- ii. Includes a base formulary assumption, including all FDA approved antiretrovirals and all drugs included in PHS Guidelines for the Treatment and Prevention of Opportunistic Infections; and
  - iii. Accounts for the number of ADAP clients who have and do not have access to primary medical care and the source of that care.
  - iv. Requires by 2007 that the Secretary will provide to Congress a comprehensive report based on the model on or before the date on which the President provides his budget to Congress.
3. Title II Emerging Community Funding: This funding is critical to those states that use these funds to ensure access to a wide array of otherwise restricted services, including primary medical care, dental care, case management, etc. We recommend that this funding become a permanent part of a qualifying state's Title II base allocation in order to assure that services are not disrupted. We also support the recommendation of the Southern AIDS Coalition (SAC) that once a state qualifies for Emerging Community Funding that the funding become permanent.
4. Title III: Funding under Title III should be prioritized to grantees in states that receive no Title I funding.
5. Early Treatment of HIV Act (ETHA): Attaching ETHA as an amendment to a reauthorized Ryan White CARE Act would allow states to begin coordinating the systems of care required by the new entitlement program and would also serve as an early test of the viability and cost-benefit of the new entitlement.

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**Approved by the Title II Community AIDS National Network Board of Directors on May 20, 2005**