Strengthening the Ryan White CARE Act

Recommendations for the 2005 Reauthorization of the CARE Act from the American Academy of HIV Medicine and the HIV Medicine Association

ACKNOWLEDGMENTS

Members of the American Academy of HIV Medicine (AAHIVM) and the HIV Medicine Association (HIVMA) who work in programs funded by the Ryan White CARE Act developed these recommendations for improving the CARE Act. The recommendations were subsequently reviewed, approved and fully endorsed by the Board of Directors of both organizations (see Appendixes 1 and 2).

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INTRODUCTION

AAHIVM and HIVMA are the two leading associations of HIV medical providers and collectively represent nearly all of the clinicians who deliver HIV care in the United States. The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act program plays a critical role in helping us meet the medical needs of our patients. We strongly support the reauthorization of this vital program.

Without the CARE Act, many of our patients would go without lifesaving therapies and care. Programs and services funded by the CARE Act attempt to fill the void in meaningful health care coverage that is left by the U.S. health care system, which relies on private insurers and targeted federal/state programs (e.g., Medicaid and Medicare) for financing health care.

As health care providers who have witnessed the remarkable transformation of AIDS from a terminal to a chronic yet complex condition, HIVMA and AAHIVM offer the following recommendations for the reauthorization of the Ryan White CARE Act. Our recommendations reflect the current standard of HIV care in the United States and are intended to improve access to quality HIV care through programs and services supported by the CARE Act.

In addition to our recommendations for improving the delivery of services through CARE Act–funded programs, AAHIVM and HIVMA strongly support passage of the Early Treatment for HIV/AIDS Act (ETHA). ETHA is modeled after the Breast and Cervical Cancer Act and would provide states the option of offering Medicaid coverage to people with HIV before they develop AIDS and become disabled. Passage of ETHA would significantly improve the lives of low-income people with HIV by delaying the onset of AIDS through the provision of early and more reliable access to drug therapies and treatment.

Despite its significant successes, multiple years of virtual flat funding for the CARE Act have severely limited the program's ability to fill the gaps left by private insurers and federal/state programs. The CARE Act must be reauthorized and adequately funded to support the recommendations outlined in this document.

I. PRIORITIZE MEDICAL CARE IN THE RYAN WHITE CARE ACT: ENSURE ACCESS TO LIFESAVING MEDICAL CARE

As a result of improved HIV medical care, individuals with HIV are living longer.[1] Health care models have evolved from a focus on the acute, terminal illness to multidisciplinary chronic care models. Comprehensive primary health care has thus taken on a critical role in the management of people with HIV disease. As medical providers, we believe that it is a fundamental responsibility to provide consistent, high-quality medical services to uninsured and underinsured U.S. residents living with HIV/AIDS. We define primary medical care and basic medical services as the range of interventions that directly treat HIV infection and its complications and improve HIV-related health outcomes. We believe that the core function of the CARE Act is to address the gaps in coverage of primary medical care and basic medical services for people with HIV/AIDS.

HIVMA and AAHIVM recommend that primary medical care and other basic medical services be authorized and prioritized for funding under the CARE Act. Specifically, we propose that Title I and Title II grantees be required to devote at least 25 percent of their grant awards to Primary Medical Care Services and an additional 25 percent to Basic Medical Services. Primary Medical Care and Basic Medical Services are defined below.

Primary Medical Care Services

- Physician and other medical provider visits, including adherence services
- Subspecialty care related to HIV and/or HIV treatments or that plays an integral role in the success of HIV treatment with a specific population, such as obstetric and gynecological services and pediatric HIV specialists
- Medically necessary medications, including all approved antiretroviral medications
- Laboratory tests to monitor the effectiveness and safety of treatment, including HIV viral load, CD4+ T-cell testing, and appropriate resistance tests
- Clinical pharmacology consultation and services

Basic Medical Services

- Medically necessary oral health services
- Mental health services
- Substance abuse treatment
- Prevention counseling in HIV clinical settings
- Nutrition counseling

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[1] Centers for Disease Control and Prevention. HIV/AIDS Surveillance: General Epidemiology (L178 Slide Series, updated through 2002). Available at: www.cdc.gov/hiv/graphics/surveill.htm. Accessed January 28, 2005.

- Hospice

Given the disproportionate impact of poverty and comorbidities in the patients we serve, coupled with the complexities and challenges inherent in living with HIV infection and adhering to complex treatments with difficult side effects, access to essential social services that enhance patient access to medical care can be vital to ensure continuity of care and positive health outcomes.[2,3,4]

We believe that the provision of social services should continue to be an important function of CARE Act programs. We support efforts to strengthen the linkages between medical care and supportive social services and to give priority to co-location of services whenever possible. In particular, we highlight the services noted below as especially important to the well-being of our patients and their ability to access medical services.

Essential Social and Support Services

- Transportation
- Housing assistance
- Food
- Child care
- Emergency financial assistance
- Respite care services
- Case management*
- Client advocacy services, e.g., benefits and entitlement counseling and legal services including permanency planning
- Health insurance co-payments and deductibles

*Preference should be given to case management services that are integrated with medical service providers. Examples of service integration include case managers being part of a coordinated network of HIV care or being located (part or full time) within the medical care setting, and case managers and medical providers having established and routine mechanisms for communicating.

II. END AIDS DRUG ASSISTANCE PROGRAM (ADAP) WAITING LISTS: GUARANTEE ACCESS TO ANTI-HIV DRUGS TO LOW-INCOME RESIDENTS

Currently, access to HIV medications for the uninsured and underinsured varies greatly from state to state. The AIDS Drug Assistance Program (ADAP) provides lifesaving medications to approximately 136,000 individuals annually or roughly 30 percent of U.S. residents receiving

[2] Crystal S, Sambamoorthi U, Moynihan PJ, McSpiritt E. Initiation and continuation of newer antiretroviral treatments among Medicaid recipients with AIDS. *J Gen Intern Med.* 2001;16:850-859.
[3] Mitchell JM, Anderson KH. Effects of case management and new drugs on Medicaid AIDS spending. *Health Affairs.* 2000;19(4):233-243.
[4] Lo W, MacGovern T, Bradford J. Association of ancillary services with primary care utilization and retention for patients with HIV/AIDS. *AIDS Care.* 2002;14(suppl 1):S45-S57.

care.[5] At the end of 2004, more than 800 individuals remained on waiting lists for drugs despite a one-time influx of funds that provided $20 million in June 2004 to alleviate the problem.[6]

AAHIVM and HIVMA believe that the federal government should support ADAPs in providing access to a basic formulary of anti-HIV drugs to uninsured and underinsured persons with HIV/AIDS nationwide. At a minimum, the formulary should include the drug therapies recommended in the federal guidelines for the use of antiretroviral agents and treatment and prevention of opportunistic infections in HIV-infected adults, adolescents, and children. These guidelines consist of several living documents (updated regularly as new drug therapies and research results emerge) and are maintained online at http://www.aidsinfo.nih.gov. Federal funding to support this minimum standard is critical to alleviate some of the disparity that currently exists across the states in providing access to basic HIV medications.

AAHIVM and HIVMA recommend that the federal government guarantee access to a minimum formulary of anti-HIV drugs for U.S. residents with incomes less than 300 percent of the federal poverty level.[7]

Coverage of anti-HIV drugs as defined above should be the absolute minimum standard for ADAP formularies. Additionally, while anti-HIV drugs are the linchpin of HIV treatment, people living with HIV/AIDS require access to a range of medically necessary drugs to treat the disabling side effects that accompany HIV treatment, complications of HIV and the comorbidities that are common among people with HIV/AIDS, such as hepatitis C and mental illnesses.

HIVMA and AAHIVM recommend that states be authorized under the Ryan White CARE Act to develop comprehensive formularies that address the range of medical needs of people living with HIV/AIDS with federal and state funding.

The complexity and evolving pharmacologic treatment of HIV disease require special expertise and experience in treating people with HIV disease. AAHIVM and HIVMA feel that it is critical that ADAP drug formularies be developed with oversight from HIV medical experts who stay abreast of the latest standard in HIV care.

AAHIVM and HIVMA recommend that states independently or in coalition with other states develop medical advisory committees that include recognized HIV expert clinicians to oversee ADAP formulary guidelines.

[5] National ADAP Monitoring Project. *Annual Report*. May 2004. National Alliance of State & Territorial AIDS Directors, Henry J Kaiser Family Foundation, and AIDS Treatment Data Network. Available at: www.kff.org/hivaids/7076.cfm. Accessed February 18, 2005.
[6] National Alliance of State & Territorial AIDS Directors. *The ADAP Watch.* December 15, 2004. Available at: www.nastad.org/documents/public/publicpolicy/NASTAD-ADAP_Watch_Dec_04_FINAL-revised.pdf. Accessed February 17, 2005.
[7] According to the National ADAP Monitoring Project's May 2004 annual report, 74 percent of the states (37 of 50) have income eligibility levels of 300 percent of the federal poverty level or greater.

III. DEFINE AND IDENTIFY HIV MEDICAL EXPERTS: IMPROVE HEALTH CARE OUTCOMES

Care provided by experienced HIV medical providers results in improved clinical outcomes and more cost-effective care.[8,9,10] Thus, whenever possible, HIV care should be provided by health care providers with significant experience and recent training and/or ongoing continuing education related to the evolving standard of HIV care. HIVMA and AAHIVM represent the overwhelming majority of physicians, physician assistants and nurse practitioners who specialize in HIV medicine in the United States. In the absence of a nationally recognized definition of HIV expert clinicians, AAHIVM and HIVMA have developed definitions requiring experience and HIV-specific training. These definitions have been officially recognized and accepted by the states of California and New York and represent the best, current definitions of HIV expertise.[11]

We recommend that the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau work in collaboration with HIVMA and AAHIVM to develop guidance documents for CARE Act–funded programs that define HIV-experienced medical providers. The guidance would also highlight models of consultative relationships with expert medical providers for use in communities where experienced medical providers are not available or in situations in which the patient is committed to maintaining a relationship with a provider who does not meet the definition of an expert.

IV. AIDS EDUCATION AND TRAINING CENTERS (AETCs): ASSISTING CURRENT MEDICAL PROVIDERS IN PROVIDING STATE-OF-THE-ART CARE AND SUPPORTING THE NEXT GENERATION OF HIV MEDICAL PROVIDERS

No field of medicine has evolved more rapidly than HIV treatment and, therefore, continuing HIV education is essential. AAHIVM and HIVMA support education and clinical training of HIV medical providers through the AETC program. We feel strongly that AETC programs should reflect and support the multidisciplinary chronic care model that has evolved for treating HIV disease. The focus of the program should be aimed at providing critical clinical updates to practicing HIV medical providers and to assisting primary care clinicians with their efforts to identify and refer patients with HIV infection to experienced medical providers. Initiatives to ensure adequate clinical training for medical providers working in correctional settings; to provide high-quality and culturally competent care to minority patients; to provide education and training to medical providers in rural areas; and to offer web-based clinical training resources to CARE Act–funded clinical providers are all important and should be continued. Linkages

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[8] Bozzette SA, Joyce G, McCaffrey DF, et al. Expenditures for the care of HIV-infected patients in the era of highly active antiretroviral therapy. *N Engl J Med.* 2001;344(1):817-823.
[9] Kitahata MM, Van Rompaey SE, Dillingham PD, et al. Primary care delivery is associated with greater physician experience and improved survival among persons with AIDS. *J Gen Intern Med.* 2003;18:95-103.
[10] Kitahata MM, Van Rompaey SE, Shields AW. Physician experience in the care of HIV-infected persons is associated with earlier adoption of new antiretroviral therapy. *J Acquir Immune Defic Syndr.* 2000;24(2):106-114.
[11] See *California State Law Regulating Private and Medicaid Health Plans—Assembly Bill No. 2168—Amendment to the California Health and Safety Code* (available at www.calregs.com: §1300.67.60, Standing referral to HIV/AIDS specialist) and New York State Department of Health's *HIV Specialist Policy* (available at www.hivguidelines.org/public_html/left/policy/policy.htm).

between regional AETCs and expert medical providers should be strengthened, and practicing clinicians should be involved in identifying and planning educational activities.

After 23 years of the AIDS epidemic, it is vital that the authorization and funding of the AETC program be expanded to include initiatives aimed at attracting and training new medical providers to take care of the HIV patient population in the years to come. As the generation of medical providers who entered the field of HIV medicine at the advent of the epidemic begins to retire, we must begin to take steps to ensure an adequate and well-trained clinical work force. A shortage of HIV medical providers is already manifest in several geographic areas and is impeding access to care. The complexities and challenges of HIV treatment along with low reimbursement rates are compounded by the fact that HIV/AIDS disproportionately affects people who are poor, minority and disenfranchised.[12] To enter the field as a clinician requires dedication to the patient population along with a commitment to learn and maintain a medical knowledge base that crosses multiple medical specialties and becomes more complicated the longer patients are in treatment. We are very grateful for the significant advances in HIV treatment that allow our patients to live longer. However, we are seriously concerned that there will not be a qualified work force in the near future to care for our current patients and the 40,000 new people diagnosed with HIV disease annually,[13] in the near future.

HIVMA and AAHIVM recommend that the authorization and funding of the AETC program be expanded to include programs related to providing training to new clinicians interested in entering the field and to providing incentives for individuals to enter the field of HIV medicine. Specifically, we recommend that new funding be authorized for clinical training in HIV medicine in accredited programs. We also recommend that new funding be authorized for loan forgiveness programs to provide an incentive for individuals to participate in a training program in HIV medicine. Such loan forgiveness programs could be modeled on programs like the National Institutes of Health program for clinical researchers, and loan forgiveness could be granted based on a commitment to practice HIV medicine for two years in an underserved area of the United States or the developing world.

V. SUPPORT THE STANDARD OF CARE: ADEQUATELY FUND COMPLEX MEDICAL AND PSYCHOSOCIAL CARE

As HIV care becomes more complicated, medical providers must provide additional services, many of which are not adequately identified as reimbursable services under the CARE Act. Prevention counseling and adherence support services are just two examples of services that are conducted in medical care settings, are resource intensive, and are rarely reimbursed.

As a general principle, providers should be reimbursed for services that they provide. In addition to the challenges clinicians face with unfunded mandates, there is wide variability in reimbursement practices and levels in CARE Act–funded programs across the country. Further, as HIV care rapidly evolves, new services currently not authorized may be required of clinicians.

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[12] Karon JM, Fleming PL, Steketee RW, De Cock KM. HIV in the United States at the turn of the century: an epidemic in transition. *Am J Public Health.* 2001;91(7):1060-1068.
[13] Centers for Disease Control and Prevention. HIV/AIDS—United States, 1981-2000. *MMWR Morbid Mortal Wkly Rep.* 2001;50:430-433.

We recommend that HRSA be directed to work in collaboration with HIVMA and AAHIVM to develop guidance on reimbursement practices that addresses basic services that are currently not being reimbursed and that addresses regional disparities in reimbursement while retaining flexibility. Moreover, this initiative should also address strategies to recruit and retain experienced HIV medical providers by looking at CARE Act–funded staff compensation and provisions for merit-based pay increases.

VI. IMPROVE QUALITY OF CARE AND OUTCOMES EVALUATIONS

Ample evidence exists that experienced HIV medical providers deliver better care to patients with HIV, and that the quality of that care can be documented in positive health care outcomes. HIVMA and AAHIVM believe that the CARE Act program should be able to demonstrate the positive outcomes that result from the program's investment in HIV care and services.[14]

HIVMA and AAHIVM recommend that HRSA be authorized and funded to create a Quality Management Office to centralize and improve quality improvement and assurance efforts across titles and programs.

Priorities should include the activities listed below.

- Work in collaboration with AAHIVM and HIVMA to increase evidence-based accountability across programs and titles. AAHIVM and HIVMA would work with HRSA to identify, implement and evaluate evidence-based quality assurance and outcomes measures in the delivery of CARE Act–funded services.
- Establish and coordinate uniform data collection across titles and programs and eliminate duplicate reporting of data across titles.
- Streamline data reporting requirements to ensure that only relevant data is collected and with minimal burden to grantees.
- Ensure service delivery coordination among all grantees and subgrantees.
- Document effective collaborations across titles to ensure that people living with AIDS are receiving primary medical care and basic medical services and that these services are not duplicated.
- Ensure that grantees and sub-grantees can devote sufficient resources to meeting quality assurance and data collection requirements.

HIVMA and AAHIVM also recommend that the Special Programs of National Significance (SPNS) program fund demonstration programs to evaluate the effectiveness of different models of HIV clinical Centers of Excellence (systems of care that offer access to clinical and support services that are comprehensive, integrated across providers and seamless) in delivering high-quality and comprehensive care for HIV/AIDS. Demonstration projects should include an independent evaluation of the quality, cost and outcomes of services furnished.

[14] See *Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White* (2004), produced by the Institute of Medicine's Committee on the Public Financing and Delivery of HIV Care (available at: www.nap.edu/books/0309092280/html/).

VI. SUPPORT MANAGEMENT OF HEPATITIS C WHENEVER POSSIBLE

Nationally, 16-25 percent of all HIV-infected individuals are estimated to have comorbid hepatitis C (HCV) infection.[15,16] Chronic HCV infection develops in 75-85 percent of HCV-HIV co-infected persons and leads to chronic liver disease in 70 percent of these individuals.[15] In the past few years, death due to end-stage liver disease has become an increasingly common cause of death in HIV-infected persons. The latest federal guidelines on *Treating Opportunistic Infections Among HIV-Infected Adults and Adolescents* recommend that all HIV-infected persons be screened for HCV infection. The guidelines also identify management of HCV in people with HIV as essential.

AAHIVM and HIVMA recognize that treatment for HCV is critical for a subset of our patients with HIV. However, we are concerned that current funding for the CARE Act is completely inadequate to support screening and universal treatment for all those co-infected with HCV. We strongly support maintaining HCV screening and treatment services as authorized services under the CARE Act. We also strongly support states having the option to add HCV medications to state ADAP formularies**. A substantial infusion of additional resources is needed and warranted to address the medical needs of uninsured and underinsured persons who are co-infected with HIV and HCV.** Ensuring access to HIV primary care and antiviral medications must remain primary under the CARE Act.

VII. IMPROVE PROGRAM ADMINISTRATION

HIVMA and AAHIVM feel strongly that it is important for the prioritization of primary medical care and basic medical services to be supported by representation on the Title I Planning Council and Title II consortia. Specifically, **AAHIVM and HIVMA recommend that the clinicians who provide the services identified as primary and basic medical services have significant representation on Title I and Title II planning bodies so that these councils have the expertise and capacity to determine community needs. Representation should include physicians, nurse practitioners, physician assistants, nurses, nutritionists, and mental health and substance abuse professionals.**

The administrative burden on programs that must resubmit grant applications annually should be reduced to allow for a more effective use of program resources. **AAHIVM and HIVMA recommend that all grant cycles be increased from one to two years.**

Implementing the recommendations described herein will significantly improve the Ryan White CARE Act to reflect the current standard of HIV care in the United States. AAHIVM and HIVMA strongly urge the reauthorization of the Ryan White CARE Act, on which many of our patients depend for access to lifesaving medical care, with these recommendations in place.

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[15] Centers for Disease Control and Prevention. Frequently Asked Questions and Answers About Coinfection With HIV and Hepatitis C Virus. Available at: www.cdc.gov/hiv/pubs/facts/HIV-HCV_Coinfection.htm. Accessed January 28, 2005.

[16] Sherman KE, Rouster SD, Chung RT, Rajicic N. Hepatitis C virus prevalence among patients infected with human immunodeficiency virus: a cross-sectional analysis of the US adult AIDS clinical trials group. *Clin Infect Dis.* 2002;34:831-837.