

## Caring for “Ryan White”: The Fundamentals of HIV/AIDS Treatment Policy

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**OVERVIEW** — *This background paper provides an overview of the HIV/AIDS epidemic in the United States and discusses how treatment of the disease and the populations most affected by it have changed over time. The federal government’s domestic and global efforts in prevention, research, and treatment of the disease are highlighted. The paper outlines the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, a set of programs that fund treatment services for uninsured and underinsured individuals living with HIV/AIDS, and places it in the context of other federal programs that fund treatment for HIV/AIDS. Policy issues for Ryan White’s potential congressional reauthorization are also discussed.*

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# Caring for “Ryan White”: The Fundamentals of HIV/AIDS Treatment Policy

Twenty-five years ago, becoming infected with HIV (human immunodeficiency virus) was considered a death sentence. There was little the medical establishment could do but comfort a patient with HIV as the virus replicated in the body unchecked, completely destroying the immune system and ultimately resulting in diagnosis with AIDS (acquired immunodeficiency syndrome). Death followed months of progressive weakening and wasting, often preceded by blindness and/or dementia. Tens of thousands died this way before remarkable treatments were discovered in the mid 1990s. Those discoveries have transformed HIV/AIDS from a terminal illness to a chronic condition. People who are able to receive treatment are able to live long, productive lives.

Still, after two decades of gathering knowledge about the cause of the disease and a decade after the life-extending drugs became available, AIDS is the number one killer of African American women aged 25 to 34 in the United States, and the number of new infections each year has not abated. What began as a disease mostly transmitted by men who have sex with men has become one that increasingly affects heterosexual populations and reaches the most vulnerable segments of American society: the low-income, the uninsured, and racial and ethnic minority populations. The increasing HIV/AIDS disease burden borne by vulnerable populations in this country makes it ever more important to consider the viability of funding sources for treatment.

Although Medicaid is the largest funder of care for low-income people with HIV/AIDS, the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, known simply as “Ryan White,” funds treatment for those who are not eligible for Medicaid but are low-income and uninsured or underinsured. The Act was named in honor of Ryan White, a hemophiliac who contracted HIV from a blood transfusion and faced tremendous discrimination due to others’ fear and lack of understanding of his disease. The Act was originally authorized in 1990, the year he died, and was reauthorized in 1996 and 2000; the current authorization is set to expire on September 30, 2005. The program has grown increasingly complex through each reauthorization, reflecting scientists’ evolving understanding of the disease, how it should be treated, and the populations it affects.

As policymakers consider whether and how to reauthorize this important program, they must anticipate the future: they have to envision who will need services funded by Ryan White over the next five years,

consider the type of care they will need, and determine how much money to allocate for it. They will need to struggle with the paradox of providing equitable access to services and life-extending prescription drugs through a program designed to fill the access gaps unique to each state's health care safety net. They will contemplate the next phase of Ryan White against the backdrop of significant federal deficits, Medicaid reform debates, an estimated 45 million uninsured, and continually increasing health care costs. A significant policymaking challenge lies ahead.

This background paper is divided into four sections.

- The first section discusses the disease's pathology and its treatment, provides information on the data used to understand the magnitude of the epidemic, and profiles the populations most affected by HIV/AIDS in the United States. This background section is essential for understanding the key resource allocation and funding prioritization debates discussed in the last section of the paper.
- Section two examines how the federal government addresses HIV/AIDS both domestically and globally. It highlights treatment, research, and prevention efforts by discussing the agencies involved and the funds allocated. Special emphasis is placed on providing a context for Ryan White as the payer of last resort amidst other federal programs that fund HIV/AIDS treatment services.
- The third section lays out the statutory structure of the CARE Act, including a discussion of the mechanisms used for distributing funds, the recipients of those funds, and their intended purpose.
- The final section examines policy issues for consideration in the next reauthorization, should one occur.

## BACKGROUND

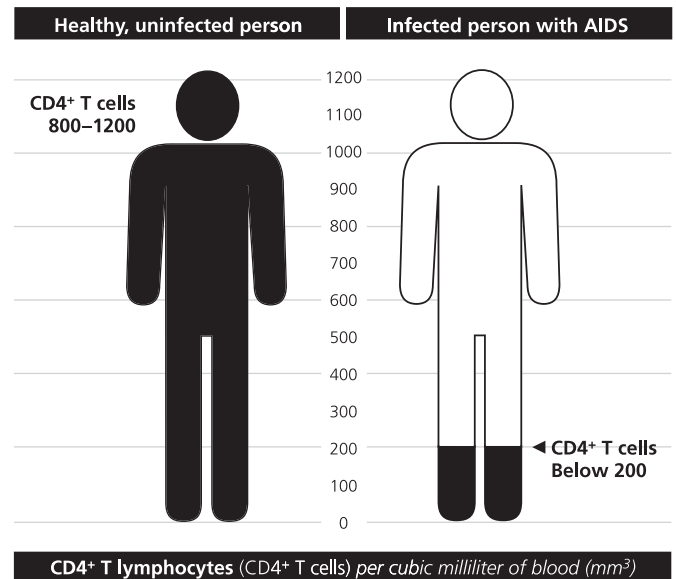
The HIV/AIDS epidemic in the United States is well into its third decade. The first cases of Acquired Immunodeficiency Syndrome (AIDS) were reported in the United States in 1981; since then 524,060 people with AIDS have died.<sup>1</sup> In 1984, scientists identified HIV as the cause of AIDS.

### HIV/AIDS Disease and Treatment

Most commonly, HIV is contracted through sexual contact with an infected person, sharing needles or syringes with an infected person, or, less commonly, by receiving infected blood products. Babies born to HIV-positive mothers may become infected before or during birth or through breastfeeding. There is currently no vaccine to prevent transmission of HIV and no cure.

HIV commandeers the body's immune system by destroying white blood cells called CD4<sup>+</sup> T lymphocytes (CD4<sup>+</sup> T cells) that are a critical part of

the immune system. A healthy, uninfected person usually has between 800 and 1200 CD4<sup>+</sup> T cells per cubic milliliter of blood (mm<sup>3</sup>). A person's condition is said to have progressed to AIDS when their CD4<sup>+</sup> T cell count has fallen below 200 cells per mm<sup>3</sup> of blood, severely hindering the body's ability to ward off infection. Specific "opportunistic infections" thrive in the immune-compromised body; for instance, yeast can infect the mouth, which is known as oral thrush, and a certain type of cancer called Kaposi's sarcoma causes lesions on the skin and other parts of the body. Conditions such as these are extremely rare—if found at all—in people with uncompromised immune systems, and thus signal the advanced stage of HIV infection, or AIDS. HIV/AIDS refers to all persons known to be infected with HIV even if they have not been diagnosed with AIDS.



When AIDS was first diagnosed in the United States in the 1980s, patients typically lived less than a few years and little more than end-of-life or palliative care was available. Since then, researchers have created a number of drugs that can suppress HIV in the body and extend lifespan significantly. The category of medications that fight HIV by preventing replication is called antiretrovirals. The Food and Drug Administration (FDA) has approved more than 20 antiretroviral medications or combinations of antiretrovirals for HIV treatment that fall into four classes, corresponding to the way the body can fight the virus. Because HIV can become resistant to any one drug, people living with HIV/AIDS typically take a combination of drugs from different classes. This combination treatment is known as highly active antiretroviral therapy (HAART). The Public Health Service (PHS) publishes HIV treatment guidelines, which are widely accepted as the standard of care for HIV/AIDS.

Access and adherence to comprehensive antiretroviral therapy is the cornerstone of HIV care. High levels of treatment adherence are critical to suppress the virus in the blood and also to prevent development of drug-resistant strains of the virus. Patients often find it challenging to adhere to the HAART regimen because it is complex with multiple dosing and dietary restrictions, and the medications often have side effects that can make patients feel worse. In addition, the regimen is extraordinarily expensive: a year's supply of antiretrovirals can cost \$12,000 or more per person, and when the costs of doctor's visits, laboratory tests, and drugs to prevent or treat opportunistic infections are added in, the total can grow to \$18,000 to \$20,000.<sup>2</sup>

With the introduction of HAART in 1996, the standard of care for HIV/AIDS shifted from acute, hospital-based, and palliative care to chronic disease management through primary medical care and related supportive services. The percentage of deaths attributable to AIDS peaked in 1995 and declined by 70 percent between 1995 and 2002 as a result of

HAART. There were an estimated 18,017 deaths of persons with AIDS in the United States in 2003 for a total of 524,060 since the beginning of the epidemic. Antiretrovirals have also led to dramatic successes in curbing perinatal (mother to child) transmission of HIV/AIDS. Perinatal transmission has declined from a 25 percent risk of transmission to less than 2 percent when antiretrovirals are administered during pregnancy and certain obstetrical interventions are followed.<sup>3</sup>

## Counting Cases

Testing individuals for HIV and reporting positive diagnoses to public health authorities is critical to determining the magnitude of the HIV/AIDS epidemic in the United States, informing prevention activities, estimating treatment needs, and initiating treatment. Since the beginning of the epidemic, standard testing for HIV involved drawing blood to test for the presence of antibodies specific to HIV. Antibodies occur in the bloodstream when the body is fighting an infection, and these antibodies are uniquely configured to match invading microorganisms. There are limitations to testing the blood for HIV, namely that it does not detect the infection in its earliest stage, when people have the highest viral load and are most infectious. It may take three months or longer until detectable antibodies develop, and test results typically take several days to two weeks to process, which requires those tested to follow up to learn their results. In 2000, 31 percent of people who tested positive for HIV through the Centers for Disease Control and Prevention (CDC)-funded tests did not return for their results.<sup>4</sup>

Continual improvements in testing techniques for HIV have addressed some of the concerns with existing tests, but challenges remain. In 2002, the FDA began approving “rapid” HIV tests that use blood from a finger prick, instead of blood drawn from a vein. In 2004, the FDA approved the first rapid test using oral fluid instead of blood.<sup>5</sup> These tests can produce initial results in as little as 20 minutes, eliminating the problem of individuals having to return days later to learn their results. The CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA) have both been purchasing and deploying these rapid HIV tests. However, rapid testing, like traditional testing, does not detect the virus in the earliest stages of infection.

Testing for the virus itself, by testing for its genetic information called RNA (as opposed to testing for the antibodies that recognize the virus), is possible but is more expensive than testing for antibodies and is not widely used for diagnostic purposes. This type of test is typically used to monitor viral loads and guide treatment of those who have already tested HIV-positive. Only one state, North Carolina, uses it for all of its publicly funded testing.<sup>6</sup> Commercial viral load tests can cost \$200 to \$300 each, compared with \$5 for the antibody test. As a double-check measure, North Carolina takes the blood of every person who tests negative using the antibody test at their sexually transmitted disease (STD) clinics and pools them

into batches of 90 to test the viral load. Any batch that tests positive is subdivided and tested until the positive sample is found. By using this dual testing process, North Carolina has identified an additional 6 percent of HIV cases in its clinics. The state has reduced the cost of combined HIV antibody and viral load testing from \$90 to \$3.63. San Francisco has been doing the same thing in its STD clinics since 2003 and estimates its costs at about \$30 per person.<sup>7</sup>

The testing and reporting of positive test results to public health authorities can be done either confidentially or anonymously. With confidential testing and reporting, the person's name is recorded with the test results; with anonymous testing, no name is recorded (see text box). All 50 states have had mandatory confidential name-based AIDS case reporting since

### What's in a Name? HIV Case Reporting

Name-based HIV case reporting has been more contentious than name-based AIDS reporting. The controversy revolves around fear that government entities will not safeguard the information appropriately and that the risks of invasion of privacy and discrimination outweigh the public benefit from the appropriate use of the information. There was less resistance to name-based AIDS case reporting from the beginning of the epidemic because the length of time between AIDS diagnosis and death was so short and the need for medical services was so great that these needs outweighed privacy concerns.

Although all states now report HIV cases, they do it in three different ways, which creates problems for the comparison and aggregation of data at the national level. Currently, 38 states report HIV cases by name; 7 states report HIV cases by code, and 5 states initially report by name but then convert the information to code after follow-up and data collection are complete. The District of Columbia and the city of Philadelphia report HIV cases by code, and Puerto Rico reports by name. Georgia is the most recent state to implement a name-based HIV reporting system; it began providing data to the CDC in December 2003. It is important to note that the CDC never receives actual names with AIDS or HIV reports. Name-based reporting refers to the way the case is reported from the laboratory to the local authorities and then the local to the state authorities. All name-based AIDS and HIV case reports are converted to

an alphanumeric code based on the person's last name, gender, date of birth, and social security number before being submitted to the CDC. The CDC checks these alphanumeric codes for apparent duplication and goes back to any state(s) involved to work out any suspected duplications.

Because all states do not collect name-based HIV reports, they cannot provide an alphanumeric code to the CDC that would allow the agency to eliminate duplication. Therefore, the CDC's national HIV estimates include data from only the 33 areas (32 states and the U.S. Virgin Islands) that they consider to have mature, name-based surveillance systems. HIV surveillance system maturity is important to ensure data accuracy. Many states with recent HIV reporting systems have significantly fewer reports because of the time lag in entering cases found before the new system was put in place.

The CDC's HIV estimates exclude data from four of the ten states with the highest number of cumulative AIDS cases (California, Illinois, Maryland, and Massachusetts) because those states report their HIV cases by codes that are not linked to names. The 33 areas from which CDC creates its HIV estimates represent 43 percent of total national reported AIDS cases.\*

\* Kaiser Family Foundation (KFF), "The HIV/AIDS Epidemic in the United States," fact sheet, updated December 2004; available at [www.kff.org/hiv/aids/3029-04.cfm](http://www.kff.org/hiv/aids/3029-04.cfm).

early in the epidemic and, as a result, information on national AIDS cases and new cases each year is relatively complete and available. Authority for mandating disease reporting lies with the state, but all states voluntarily report AIDS data to the CDC.

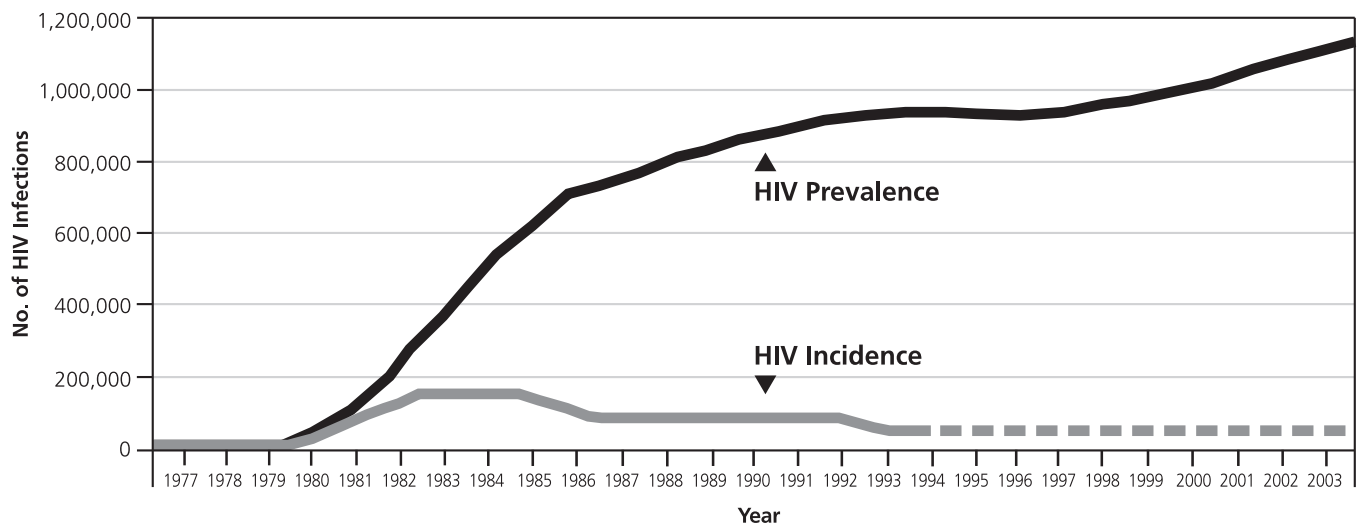
Ryan White CARE Act funds are distributed on the basis of estimated living AIDS cases (ELCs). The CDC determines ELCs by weighting annual survival rates for the most recent 10 years of reported AIDS cases in a state or metropolitan area.

### A Profile of the Epidemic

Testing and case reporting allowed the CDC to better understand how HIV/AIDS is affecting the U.S. population. Because HAART has allowed people with HIV/AIDS to live longer lives, HIV/AIDS prevalence continues to grow. The CDC estimates that between 1,039,000 and 1,185,000 people are living with HIV/AIDS in the United States (this is known as HIV/AIDS prevalence) and that a quarter of this infected population is unaware of its status.<sup>8</sup> It is estimated that this undiagnosed population is responsible for about 66 percent of new infections each year.<sup>9</sup>

Increasing numbers of people living with HIV/AIDS create greater risk for new infections in the absence of aggressive prevention and place escalating demands on the health care system (Figure 1). The CDC estimates that 40,000 new infections occur each year; this is known as HIV incidence.

**FIGURE 1**  
**Estimated HIV Infection Incidence and Prevalence in the United States, 1977 to 2003**



Note: The CDC changed the way it measures HIV incidence in 1994. For more information, contact the HIV Incidence and Case Surveillance Branch within the Divisions of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention.

Source: Adapted from figure 1 of Robert S. Janssen, CDC, "Domestic HIV/AIDS Surveillance: Current Trends and Status of HIV Reporting," testimony before Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management Government Information, and International Security, U.S. Senate, June 23, 2005; available at [www.hhs.gov/asl/testify/t050623a.html](http://www.hhs.gov/asl/testify/t050623a.html).



About 18,000 people die from AIDS-related conditions each year, and an additional 22,000 people seek HIV/AIDS services each year.<sup>10</sup>

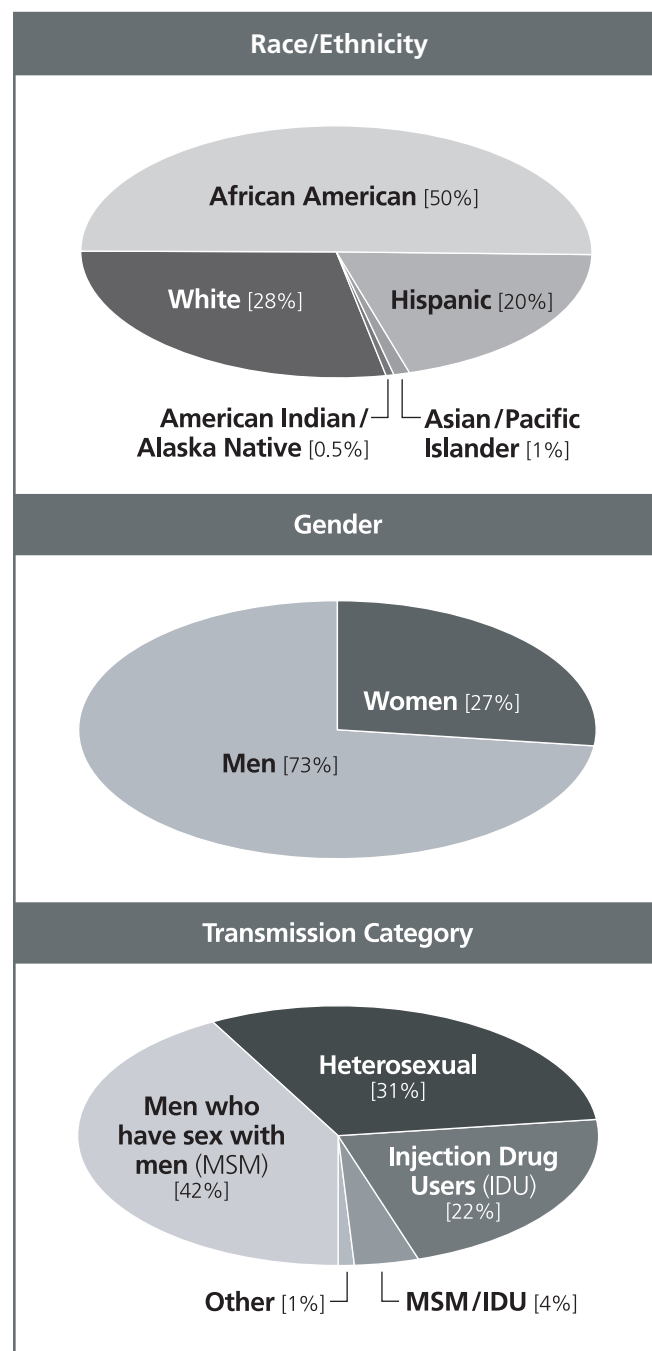
Racial and ethnic minorities, especially African Americans, have been disproportionately affected by HIV/AIDS. In 2003, African Americans comprised only 13 percent of the total U.S. population but represented 49 percent of the estimated 43,171 new AIDS cases. Women are also increasingly affected by HIV/AIDS. New AIDS diagnoses among women have increased from 8 percent in 1985 to 27 percent in 2003.

While men who have sex with men are still the largest transmission group for HIV/AIDS, heterosexual transmission has increased significantly. Between 1985 and 2003, heterosexual transmission increased from 3 to 31 percent of newly diagnosed AIDS cases. The percentage for men who have sex with men dropped from 65 to 42 percent but has been slowly increasing in the last few years. Cases attributable to injection drug use remained relatively steady rising from 19 to 22 percent in 2003 (Figure 2).<sup>11</sup>

In terms of geographic distribution of the epidemic, the southern states were home to the greatest number of people living with AIDS, the largest number of newly diagnosed AIDS cases, and the highest number of AIDS deaths in 2003. At 21.1 per 100,000 people, northeastern states had the highest AIDS case rate followed by southern states with 18.8, western states with 10.0, and mid-western states with 6.9 per 100,000 people. In 2003, the top five states by cumulative AIDS cases were New York, California, Florida, Texas, and New Jersey. The top five states or areas by case rate were the District of Columbia, New York, the Virgin Islands, Maryland, and Puerto Rico.<sup>12</sup>

It is difficult to determine insurance coverage among people with HIV/AIDS because many are not in the care system and a significant portion do not know their HIV status. The CDC estimates that just 41 to 58 percent of people with HIV/AIDS are actually receiving regular care. The HIV Cost and Services Utilization Study (HCSUS) is the only nationally representative study of people living with HIV/AIDS who are receiving care.<sup>13</sup> The study, conducted between 1996 and 1998, found that 29 percent of people living with HIV/AIDS in care were covered by Medicaid alone, 6 percent were

**FIGURE 2**  
**Percentage of New AIDS Cases in 2003, by Race/Ethnicity, Gender, and Transmission Category**



Source: CDC, HIV/AIDS Surveillance Report: Cases of HIV Infection and AIDS in the United States, 2003, 15, table 7; available at [www.cdc.gov/hiv/stats/2003SurveillanceReport.htm](http://www.cdc.gov/hiv/stats/2003SurveillanceReport.htm).

covered by Medicare only, 31 percent had private insurance, and 20 percent were uninsured. About 12 to 13 percent of people with HIV/AIDS in care are dually eligible for Medicaid and Medicare. By comparison, for American adults overall, 8 percent were covered by Medicaid, 2 percent by Medicare, 70 percent by private insurance, and 20 percent were uninsured.<sup>14</sup>

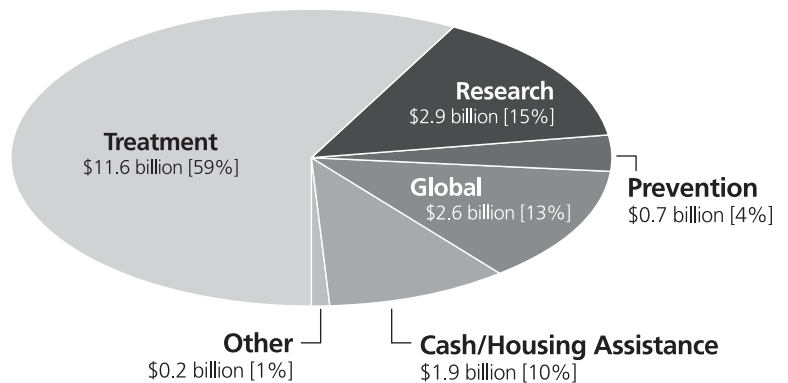
People living with HIV/AIDS increasingly have complex needs that further complicate treatment and impede adherence to treatment. These special needs include comorbidities, additional diseases or conditions, such as mental illness, substance abuse disorders, hepatitis, sexually transmitted diseases, or tuberculosis, as well as vulnerable social conditions such as homelessness and incarceration. These medical comorbidities and social vulnerabilities often coexist, as well. It is estimated that about 50 percent of people with HIV who are in care have some form of comorbid mental illness.<sup>15</sup> About one-quarter of all HIV-infected individuals are estimated to have comorbid hepatitis C infection.<sup>16</sup> One analysis found that between 20 and 26 percent of all people living with HIV/AIDS passed through a correctional facility in 1997.<sup>17</sup>

## FEDERAL HIV/AIDS EFFORTS

The changes in HIV/AIDS treatment from a palliative care to a chronic care model and the shifting demographics with respect to race and ethnicity, mode of transmission, gender, and geography make crafting a health care system and public financing response to the disease challenging. Whether for humanitarian or public health reasons, there are compelling arguments for addressing the epidemic domestically and globally. The federal government's efforts to address the HIV/AIDS epidemic focus on providing treatment and support services, conducting research, and trying to prevent new infections (Figure 3, above). The challenge lies in developing and funding these separate activities but also in integrating the experiences from each to inform the other both domestically and globally. (See text box, "The Global HIV/AIDS Epidemic," next page.)

There are a number of organizations involved in crafting federal domestic HIV/AIDS policy. In the Executive branch, efforts are spearheaded by the White House Domestic Policy Council and Office of National AIDS Policy (ONAP). The President's Advisory Council on HIV/AIDS (PACHA) also makes policy recommendations to the White House.

**FIGURE 3**  
**Federal Funding of HIV/AIDS**  
**for FY 2005**



Source: Adapted from Kaiser Family Foundation "U.S. Federal Funding for HIV/AIDS: The FY 2006 Budget Request," fact sheet, February 2005; available at [www.kff.org/hivaids/upload/Fact-Sheet-U-S-Federal-Funding-for-HIV-AIDS-The-FY-2006-Budget-Request.pdf](http://www.kff.org/hivaids/upload/Fact-Sheet-U-S-Federal-Funding-for-HIV-AIDS-The-FY-2006-Budget-Request.pdf).

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## The Global HIV/AIDS Epidemic

In the over two decades since the beginning of the HIV/AIDS epidemic, over 60 million people have become infected and over 20 million have died of AIDS-related causes. In 2004 there were 39.4 million people estimated to be living with HIV/AIDS worldwide. HIV is the leading cause of death globally for people ages 15 to 59. Sub-Saharan Africa, a region that comprises 10 percent of the world's population, bears the brunt of the global epidemic with 64 percent of the entire global infected population. There is concern that a new wave of the epidemic is taking place in Asia and Eastern Europe. Unlike the United States, where women constitute about 25 percent of HIV/AIDS cases, women represent 45 percent of people living with HIV/AIDS globally and 57 percent of the infected population in sub-Saharan Africa. The United Nations estimates that nine out of ten people who need treatment for HIV/AIDS are not receiving it.\*

The U.S. government plays a key role in funding prevention, treatment, and research efforts to respond to the global HIV/AIDS epidemic. The United States donates to the Global Fund to Fight AIDS, Tuberculosis, and Malaria, an independent, international public-private partnership created in 2001 to fund prevention, treatment, and research efforts. In addition, in 2003, Congress and President Bush created the President's Emergency Plan for AIDS Relief (PEPFAR) a five-year, \$15 billion effort. PEPFAR is targeting funds to 15 focus countries in Africa, Asia, and the Caribbean that comprise about half of all infections globally. Its goals are to support treatment for 2 million people, prevent 7 million new infections, and support care for those infected and affected by the epidemic by 2008. The Office of the U.S. Global AIDS Coordinator at the U.S. Department of State coordinates the global AIDS response of the United States. U.S. funding to combat the global epidemic totaled \$2.6 billion in FY 2005, including \$347 million for the Global Fund, \$1.4 billion for the Global AIDS Coordinator's Office, and the remainder for efforts

funded through the U.S. Agency for International Development (USAID), Department of Health and Human Services (DHHS), Department of Defense, and Department of Labor.\*\*

There have been some controversies surrounding PEPFAR policies. The U.S. government requires that any antiretroviral purchased using PEPFAR funds be FDA approved. The only FDA-approved antiretrovirals sold in the United States are brand name, not generic, because of drug manufacturer patents and exclusivity agreements. Many HIV/AIDS advocates have criticized the Bush administration for requiring FDA approval for PEPFAR-purchased drugs. They argue that the requirement increases the profits of U.S. patent-holding pharmaceutical companies at the expense of people with HIV/AIDS in developing countries, more of whom could be treated if less expensive, generic drugs could be purchased by PEPFAR. In response, in May 2004, DHHS announced an expedited FDA review process for single-ingredient, fixed-dose combination, and co-packaged generic antiretrovirals as well as brand-name fixed-dose combination and co-packaged antiretrovirals.\*\*\* The agency has approved nine medications since it implemented the expedited process. The Bush administration has also been criticized for overemphasizing abstinence as a prevention method, compared with other strategies like promoting condom use.

\* UNAIDS, 2004 Report on the Global AIDS Epidemic, July 2004; available at [www.unaids.org/bangkok2004/GAR2004\\_html/GAR2004\\_00\\_en.htm](http://www.unaids.org/bangkok2004/GAR2004_html/GAR2004_00_en.htm); and UNAIDS, AIDS Epidemic Update, December 2004; available at [www.unaids.org/wad2004/EPIupdate2004\\_html\\_en/epi04\\_00\\_en.htm](http://www.unaids.org/wad2004/EPIupdate2004_html_en/epi04_00_en.htm)

\*\* KFF, "U.S. Federal Funding for HIV/AIDS: The FY 2006 Budget Request," HIV/AIDS Policy fact sheet, February 2005; available at [www.kff.org/hiv/aids/upload/Fact-Sheet-U-S-Federal-Funding-for-HIV-AIDS-The-FY-2006-Budget-Request.pdf](http://www.kff.org/hiv/aids/upload/Fact-Sheet-U-S-Federal-Funding-for-HIV-AIDS-The-FY-2006-Budget-Request.pdf).

\*\*\* Fixed-dose combination drugs create one pill out of two or three individual drugs, whereas co-packaging means putting two or three pills into a single package for distribution. FDA, "FDA Review of HIV Drugs," fact sheet, May 16, 2004; available at [www.hhs.gov/news/press/2004pres/20040516a.html](http://www.hhs.gov/news/press/2004pres/20040516a.html).

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The bulk of federal effort and funding for health-related efforts for people living with HIV/AIDS is housed within the Department of Health and Human Services (DHHS). Within DHHS, the Office of HIV/AIDS Policy (OHAP) serves as the coordinator for the efforts in treatment (the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, and SAMHSA), in research (the National Institutes of Health), and in prevention (the CDC). The Departments of Veterans Affairs and Housing and Urban Development and the Social Security Administration also fund key programs that provide health care, housing, and income support to people living with HIV/AIDS.

### Treatment Funding Streams

At a public health level, treating people with HIV/AIDS is critical for reducing viral load, and therefore infectiousness and transmission, and for providing the opportunity to reinforce prevention. In terms of federal dollars for treatment, the Medicaid program is the largest funder of health care services for people living with HIV/AIDS, with Medicare second, and Ryan White third. Both Medicaid and Medicare are entitlement programs, meaning that the federal government must pay for services as long as eligible individuals seek them; federal funding cannot be capped nor can waiting lists be created. Ryan White, on the other hand, is a discretionary grant program, meaning that it is appropriated a finite amount of funds by Congress each year which may or may not be sufficient to meet the demand for services by those who rely on it. In fiscal year 2005, Medicaid spent \$5.7 billion in federal matching funds to finance HIV/AIDS treatment, Medicare financed \$2.9 billion for treatment of HIV/AIDS, and Ryan White was appropriated \$ 2.1 billion.

**Medicaid** — Medicaid is a state/federal program to finance health care coverage for certain low-income children, families, and pregnant women, as well as the elderly and disabled. It covers approximately 55 percent of people living with AIDS and up to 90 percent of all children with AIDS.<sup>18</sup> The vast majority of people living with HIV/AIDS who qualify for Medicaid do so because they are disabled and receive cash assistance through the Supplemental Security Income (SSI) program.<sup>19</sup> To meet the SSI medical definition of disability, an individual's HIV infection must have progressed significantly, meaning that he or she qualifies for Medicaid at a time when the disease is more advanced and his or her care needs are highest and potentially most expensive. In addition to meeting the SSI definition of disability, individuals must also be low-income and have limited resources to receive SSI cash benefits.<sup>20</sup>

Within the federal Medicaid framework, states have significant flexibility to define eligibility categories, the scope and duration of benefits, and provider payment rates. "Medically needy" is an optional eligibility category

**Medicaid pays for services for about 55 percent of people living with AIDS.**

under which the state can deduct the cost of an individual's medical care from their annual income so people can "spend down" to become Medicaid-eligible. According to the Henry J. Kaiser Family Foundation, 33 states use the medically needy category for the disabled, and many people living with HIV/AIDS qualify for benefits this way.

Benefits like inpatient and outpatient hospital services, physician services, and laboratory and x-ray services are mandatory in the Medicaid program, whereas prescription drug coverage, dental services, targeted case management, and hospice care are optional. All states have chosen to provide prescription drug coverage, and they cover all FDA-approved HAART drugs, but the amount and scope of coverage is at the state's discretion. Some states are trying to contain Medicaid pharmaceutical costs by limiting the number of brand-name prescriptions beneficiaries may fill each month and by encouraging the use of generic drugs. Because HIV/AIDS patients typically take a combination of at least three medications and no generic antiretrovirals are currently available in the United States, these pharmacy benefit policies negatively affect their access to care. Many more states have placed limits on the overall number of prescriptions available to a beneficiary per month. These policies place hardships on beneficiaries and increase the fiscal burden on state AIDS Drug Assistance Programs (ADAP) (discussed more later in the paper), since most persons living with HIV/AIDS require a range of medications to attack the virus, manage side effects from treatment, and treat common comorbidities.

**Medicare** — Medicare is the second largest federal payer of HIV/AIDS care in the United States. Approximately 85,000 people living with HIV/AIDS, or about 19 percent of people living with HIV/AIDS who are in care, are Medicare-eligible. About 55,000 of those beneficiaries are dually eligible for both Medicaid and Medicare.<sup>21</sup> Currently, the vast majority of Medicare beneficiaries with HIV/AIDS qualify because of disability status, not because they are age 65 or older (about 3 percent of people living with AIDS are age 65 or older).<sup>22</sup> They have met the SSA disability definition and have earned enough work credits to receive Social Security Disability Insurance (SSDI) payments. Under the SSDI program, there is a 5-month waiting period for income benefits after becoming disabled and an additional 24-month waiting period before Medicare coverage begins.<sup>23</sup> As people with HIV/AIDS continue to live longer because of HAART, more and more will become eligible for Medicare benefits as they age.

Although Medicare has not historically covered outpatient prescription drugs, most Medicare beneficiaries with HIV/AIDS are dually eligible for Medicaid and Medicare and therefore have had access to prescription drug coverage at minimal cost. Those who are not dually eligible, however, have had to find other ways to pay for HAART, like turning to state ADAPs. On January 1, 2006 a new Medicare prescription drug benefit

**Most people with HIV/AIDS who are covered by Medicaid or Medicare qualify for those programs because they are considered disabled.**

goes into effect. On that day, those who are dually eligible will begin receiving their prescription drugs from Medicare instead of Medicaid. CMS is requiring all participating prescription drug plans to offer all drugs used to treat HIV/AIDS in their formularies.<sup>24</sup> This requirement is meant to ensure that Medicare beneficiaries with HIV/AIDS will have access to the drugs they need; it is also meant to prevent drug plans from discouraging people with HIV/AIDS from joining their plans by not offering all HIV/AIDS drugs in their formularies. Despite this protection, the future impact of this program on Medicare beneficiaries with HIV/AIDS is unclear and will be important to monitor.

**The Ryan White CARE Act** — The CARE Act was named for Ryan White, a teenager from Indiana who was born a hemophiliac and contracted HIV from infected blood that he received in a transfusion. At age 10, he was barred from attending public school by parents and administrators who feared he might infect others. He spent his life educating the public about the disease until his death in 1990 at age 18. The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, named in his honor, was first authorized in 1990 and has since been reauthorized in 1996 and 2000 with a current expiration of September 30, 2005. The authorizing committees of jurisdiction are the Senate Committee on Health, Education, Labor and Pensions (HELP) and the House Committee on Energy and Commerce. Unlike Medicaid and Medicare, the CARE Act is not a health insurance program, but instead is a source of grant funding that serves as the payer of last resort for services provided to people with HIV/AIDS who are either uninsured or underinsured. Total FY 2005 federal funding for the CARE Act was \$2.1 billion.

The program provides medical and support services to low-income, uninsured, vulnerable populations disproportionately affected by the epidemic. It serves approximately 533,000 individuals and families living with HIV/AIDS each year. In 2002, 46 percent of Ryan White clients were African American, 20 percent were Hispanic, and about one-third were women. At least one of every two clients lived below the federal poverty level, about 25 percent were uninsured, less than 10 percent had any private health insurance, and about 28 percent were enrolled in Medicaid.<sup>25</sup>

## Research Programs

Federal research funding on HIV/AIDS in FY 2005 totaled \$2.9 billion, 17 percent of total federal domestic spending on HIV/AIDS that year. The NIH Office of AIDS Research is responsible for coordinating all budgetary, research, policy, and legislative aspects of the agency's AIDS research program. A number of the agency's institutes participate in HIV/AIDS research, and their efforts contribute to the \$2.9 billion total. The largest amount, \$1.5 billion, is from the National Institute of Allergy and Infectious Diseases.

NIH's research focuses on understanding the basic science of the disease (its transmission, how it progresses, and its genetic structure); investigating possible ways to prevent and reduce HIV transmission, including microbicides, vaccines, and behavioral interventions; developing better therapies for those already infected; refining approaches to address the epidemic in developing countries; and studying the behavioral and biomedical aspects of the disproportionate impact of the disease on racial and minority populations in this country. In FY 2005, 37 percent of NIH's research dollars was targeted to the basic science of the disease, 25 percent to the development of therapeutics, 17 percent to the search for a vaccine, 14 percent to behavioral interventions, and the remaining 7 percent to training, infrastructure, and information dissemination.<sup>26</sup>

Thus far, NIH funding has supported 70 clinical trials of nearly 40 vaccine candidates.<sup>27</sup> An article in the July 2005 issue of the journal *Science* discussed the feasibility of developing an effective HIV vaccine. Broadly, vaccine approaches include stimulating the production of antibodies as well as cellular immunity. Some researchers argue that a vaccine will never stop HIV, whereas others believe a vaccine is achievable. Proponents of the view that vaccines are feasible point to monkey experiments which demonstrated that vaccines could protect animals from a relative of HIV. In addition, there are studies of individuals who have an apparent innate resistance to the virus, meaning they have never become infected despite multiple exposures to HIV, to see if that resistance can be identified and mimicked. While NIH's \$507 million dedicated to the vaccine effort in FY 2005 supports numerous studies and clinical trials, author Jon Cohen concluded that discovery of an effective AIDS vaccine "remains a distant dream."<sup>28</sup>

The focus in the area of therapeutic research is multifaceted and includes creating new and better treatments with fewer side effects and toxicities, limited development of drug resistance, reduced cost, and improved potential for patient compliance. Researchers are studying optimal therapy strategies including when to start, change, sequence, or interrupt therapies. Developing treatments for coinfections like hepatitis B and C and tuberculosis is another priority, as is continuing to find safe, effective, convenient strategies for interrupting perinatal transmission. Efforts are also under way to develop treatments that can be implemented in international settings.<sup>29</sup>

## Prevention

Prevention of new HIV infections is critical to reduce disease burden and contain treatment costs. Thirty-eight percent of all HIV infections diagnosed in 2002 progressed to AIDS within 12 months, which shows there continues to be a significant need to get people tested and quickly into treatment before their disease progresses.<sup>30</sup> HIV prevention strategies have included

population-based campaigns promoting sexual abstinence or condom use. Other strategies focus on identifying individuals who are already infected to prevent further transmission. Needle exchange programs to prevent transmission among injection drug users are another type of HIV prevention that the U.S. government does not support; in fact, it is illegal to use federal dollars to support such programs.

The CDC leads the government's HIV/AIDS prevention efforts. The agency was appropriated \$732 million in FY 2005 to conduct these efforts. This federal investment in HIV/AIDS prevention amounts to 4 percent of total federal HIV/AIDS funding. The agency's National Center for HIV, STD, and TB Prevention within the newly created Coordinating Center for Infectious Diseases organizes agency-wide efforts. The CDC distributes most of its funding to state and local health departments to conduct disease surveillance; fund HIV testing, counseling, and referral; and promote public understanding and awareness.

In April 2003, the CDC launched a new initiative "Advancing HIV Prevention (AHP): New Strategies for a Changing Epidemic" that consists of targeting efforts around four strategies for preventing HIV infections: (a) making HIV testing a routine part of medical care; (b) implementing new models for diagnosing HIV outside the medical setting; (c) working with HIV-positive persons and their partners to prevent new infections; and (d) further reducing perinatal transmission of HIV.<sup>31</sup> The new initiative is an effort to help the CDC meet its current prevention goals. Two of the goals are to halve the estimated 40,000 new infections each year and to increase the proportion of HIV infected people who know their status from 70 to 95 percent by 2005.

Some researchers argue that these four interventions will likely achieve only about one-third of the CDC's goal of preventing 20,000 new infections each year. Such critics maintain that the CDC should utilize cost-effectiveness modeling to determine the most cost-effective interventions and to target limited prevention dollars accordingly. For example, strategies that target high prevalence groups like men who have sex with men or places where high prevalence groups seek care, like STD clinics, are significantly more cost-effective per infection prevented than standard counseling and testing.<sup>32</sup>

The aforementioned distribution of federal funding illustrates that the domestic HIV/AIDS policy in the United States is primarily focused on providing treatment services. Although research and prevention are clearly important, the remainder of this paper will focus on funding for HIV/AIDS treatment services, particularly Ryan White, the government's largest discretionary funder of such services.

**Federal HIV/AIDS funding in the United States is primarily focused on providing treatment, as opposed to research or prevention.**



## AN ACT, IN FOUR TITLES AND A PART

As the HIV/AIDS epidemic unfolded in the 1980s, Congress began to hear from public health officials, urban public hospitals, and those infected about the personal and financial burdens of the disease. Congress responded in the late 1980s by funding demonstration programs in those urban areas most affected by the epidemic. The programs focused on developing community-based HIV/AIDS systems of care; purchasing AZT, the first FDA-approved antiretroviral drug; and addressing the needs of HIV-infected pregnant women and children.<sup>33</sup> The demonstrations were funded through annual appropriations bills and provided the framework for the future Ryan White CARE Act. The CARE Act was signed into law on August 18, 1990 and became Title XXVI of the Public Health Service Act.

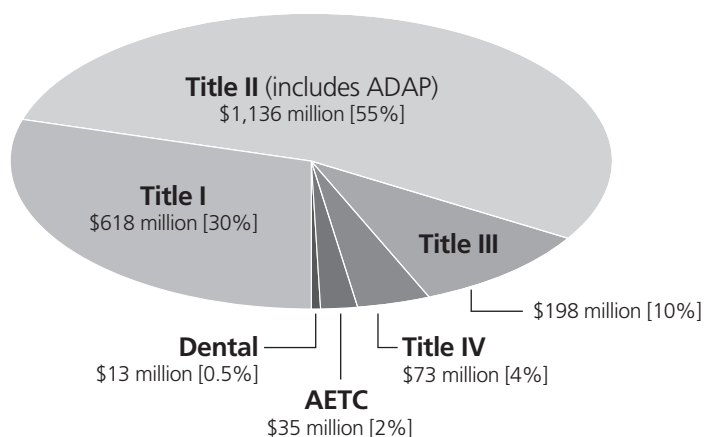
The Act authorized a discretionary grant program “to provide emergency assistance to localities that are disproportionately affected by the Human Immunodeficiency Virus epidemic and to make financial assistance available to States and other public or private nonprofit entities to provide for the development, organization, coordination and operation of more effective and cost efficient systems for the delivery of essential services to individuals and families with HIV disease.”<sup>34</sup> The Health Resources and Services Administration (HRSA) within DHHS administers the Act through the HIV/AIDS Bureau (HAB).

The Ryan White CARE Act is organized into four titles. Each title directs funds to a different type of recipient in an effort to ensure a community-driven treatment response but also to maximize state-level involvement where appropriate. For example, Title I is geared to cities, Title II to states, and Titles III and IV to community-based providers. The funding distribution mechanisms also vary across the titles. Title I uses both formula and competitive grants, Title II formula grants, and Titles III and IV competitive grants. Eighty-five percent of Ryan White funds are distributed through Titles I and II of the Act (Figure 4).

### Title I (Part A) of the CARE Act

The first title of the Act provides funds to metropolitan areas with significant need for services, specifically eligible metropolitan areas (EMAs) that have a population of at least 500,000 and more than 2,000 ELCs within the past five years. Half of the funds are distributed through formula grants and the other half through competitive supplemental

**FIGURE 4**  
**Ryan White CARE Act Funding by Title, FY 2005**



Note: Percentages do not add up to 100, due to rounding.

Source: HRSA, “Appropriations History: FY 1991 to FY 2005,” table, January 4, 2005, available at <ftp://ftp.hrsa.gov/hab/fundinghis04.xls>; and HRSA, Fiscal Year 2006: Justification of Estimates for Appropriations Committees, available at [www.hhs.gov/budget/06budget/documents/HRSABudget06.pdf](http://www.hhs.gov/budget/06budget/documents/HRSABudget06.pdf).

grants on the basis of severity of need criteria. The FY 2005 appropriation for Title I was \$618 million.

An EMA's formula grant is based on its proportion of ELCs compared to all ELCs across all EMAs. In FY 2005, 51 EMAs were funded in 21 states, Puerto Rico, and the District of Columbia (see text box, below). Supplemental grants are awarded through a narrative grant application process that is designed to illustrate an EMA's severe need for supplemental financial assistance, its local resources committed to address the disease, its ability to utilize funds cost-effectively, and its ability to allocate resources according to local disease demographics. By statute, the severe need criteria accounts for one-third of the weight of all application review factors.

Title I grant funds may be used for "outpatient and ambulatory health services, including substance abuse treatment, mental health treatment, and comprehensive treatment services,...outpatient and ambulatory support services (including case management), to the extent that such services facilitate, enhance, support, or sustain the delivery, continuity, or benefits of health services for individuals and families with HIV disease."<sup>35</sup> They may also be used for inpatient case management services and outreach activities focused on identifying people who know their HIV status and

### CARE Act Eligible Metropolitan Areas (EMAs), FY 2005

Atlanta, GA	Fort Worth, TX	New Haven, CT	St. Louis, MO
Austin, TX	Hartford, CT	New Orleans, LA	San Antonio, TX
Baltimore, MD	Houston, TX	New York, NY	San Diego, CA
Bergen-Passaic, NJ	Jacksonville, FL	Norfolk, VA	San Francisco, CA
Boston, MA	Jersey City, NJ	Oakland, CA	San Jose, CA
Caguas, PR	Kansas City, MO	Orange County, CA	San Juan, PR
Chicago, IL	Las Vegas, NV	Orlando, FL	Santa Rosa-Petaluma, CA
Cleveland-Lorain-Elyria, OH	Los Angeles, CA	Philadelphia, PA	Seattle, WA
Dallas, TX	Miami, FL	Phoenix, AZ	Tampa-St. Petersburg, FL
Denver, CO	Middlesex-Somerset-Hunterdon, NJ	Ponce, PR	Vineland-Millville-Bridgeton, NJ
Detroit, MI	Minneapolis-St. Paul, MN	Portland, OR	Washington, DC
Dutchess County, NY	Nassau-Suffolk, NY	Riverside-San Bernardino, CA	West Palm Beach, FL
Fort Lauderdale, FL	Newark, NJ	Sacramento, CA	

are not treating their disease. The statute mandates that funds be allocated to services for infants, children, and women in the proportion that they are represented in the HIV/AIDS population of the EMA.

Grants are awarded to the chief elected official of the city or county agency that provides health care services to the largest number of people living with AIDS, generally the local health department. That official appoints a local planning council, of which at least 33 percent of the members must be either people living with HIV/AIDS or the parent or a caregiver of a child with HIV/AIDS. There must also be representation from health care providers, mental health and substance abuse providers, and the prison system, among others. The local planning council's key duties are (a) to determine the size and demographics of the HIV-positive population; (b) to determine the needs of the population, with special attention to those who know their positive status but are not in care and those disproportionately affected and historically underserved populations; (c) to establish funding priorities; and (d) to develop a comprehensive plan for the delivery of health and support services to the population.

The 1996 reauthorization changed the basis of the funding formula for Titles I and II from cumulative AIDS cases (living or deceased) since 1981 to the number of ELCs. Had this change been implemented without modification, it would have created significant shifts in funding away from areas most affected by the epidemic in the early years. As a result, Congress added a hold harmless provision to Title I that would be triggered if any changes in ELCs for an EMA would result in decreased funding. Once the provision is triggered, the grant will decline each year to 98 percent, 95 percent, 92 percent, and 89 percent of the base year grant. In all subsequent years, the EMA will receive 85 percent of its base year grant. Another provision in the 1996 reauthorization "grandfathered" existing EMAs by establishing that if an EMA was eligible in FY 1996 for Title I funding, it will always receive funding regardless of whether its ELCs or population size drops below statutory levels.

The 2000 reauthorization included a study by the Institute of Medicine (IOM) to examine, among other things, the overall financial impact of distributing Ryan White funding on the basis of HIV infection instead of AIDS diagnosis. Following the recommendations of that report, the reauthorization required the Secretary of DHHS to determine whether state HIV data was accurate and reliable enough to be used in place of AIDS data for Ryan White planning and funding allocation. To date, the Secretary has determined that Ryan White funding allocations should continue to be made based on AIDS case data. Regardless of the IOM's report and Secretary's decision, the statute currently requires that HIV data be used as the basis for allocating funds starting in FY 2007.

## Title II (Part B) of the CARE Act

Title II funds three types of formula grants: base grants, AIDS Drug Assistance Program (ADAP) grants, and emerging communities grants. In FY 2005, Congress appropriated \$1.14 billion for Title II.

**Base Grants** — The Title II base grant is a formula grant that goes to all 50 states, the District of Columbia, Puerto Rico, Guam, the U.S. Virgin Islands, and five U.S. Pacific territories. It has two parts. Eighty percent of the award is based on a state's proportion of all estimated living AIDS cases, and the other 20 percent comes from the state's proportion of AIDS cases within the state but outside of its EMAs. For states with fewer than 90 AIDS cases, the minimum grant is \$200,000; states with more than 90 cases receive a minimum of \$500,000, and territories receive at least \$50,000.

**ADAP** — About one-third of all Ryan White funding and the majority of Title II funds—\$788 million in FY 2005—is earmarked by Congress for ADAP. Although ADAP was incorporated in Title II in the original authorization in 1990, the ADAP earmark within the Title II appropriation started in 1996, with the emergence of HAART. Federal ADAP funds are distributed according to a formula based on each state's proportion of the nation's living AIDS cases. In addition to the federal grant, some ADAPs receive state general revenue funding, funds from other parts of the CARE Act, or funds from negotiated drug rebates from drug manufacturers. In 2002, 136,345 clients were served through state ADAPs.<sup>36</sup>

ADAPs operate in 57 jurisdictions including all 50 states, Puerto Rico, the District of Columbia, the U.S. Virgin Islands, the Marshall Islands, Guam, American Samoa, and the Northern Mariana Islands. They primarily provide FDA-approved prescription drugs to eligible individuals, but they may also use funds to pay to continue an eligible individual's private health insurance if it includes prescription drug coverage. Up to 5 percent and, in some cases, 10 percent of a state's ADAP funds may be used to support programs to help clients adhere to their drug treatment regimens, which as mentioned in the treatment section of this paper is critical for reducing drug resistance and for ensuring treatment efficacy.

States must ensure that an individual has been medically diagnosed with HIV and that he or she is considered low-income as defined by the state to receive services from ADAP. The statute gives states flexibility in designing ADAPs, including establishing income-eligibility criteria. A few states have set medical eligibility criteria related to either the count of CD4<sup>+</sup> T cells or the viral load.

### Ryan White CARE Act Structure at a Glance

**Title I (Cities)** — Base grants and supplemental grants to eligible metropolitan areas

**Title II (States)** — Base grants, ADAP grants, ADAP supplemental grants to states, and grants to emerging communities

**Title III (Communities)** — Grants to public or private nonprofits to provide early intervention services

**Title IV (Communities)** — Grants to public or private nonprofits to serve women, infants, children, and youth

**Part F** — AIDS Education Training Centers, dental grants, Special Projects of National Significance

Thirty-eight ADAPs provide prescription drugs to individuals with incomes at or above 300 percent of the federal poverty level (FPL).<sup>37</sup> (The FPL, for one person in the contiguous 48 states and District of Columbia, was \$9,570 in 2005; 300 percent of the FPL would be \$28,710.) Eleven states set their income levels at 200 percent of the FPL, and North Carolina set its level at 125 percent of the FPL, the lowest of all the states.<sup>38</sup> Similarly, the formularies set by ADAPs vary widely; 17 ADAPs do not provide all FDA-approved antiretrovirals.<sup>39</sup>

As the payer of last resort for HAART, many state ADAPs have experienced more demand for drugs than they have resources to meet. As of July 2005, eight states had instituted waiting lists for drugs, with a total of 435 people on them. In response to growing waiting lists, in June 2004 President Bush authorized one-time, emergency funding of \$20 million to serve people on waiting lists in 10 states. Currently, 1,487 individuals are enrolled in the emergency program. That funding will expire in September 2005, and those individuals will presumably revert back to their state's waiting lists, which will likely increase the total number of individual on waiting lists to 1,922 in nine states.<sup>40</sup>

In this time of continued fiscal belt-tightening among most government jurisdictions, states are also implementing a variety of cost-containment strategies in their ADAPs. Arkansas, Missouri, New Hampshire, and Utah have reduced their formularies, and Oklahoma and South Dakota have established annual per capita expenditure limits. Nine ADAPs anticipate instituting new or additional measures before the end of the current ADAP fiscal year, March 31, 2006.<sup>41</sup>

The 2000 reauthorization added a supplemental ADAP grant program to help states with demonstrated severe need to increase access to medications. Three percent of ADAP funding is reserved for this program, and states must meet certain eligibility criteria to receive it. States may only use these funds to purchase drugs and they must match a dollar for every four federal dollars provided through this program. Not all eligible states take advantage of this additional money because they cannot come up with the state match.

**Emerging Communities Grants** — In an attempt to respond to the growing epidemic in small urban centers, and in suburban and rural areas, in the 2000 reauthorization Congress added the emerging communities formula grant program to Title II. It is unclear why Congress placed this grant program in Title II, which funds states, instead of in Title I, which funds cities. Funds are distributed to communities with a population of at least 50,000 that have had between 500 and 1,999 reported AIDS cases over the last five years. Funding is divided into two tiers, with 50 percent awarded to communities with 1,000 to 1,999 AIDS cases and 50 percent to communities with 500 to 999 AIDS cases. Within the two tiers, funds are distributed to communities based on their proportion of AIDS cases within

the tier. In FY 2004, four qualifying communities had between 1,000 and 1,999 cases, and 25 communities had between 500 and 999. Unlike Title I grants to EMAs, funding for emerging communities runs from year to year, with no guarantee of future funding.

Title II also has a hold harmless provision that applies to the base grant and ADAP grant programs. If the funding formula would result in a state's base grant or ADAP grant declining, the hold harmless provision would ensure that the award would not decline more than 1 percent per year from the FY 2000 award. The provision is written so that the base and ADAP awards will never drop below 95 percent of the state's FY 2000 appropriation.

### **Title III (Part C) of the CARE Act**

Whereas the first two titles of the Act provide funds to metropolitan areas and states, the third title awards competitive grants to community-based organizations that serve people living with HIV/AIDS. Grantees are public and private nonprofit primary care providers—mostly federally qualified health centers (FQHCs), city and county health departments, hemophilia treatment centers, and outpatient facilities at academic medical centers. Ninety-eight percent of Title III funds are used to provide early intervention services for uninsured and underinsured individuals. Early intervention services include counseling, testing, primary care, drug therapy, case management, and mental health services, among others. The remaining 2 percent of funds is awarded for capacity building and planning to enable communities to serve this population more effectively. The FY 2005 appropriation for this title was \$198 million, 10 percent of total Ryan White funding.

### **Title IV (Part D) of the CARE Act**

Title IV awards competitive grants to public and private nonprofit organizations to provide primary and specialty care; substance abuse and mental health services; support services such as transportation, child care, and housing assistance; care coordination; access to clinical trials and clinical research to HIV-positive women, infants, children, and youth; and supportive services to family members and others who care for them. A special focus of Title IV is to identify HIV-positive pregnant women and ensure that they have access to prenatal care in order to prevent perinatal transmission of the virus. Congress appropriated \$73 million for Title IV in FY 2005, which is 4 percent of total Ryan White funding.

**Part E** authorizes grants for emergency response employees and establishes notification procedures in case of exposure to infectious diseases, but the corresponding funds have never been appropriated.

## Part F: Provider Training, Dental Reimbursement, and Special Projects

The 1996 reauthorization added three other grant programs as Part F of the Act. The AIDS Education and Training Centers (AETC) Program is the clinical training component of the Act, and it funds a network of 11 regional centers with more than 130 sites that conduct multidisciplinary training and education programs for health care providers who treat patients with HIV/AIDS. From June 2002 to June 2003, about 62,000 clinicians were trained in AETCs; the majority (64 percent) were physicians. Other trainees include physician assistants, nurses, nurse practitioners, oral health professionals, pharmacists, and clinical faculty.<sup>42</sup> The AETC appropriation for FY 2005 was \$35 million, or 2 percent of total Ryan White funding.

Early signs of AIDS often manifest in the mouth through conditions such as thrush, warts, and gum disease. Maintaining good oral health, good nutrition, and other healthy lifestyle habits can reduce the risk of opportunistic infections for an individual with HIV. The Ryan White dental program was created to alleviate significant difficulties in access to dental care for people living with HIV/AIDS. It was transferred from Title VII of the Public Health Service Act to Ryan White (Title XXVI) in 1996. The program reimburses dental schools, postdoctoral dental programs, and, since the 2000 reauthorization, dental hygiene programs for the uncompensated services they provide to people living with HIV/AIDS. The FY 2005 appropriation for the dental reimbursement program was \$13 million, or about 0.5 percent of total Ryan White funding.

The Special Projects of National Significance Program (SPNS) supports the development and replication of innovative models in HIV/AIDS care and service delivery. SPNS is normally funded by set-asides from Titles I through IV of at least \$20 million but not more than \$25 million in any given fiscal year, but appropriations language for FY 2003–2005 directed that SPNS be funded from Public Health Service evaluation set-asides instead. For FY 2005, SPNS was funded at \$25 million. Grantee organizations include academic health center clinics, FQHCs, community-based organizations, state and local health departments, among others. Grantees test new models of care to find ways to increase treatment effectiveness for specific populations, such as those living along the U.S.–Mexico border or in correctional settings, or for improving treatment for those with comorbidities. HRSA awards grants competitively, and the grants typically last three to five years (Table 1, see next page).

**The steady expansion of people living with HIV/AIDS increasingly burdens local care systems and Ryan White as the payer of last resort.**

**TABLE 1**  
**Ryan White CARE Act Federal Appropriations by Title, Fiscal Years 1995–2006**

Fiscal Year	millions \$							Total (billions \$)
	Title I	Title II (includes ADAP)	ADAP	Title III	Title IV	AETC	Dental	
1995	\$357	\$ 198	N/A	\$ 52	\$26	N/A	N/A	<b>\$0.63</b>
1996	392	261	\$ 52	57	29	N/A	N/A	<b>0.74</b>
1997	450	417	167	70	36	\$16	\$ 8	<b>1.00</b>
1998	465	543	286	76	41	17	8	<b>1.15</b>
1999	505	738	461	94	46	20	8	<b>1.41</b>
2000	546	824	528	138	51	27	8	<b>1.60</b>
2001	604	911	589	186	65	32	10	<b>1.81</b>
2002	619	977	639	194	71	35	13	<b>1.91</b>
2003	627	1,067	714	201	75	36	13	<b>2.02</b>
2004	623	1,100	749*	200	74	35	13	<b>2.04</b>
2005	618	1,136	788	198	73	35	13	<b>2.07</b>
2006**	\$618	\$1,146	\$798	\$198	\$73	\$35	\$13	<b>\$2.08</b>

\* This does not include an additional \$20 million that was appropriated in FY 2004 for emergency funding for ADAPs.

\*\* President's budget request.

Source: HRSA, "Appropriations History FY 1991 to FY 2005," table, January 4, 2005, available at <ftp://ftp.hrsa.gov/hab/fundinghis04.xls>, and HRSA, Fiscal Year 2006: Justification of Estimates for Appropriations Committees, available at [www.hhs.gov/budget/06budget/documents/HRSABudget06.pdf](http://www.hhs.gov/budget/06budget/documents/HRSABudget06.pdf).

## POLICY ISSUES FOR REAUTHORIZATION

As with deliberations over past reauthorizations, policymakers must consider the changing HIV/AIDS epidemic and advances in prevention and treatment when reflecting on the adequacy of the existing statute. They need to consider what the epidemic will look like over the next five years, what treatment needs will be, and what might be the CARE Act's role in addressing those needs. They cannot ignore that the steady expansion of people living with HIV/AIDS—the hundreds of thousands not in care, and the additional 22,000 seeking services each year—increasingly burdens local health care systems and Ryan White as the payer of last resort.

Although some state budgets are beginning to show signs of improvement, Medicaid continues to consume an average of nearly 20 percent of state resources. In response, some states are scaling back provider



payments, income eligibility levels, and benefits—especially pharmaceutical benefits, which put additional pressure on the CARE Act. African Americans and other minority groups continue to bear a disproportionate disease burden and women, particularly women of color, are increasingly infected with the virus. Preexisting disparities in access to care for minority populations make treatment financed through Ryan White ever more needed and ever more challenging to provide.

Most of the reauthorization debate focuses on changes within the existing four-title structure, but some do advocate for major restructuring. Assuming maintenance of the four title structure, key areas of debate include (a) whether and what changes should be made to allocate treatment dollars more equitably, (b) whether the statute needs to be modified to reinforce the shift to a chronic disease model from a palliative care model by defining a core set of services, (c) whether there is a congressional role to be played in stabilizing and providing more uniformity to ADAPs, and (d) ways to improve grantee accountability.

### Improving Access Equity Through Funding Allocation Changes

There are a number of issues under debate related to Ryan White funding formulas. One revolves around the data that goes into the formulas in Titles I and II. The current statute mandates a shift from using AIDS to HIV data by FY 2007, but there are questions about the impact and feasibility of such a switch. Some HIV/AIDS policymakers would like to see other variables such as uninsurance rates, relative costs of care, public and private insurance coverage, and relative generosity of a state's Medicaid program included in the formula for determining a jurisdiction's grant award. Others would like to reduce funding inequities that result from formula design as well as the hold harmless and grandfathering provisions in Titles I and II.

**What's in a Number?** At present, Title I and II formula grants are distributed on the basis of one measure: relative disease burden, calculated from AIDS data. By continuing to distribute Ryan White funds on the basis of AIDS data, the statute ignores the reality that the majority of the HIV/AIDS population in need of treatment is HIV positive but their disease has not progressed to AIDS. Using AIDS data instead of HIV data also fails to compensate jurisdictions for working hard to get HIV-positive people diagnosed and into treatment early, thereby preventing their deterioration from HIV status to AIDS. Many argue that areas with emerging HIV epidemics and therefore limited AIDS case history, like the southeastern states, are underfunded because HIV cases are not counted in the formulas.

There is general consensus that using valid HIV data to distribute Ryan White dollars would more accurately reflect the nature of the epidemic and treatment needs, as well as create an additional incentive for states

**There is general consensus that using valid HIV data to distribute Ryan White dollars would more accurately reflect the nature of the epidemic and treatment needs.**

and localities to identify a higher proportion of people infected with HIV. The debate continues to lie in determining whether FY 2007 is the appropriate time for that switch. Concerns about switching from AIDS to HIV data center on the lack of nationally available comparable HIV data and the level of maturity and reliability of the HIV data that is collected. As mentioned earlier in this paper, the CDC accepts only confidential, name-based reports for inclusion in its national HIV prevalence estimate. Although 38 states currently provide name-based reports to the CDC, the CDC only uses data from the 32 states that it considers to have mature data collection systems.

As directed by the 2000 reauthorization, the IOM explored the feasibility of switching to HIV data. The IOM committee determined that HIV data was not ready for inclusion at the time of its 2004 report. It made several recommendations to DHHS and others to either justify the inclusion of HIV data by FY 2007, as Congress has contemplated, or to conclude that reported HIV cases do not result in a more equitable resource allocation and, thus advising Congress that it should reconsider its recommendation prior to FY 2007.<sup>43</sup> On July 27, 2005, the Bush administration released its principles for Ryan White reauthorization. One of the principles is to maintain the current statutory requirement that all states must submit name-based HIV data by FY 2007.<sup>44</sup>

The Government Accountability Office (GAO) analyzed the impact of using HIV and AIDS data in distributing Title II base grant funds for FY 2004 and found that incorporating HIV data would result in funding shifts; about half of the states would experience funding increases (a large portion of those increases would be in the southern states), and half would experience decreases. Maintaining hold harmless and minimum grant provisions would significantly mediate these shifts, however. The analysis found that if hold harmless provisions were removed from the modified formula, about 10 percent, or \$28.4 million, of Title II base grants would shift across states. Twenty-six grantees, including 11 from the South, would receive funding increases and 26 would receive decreases; California, New York, and Georgia would experience the largest decreases. "States that would benefit from the use of HIV cases tend to be those with the oldest HIV case reporting systems. Those states with the oldest systems include 11 southern states whose HIV reporting systems were implemented prior to 1995."<sup>45</sup> At least initially, maintaining the hold harmless and minimum grant requirements would result in just a 4 percent shift in funds instead of the 10 percent shift if they were eliminated.

Many argue that the best way to improve HIV surveillance data is to tie states' prevention and treatment funding to reporting name-based data to the CDC. Such an approach would encourage states to intensify their testing programs to capture their share of the 250,000 to 300,000 people living with HIV/AIDS that the CDC estimates are currently undiagnosed. Ultimately, policymakers must decide whether the future benefit of improved

HIV surveillance data is worth the tradeoff of using the imperfect HIV data currently available and the resulting funding shifts that would occur. As the GAO study demonstrated, part of that decision requires that policymakers should recognize that switching to HIV data as a means to achieve more equitable funding distribution is less meaningful if hold harmless provisions are kept intact.

**Beyond Disease Burden: Measuring Need** — Determining resource needs for a given area requires knowing its disease burden, the costs of providing care, and the available resources. Currently, the CARE Act's formulas rely solely on disease burden to distribute funding. Different parts of the CARE Act—Title I supplemental grant awards and Title III and IV awards—attempt to take other factors into account in allocating funding. The IOM committee that published *Measuring What Matters* examined the method for determining severity of need for the Title I supplemental grant program, the largest of the Act's competitive grant programs in terms of funding. Although the committee's findings are focused specifically on the process for this grant program, they are relevant to any attempt to incorporate other measures, beyond AIDS or HIV data, into determining need throughout the Act.

The committee found that although HRSA requests extensive information in the application process about the epidemiology of HIV infection and AIDS, the prevalence of comorbid conditions, poverty and insurance status, and populations with special needs, there are no reliable, consistent, and comparable data at a local level to make the responses meaningful. The committee therefore recommended that HRSA undergo a consultative process to develop models based on publicly available data to estimate EMA-level resource needs. They added that HRSA needs to find a way to measure actual need in a number of areas to check the estimates generated by the model. In its reauthorization principles, the Bush administration recommends providing the Secretary of DHHS the authority to create a severity of need core services index (SNCSI) based on objective criteria to distribute funds to the neediest metropolitan areas and states first. The SNCSI would use data-driven criteria to capture HIV prevalence, poverty levels, and availability of other local, private, state, and federal resources. They argue that distributing funds in this way, coupled with a maintenance of effort requirement, would make the program more responsive to populations most in need.<sup>46</sup>

On the surface, it may seem more equitable to develop such models in an attempt to distribute resources on the basis of a number of objective measures of need, not just disease burden, but some policymakers argue that this process would penalize EMAs and states that have worked hard to make more resources available by strengthening their safety nets and expanding their Medicaid programs. They question whether such an approach would create perverse incentives for jurisdictions to invest less in the safety

**As currently written, the statute distributes more funding to states with eligible EMAs than states without them, regardless of whether the states have similar total AIDS cases.**

net and Medicaid to qualify for more Ryan White funding. On the other hand, Ryan White dollars are small in comparison to the federal matching funds states receive for Medicaid, so if states have expanded Medicaid coverage, less Ryan White funding might not be a significant issue.

**Double Counting: Fair Play or Dubious Practice?** The current statute distributes more funding to states with eligible EMAs than states without them, regardless of whether the states have similar total AIDS cases. The double counting of AIDS cases in EMAs—in the Title I formula and again for 80 percent of the base grant for Title II—means that states with similar numbers of AIDS cases but differences in population centers can receive significantly different funding for each AIDS case, even if they have a similar number of total AIDS cases. The GAO testified before a congressional subcommittee to this point in June 2005 and provided the example of South Carolina and Connecticut. For fiscal year 2004, Connecticut had 5,363 AIDS cases and South Carolina had 5,563. “However, Connecticut had two EMAs that accounted for 91.3 percent of its cases while South Carolina had none. Connecticut received \$26,797,308 (\$4,997 per AIDS case) in combined Title I and Title II funding while South Carolina, with 200 more cases, received \$20,705,328 (\$3,722 per AIDS case). Connecticut received 29 percent more funding than South Carolina, a difference of \$6,091,980, or \$1,275 per AIDS case.”<sup>47</sup>

Some might argue that the cost of treatment in Connecticut is higher than South Carolina and therefore the per AIDS case funding discrepancy is justified, but in the absence of formulas that take treatment cost data into account, these per-case discrepancies appear unfair. The Bush administration has said it will support the elimination of the double counting of cases between EMAs and states in Titles I and II.<sup>48</sup>

**Harmless to Some; Harmful to Others** — The goal of the Title I and II hold harmless provisions is to minimize the shifts in funding to EMAs and states from year to year and the service disruptions that might result. Hold harmless funds are added to an EMA’s formula grant to bring it up to the level defined in statute (at least 85 percent of its base year for Title I and 95 percent for Title II). The downside of such provisions is that they make it difficult for policymakers to distribute funding to areas most affected by the epidemic. In addition, the money that is set aside to pay for the hold harmless provision would otherwise be distributed to eligible grantees.

As written, the current Title I hold harmless provision benefits 21 EMAs, but San Francisco receives almost 92 percent of the hold harmless dollars (\$7,358,239 in FY 2004).<sup>49</sup> In San Francisco’s case, hold harmless dollars represent 45.5 percent of its Title I base grant award.<sup>50</sup> The administration has stated it supports the elimination of current hold harmless provisions altogether.<sup>51</sup> Some advocacy groups would prefer a less drastic change; they recommend changing the Title I hold harmless provision so that it will provide 79 percent of a jurisdiction’s base year award instead of the current 85 percent.<sup>52</sup>

Similarly, in 1996 when the authorizers grandfathered EMAs eligible as of FY 1996, they limited the program's future ability to distribute funds to areas most in need. For example, in FY 2004, 29 of 51 EMAs did not meet the statutory threshold of 2,000 ELCs within the past five years. Those 29 EMAs reported AIDS cases ranging in number from 223 to 1,941 within the past five years. This provision creates disparities in per case funding between grandfathered EMAs in Title I and those smaller urban areas receiving funds under the emerging communities program in Title II. For instance Memphis, which receives an emerging community grant, reported more AIDS cases than 26 grandfathered EMAs.<sup>53</sup> About 20 percent of Title I funding, or \$116 million, was directed to these grandfathered EMAs.

### **Mandating a Set of Core Services: Positive or Punitive?**

Community-level decision making and administrative flexibility have always been at the center of the CARE Act. A second key reauthorization debate focuses on whether that flexibility should be curtailed by defining a core set of services and a specific proportion of grant funds to be spent on those core services in an effort to create more equitable access to treatment across the country. As the funder of last resort, Ryan White is meant to fill gaps left by Medicaid, Medicare, private insurance, and state and community programs, which leads to significant variation in access across states and jurisdictions.

Core services would include primary medical care, medications, laboratory tests, oral health, mental health and substance abuse services, case management, and nutrition and treatment adherence counseling. According to FY 2003 data, about 53 percent of Title I grant funds across all EMAs were used to provide health care services, 23 percent went to fund support services, 12 percent for case management, and the remainder for planning council support and other grant administration. In individual EMAs, proportions dedicated to health care services ranged from highs of 79 percent in San Juan, 75 percent in Atlanta, and 70 percent in Denver to lows of 9 percent in Minneapolis, 23 percent in Oakland, California, and 27 percent in Boston.<sup>54</sup>

**Ryan White fills the gaps left by Medicaid, Medicare, private insurance, and state and community programs, which leads to significant variation in access across jurisdictions.**

One analysis funded by HRSA found that for Title I grantees there was no significant relationship between a jurisdiction's HIV health care financing environment (they were deemed low, medium, or high based on Medicaid, insurance rates, and other factors) and its Title I health care expenditures. The analyses actually found a slight, nonsignificant trend that the more resources there were in a health care financing environment, the more Title I and II funds were spent on health care services.<sup>55</sup>

In response to this variation, a number of key HIV/AIDS advocacy organizations are recommending mandating a set of core services and funding set-asides. The AIDS Healthcare Foundation, recommends mandating that

at least 65 percent of Title I funds be spent on medical services. The HIV Medicine Association and American Academy of HIV Medicine also support a core services mandate. They advocate that at least 25 percent of awards be used for primary medical care services and 25 percent for basic medical services. The Bush administration also supports defining a set of core medical services (defined as “basic, primary medical care and medication”) and wants 75 percent of Ryan White funds across the four titles to be used for core medical services.<sup>56</sup>

Other key advocacy groups including the National Alliance of State and Territorial AIDS Directors (NASTAD), the Communities Advocating Emergency AIDS Relief (CAEAR) Coalition, and AIDS Action oppose defining a mandatory set of services or funding set-asides for those services.<sup>57</sup> They contend that such mandates would prove detrimental in a number of ways. They argue that jurisdictions that have created an adequate health care safety net, which provides access to primary care services to the uninsured or underserved with HIV/AIDS, need maximum flexibility to be able to target most of their dollars to support services. Such a mandate for medical services could also have a negative effect in resource-poor areas, where Ryan White dollars may be the only source of funding for support services. These organizations argue that instead of mandating such a priority, HRSA should exercise greater administrative oversight of grantees to ensure Ryan White resource allocation complements local capacity.

**Despite a 15-fold increase in the national ADAP earmark over the last 10 years, some ADAPs cannot meet demand and are implementing waiting lists.**

### Can ADAPs Adapt, or Should Congress Help Out?

Access to ADAP pharmaceuticals varies from state to state. Demand for a state’s ADAP services depends on a number of factors, including the drug coverage its Medicaid program offers and whether there is a state pharmacy assistance program in operation. States have the flexibility to define income eligibility levels and set their formularies. Despite a 15-fold increase in the national ADAP earmark between FY 1996 and FY 2005, some ADAPs do not have the resources to meet demand and are implementing waiting lists and cost-containment measures. In light of this trend, part of the debate around ADAP reauthorization focuses on finding ways to financially stabilize those ADAPs that are unable to meet existing demand. At the same time, some in the HIV/AIDS community advocate a minimum income eligibility standard and standard formulary as a way to improve access equity across states, but these changes would prove costly to those ADAPs already experiencing resource problems.

In addition to these issues, there is concern that the new Medicare prescription drug benefit, due to begin on January 1, 2006, may negatively affect some ADAPs. Most Medicare beneficiaries with HIV/AIDS are

dually eligible for Medicaid and will receive a low-income subsidy or “extra help” from the government to pay for premiums, deductibles, coinsurance, and any gaps in coverage under the new benefit. The estimated 35 percent of Medicare beneficiaries with HIV/AIDS who are not dual eligibles, however, will have to pay \$3,600 in out-of-pocket costs (such as deductibles, monthly premiums, coinsurance) before Medicare catastrophic drug coverage begins. If a beneficiary needs help paying premiums, deductibles, or other cost sharing, any contribution made by an ADAP toward those costs would not count toward the beneficiary’s true out-of-pocket costs. Unless the beneficiary could pay for these costs him or herself, catastrophic coverage would never be triggered, leaving the beneficiary in a coverage gap and responsible for 100 percent of their drug costs. At this point they would likely return to ADAPs as their source for prescription drugs again.<sup>58</sup>

In terms of improving the programs’ financial status, ADAPs are currently eligible to receive significant discounts on prescription drugs through the federal “340B” drug discount program. As of June 2004, 51 of 57 ADAPs participated in the 340B program. One suggested way to increase ADAPs’ purchasing power beyond that of the 340B program is to extend to ADAPs the federal ceiling price that is currently given by drug manufacturers to the Department of Veterans Affairs, Department of Defense, PHS, and the Coast Guard. NASTAD, the CAEAR Coalition, and AIDS Action support this option. Among other ways to stabilize ADAPs, the Bush administration recommends giving the Secretary of DHHS the authority to redistribute any Title I and II funds unspent by grantees to state ADAPs with the greatest need. Others have suggested that ADAPs could collect significant revenues by consistently collecting income-based fees as outlined in the statute.<sup>59</sup>

Aside from funding of ADAPs specifically, issues of core formularies and standardized income eligibility levels remain debatable. The Bush administration supports giving the Secretary the authority to develop a list of core medications based on the PHS HIV/AIDS Clinical Practice Guidelines that would be the priority for federal funding, but it does not recommend a minimum income eligibility level.<sup>60</sup> AIDS Action supports setting a minimum income eligibility level of 350 percent of the FPL and establishing an open formulary. The HIV Medicine Association, the American Academy of HIV Medicine, and the Southern AIDS Coalition recommend setting an income eligibility floor at 300 percent of the FPL.<sup>61</sup> NASTAD opposes any core formulary requirement or minimum income eligibility level; it argues that setting a standard formulary might actually reduce access by creating a formulary ceiling above which more generous states might not continue to go. (NASTAD also asserts that states might redirect state revenues to other areas, instead.) Defining a core formulary would also place financial strains on those states with leaner formularies, perhaps forcing them to redirect their Title II base awards to bring their ADAPs into compliance.

## Spotlight on Accountability

The Bush administration has put forth a number of recommendations focused on improving accountability for Ryan White resources. They include improving grantee reporting of system and client-level data and strengthening the payer of last resort role by conducting regular audits.<sup>62</sup> The DHHS Office of the Inspector General found in a 2004 report that Ryan White Title I and II grantees' monitoring of their subgrantees was limited and could be improved through guidance from HRSA.<sup>63</sup> NASTAD cautions against mandating any one-size-fits-all approaches to monitoring grantees. It supports increased data sharing between Medicaid and Medicare with ADAPs to ensure that ADAP funds only pay for drugs when no other coverage is available.<sup>64</sup>

## Starting from Scratch: Scrapping the Existing Title Structure

A small but vocal minority argue that the existing title structure should be done away with completely and that the authorizers should create an entirely new program. One suggestion would be to direct all funding to states in two streams—one for medical and support services and the other for drug assistance—allowing states to set priorities and distribute funds. Along this line, the AIDS Healthcare Foundation has proposed streamlining the Act into two programs: one for services and one for drugs, with grants available to cities and to states. They argue that reducing the title structure to two would improve coordination across grantees and reduce administrative costs. Supporters of maintaining the current title structure argue that such changes would create major dislocations in funding, which could lead to discontinuity in services for many people living with HIV/AIDS.

## CONCLUSION

Many people with HIV/AIDS who are able to access HAART are living longer, more productive lives. With somewhere between 40 and 60 percent of people with HIV/AIDS not receiving regular treatment and an estimated 22,000 new people with HIV in need of services each year, pressure continues to mount on safety net programs that serve or are designed for people with HIV/AIDS, like Medicaid and the Ryan White CARE Act. Policymakers have the difficult task of balancing the policy goal of providing equitable access to treatment for low-income, uninsured people living with HIV/AIDS across the country with the reality of finite resources, 15 years of funding history, and the voices of a variety of interest groups.



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