



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

October 15, 1996

NOTE FOR THE DIRECTOR

FROM: Nancy-Ann Min

*NAM*

RE: Highlights of Federal HIV/AIDS Funding and Initiatives during Clinton Administration

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The attached table and bullets provide information about our record with respect to funding for AIDS research, prevention, treatment, and services. (This does not include a few relatively small items such as AIDS research at DOD, because we do not have updated numbers for these initiatives).

I thought you might find this background to be useful.

cc: Jack Lew  
John Koskinen  
Larry Haas  
Barry Clendenin

Carol Rasco  
George Stephanopoulos  
Don Baer  
Alexis Herman  
Patsy Fleming  
Jeremy Ben-Ami  
Chris Jennings

## Highlights of Federal HIV/AIDS Funding and Initiatives: FY 1993- FY 1997

### Funding History of Selected HIV/AIDS Activities: FY 1993-97

(BA -- \$ in Millions)

	<u>FY 1993</u>	<u>FY 1997</u>	<u>\$ Increase over FY93</u>	<u>% Increase Over FY93</u>
NIH AIDS Research	1,071	1,502	+431	+40%
HRSA Ryan White AIDS Treatment Grants	386*	996	+610	+158%
CDC HIV Prevention	498	617	+119	+24%
HUD Housing Opportunities for People with AIDS	100	196 **	+96	+96%
<b>Medicaid Federal Share (Mandatory)</b>	<b>1,290</b>	<b>1,970</b>	<b>+680</b>	<b>+53%</b>
<b>Medicare (Mandatory)</b>	<b>385</b>	<b>780</b>	<b>+395</b>	<b>+102%</b>

\*Comparable estimate to grants currently authorized under Ryan White. Two grants that are currently authorized in the Ryan White CARE Act 1996, Pediatric AIDS Demonstration Grants and AIDS Education and Training Centers, were not funded through Ryan White in FY93. The FY93 estimate includes \$21 million for Title IV Pediatric AIDS and \$16 million for AIDS Education and Training Centers. Both of these grants are now authorized as part of the current Ryan White CARE Act of 1996.

\*\*Assumes \$25 million of Section 8 Rental Assistance is recaptured and transferred to HOPWA, as provided in Section 214 (b) (2) of the VA/HUD/Independent Agencies Appropriation Act of 1997 (P.L. 104-204).

- FY 1997 Funding for AIDS Research, Treatment and Prevention** -- Funding for several discretionary HIV/AIDS activities has increased substantially in FY 1997 as compared to FY 1993. These include a 40% increase in NIH AIDS research, a 158% increase in Ryan White AIDS treatment grants, a 24% increase in CDC HIV prevention activities and a 96% increase for HUD's Housing Opportunities for People with AIDS (HOPWA) program.
- Support for State AIDS Drug Assistance Programs (ADAP)** -- Soon after the Food and Drug Administration (FDA) began approving an expensive new class of AIDS therapies called "Protease Inhibitors" in early 1996, the Administration proposed Budget Amendments of \$52 million and \$65 million in FY 1996 and FY 1997 respectively to increase specific funding for AIDS Drug Assistance Programs (ADAP) through Ryan White. (ADAPs provide access to medications for people with HIV disease who are not covered by Medicaid or do not receive prescription drug coverage through private sources.) Between March 1st and October 1st, 1996, funds appropriated for ADAP activities increased by at least \$167 million.
- Federal Medicaid Spending on HIV/AIDS** -- The Health Care Financing Administration (HCFA) estimates that at least 50% of people with AIDS and more than 90% of children with AIDS are covered under Medicaid. Federal Medicaid spending on AIDS/HIV treatment has increased 53% since FY 93. Currently, approximately 100,000 Medicaid beneficiaries are HIV positive, and Federal Medicaid expenditures on AIDS are estimated to be \$1.97 billion in FY 97 according to HCFA. HCFA considers these expenditures and population estimates to be "rough", as the population with AIDS, treatment methods and AIDS medical costs have evolved substantially in recent years.

However, Medicaid is clearly the largest single payer of direct medical services for people living with AIDS.

- **Medicaid Coverage of Protease Inhibitors** -- On June 19, 1996 HCFA sent a letter advising States that they are required to cover protease inhibitors and encouraging them to ensure that appropriate nutritional services are provided to persons living with HIV/AIDS.
- **Federal Medicare Spending on HIV/AIDS** -- Medicare spending on persons with HIV/AIDS grew by 102% since FY 93. There are approximately 10,000 persons on Medicare who are HIV positive according to HCFA. Persons with AIDS qualify for the Medicare program by first qualifying for the Social Security Disability Insurance Program (SSDI). A person must wait 29 months after becoming disabled and qualifying for SSDI before becoming eligible for Medicare. As the life span for this population is fairly short after reaching the disabled stage, many people do not live long enough to qualify for Medicare. This is likely to change, however, with the advent of new drugs and better treatments.

*October 15, 1996*

Date: Thursday, February 27, 1997  
 FACT SHEET  
 Contact: HHS Press Office, (202) 690-6343

File AIDS  
 JAHK Background

## CLINTON ADMINISTRATION RECORD ON HIV/AIDS

**"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect all the rest of us from the virus. A cure and a vaccine, that must be our first and top priority."**

— President Clinton

**Overview:** AIDS is the leading cause of death among Americans between the ages of 25 and 44, accounting for more than 40,000 deaths each year. An estimated 650,000 to 900,000 Americans are believed to be living with HIV, the virus that causes AIDS. Since the AIDS epidemic began in 1981, more than 500,000 Americans have been diagnosed with AIDS and more than 300,000 men, women, and children have lost their lives to this disease.

The Clinton Administration has responded aggressively to the significant threat posed by HIV/AIDS with increased attention to research, prevention, and treatment. Overall funding for AIDS-related programs has risen by 55 percent in the first four years of the Clinton Administration, with funding for AIDS care under the Ryan White CARE Act increasing by 158 percent and assistance for the purchase of AIDS drugs nearly tripling.

At the same time, the Administration has sharpened the focus of its AIDS programs by strengthening the Office of AIDS Research at the National Institutes of Health, creating a new Center for HIV/STD/TB Prevention at the Centers for Disease Control and Prevention, and establishing a new Office of National AIDS Policy at the White House. The Administration released the first National AIDS Strategy, establishing goals for the nation and opportunities for immediate progress. And in December of 1995, President Clinton convened the first-ever White House Conference on HIV and AIDS, bringing more than 300 experts, activists, and citizens to the White House for a full day of discussions of key issues.

In February 1997, the Centers for Disease Control and Prevention (CDC) reported that in the first six months of 1996, for the first time since the epidemic took hold, the number of Americans who died of AIDS declined by 12 percent. In November 1996, the CDC reported a sharp decline in the number of infants born HIV-infected.

### HHS Spending on HIV/AIDS

In the four budgets approved under President Clinton, spending for AIDS research, prevention, and treatment increased by 54 percent. These increases include:

Program	FY93	FY97	FY93-97 Change
(in thousands)			
Research (NIH)	\$1,071,457	\$1,501,720	+40%
Prevention (CDC)	\$ 498,263	\$ 618,081	+24%
Treatment (HRSA)	\$ 385,345	\$ 996,252	+173%

*Note: Altogether, discretionary AIDS-related spending by HHS in FY 1997 will total \$3.2 billion, an increase of 55 percent from FY 1993. An additional \$2.8 billion is expected to be expended in FY 1997 for AIDS care under Medicare and Medicaid. It is estimated that more than 50 percent of Americans living with AIDS rely on Medicaid for their health care coverage.*

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## Administration Initiatives on HIV/AIDS

*Under President Clinton, a wide array of initiatives have been undertaken including:*

**AIDS Policy.** The President created the Office of National AIDS Policy within the White House to advise him on AIDS policy issues and coordinate interdepartmental activities.

**AIDS Conference.** On December 6, 1995, the President convened the first White House Conference on HIV and AIDS in the history of the epidemic. Nearly 300 people from 37 states, the District of Columbia, and Puerto Rico participated.

**AIDS Strategy.** On December 17, 1996, the Clinton Administration released the first National AIDS Strategy, establishing goals for the nation and opportunities for immediate progress.

**Advisory Council.** The President created the Presidential Advisory Council on HIV and AIDS to provide him and his Administration with expert outside advice on the ways in which the Federal government should respond to the HIV/AIDS epidemic.

**Disability Eligibility.** The Social Security Administration published revised regulations expanding the list of health manifestations that will be considered in determining eligibility due to HIV/AIDS for Social Security and Supplemental Security Income disability benefits.

**Drug Approval.** The FDA has approved 23 new AIDS drugs in the last four years and accelerated approval to record times. Included in those approvals are a new class of drugs known as protease inhibitors, which show tremendous promise in the treatment of HIV disease.

**Housing.** The Department of Housing and Urban Development has established the National Office of HIV/AIDS Housing to assist people with HIV/AIDS to pay for housing. Funding for the Housing Opportunities for People with AIDS program has increased by 96 percent. HUD and HHS have launched collaborative efforts to combine housing assistance and medical and social services for people living with HIV/AIDS.

**Mental Health.** The Substance Abuse and Mental Health Administration awarded the first Federal grants to develop mental health services for persons living with HIV/AIDS and their families and partners.

**Perinatal Transmission.** Following the release of research findings from an NIH-sponsored AIDS clinical trial that indicated that use of AZT by HIV-infected pregnant women dramatically reduced the rate of HIV transmission from mother to infant, the U.S. Public Health Service issued guidelines recommending routine counseling and voluntary HIV testing for all pregnant women.

**Prevention.** The Centers for Disease Control and Prevention (CDC) launched the Prevention Marketing Initiative aimed at young adults (ages 18-25) to change behaviors that contribute to the transmission of HIV. The initiative features production of public service announcements promoting both sexual abstinence and the consistent and correct use of latex condoms. A new community planning process gives local communities more authority over the shape and direction of AIDS prevention efforts.

**Research.** In one of his first acts in office, President Clinton signed the National Institutes of Health Revitalization Act of 1993, placing full responsibility for planning, budgeting, and evaluation of the AIDS research program at NIH in the Office of AIDS Research. The President requested and received

the first federal plan for biomedical research on AIDS.

**Ryan White CARE Act.** Funding for the CARE Act has increased by 158 percent and on May 20, 1996, President Clinton signed a five-year reauthorization of this program, guaranteeing assistance until the year 2001. Funding for AIDS drug assistance has increased by 221 percent.

**Water Safety.** The CDC and the Environmental Protection Agency issued guidelines recommending steps to purify drinking water to protect vulnerable populations against *Cryptosporidium*, which can be fatal to those with compromised immune systems.

**Youth.** The Office of National AIDS Policy issued a report to the President on the rising rates of HIV transmission among adolescents. The report noted that an average of at least one American teenager becomes infected with HIV every hour of every day and recommended steps to increase youth involvement in AIDS prevention, care, and research efforts.

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HIV/AIDS BUREAU  
OFFICE OF COMMUNICATIONS  
301 443-6652  
FAX: 301 443-0791

TITLE I  
CARE increased  
by 116% following  
Total 144%

FACSIMILE TRANSMITTAL SHEET

TO: ARON KETABEL FROM: DOROTHY BAILEY  
 COMPANY: \_\_\_\_\_ DATE: 8/20/98  
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- URGENT     FOR REVIEW     PLEASE COMMENT     PLEASE REPLY     PLEASE RECYCLE

NOTES/COMMENTS:

Aron - all send added info by early afternoon  
Should you have questions, my direct  
line is 301-443-1745.

Dorothy B.

~~XXXXXXXXXX~~  
Title IV adolescent  
confirmation of existing programs  
SPARS



# FACT SHEET

HIV/AIDS BUREAU

MAY 1998

## HIV/AIDS Bureau

The HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA), administers the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. The CARE Act was signed into law on August 18, 1990 to improve the quality and availability of care for people with HIV/AIDS and their families. Amended and reauthorized in May 1996, the Act is named after the Indiana teenager, Ryan White, who became an active public educator on HIV/AIDS after he contracted the disease. He died the same year the legislation was passed.

Within the HIV/AIDS Bureau, the Division of Service Systems administers Titles I, II and the AIDS Drug Assistance Program (ADAP); the Division of Community Based Programs administers Titles III, IV and the HIV/AIDS Dental Reimbursement Program; and the Division of Training and Technical Assistance administers the AIDS Education and Training Center (AETC) Program. The Bureau's Office of Science & Epidemiology administers the Special Projects of National Significance (SPNS) Program.

HRSA's HIV/AIDS Bureau conducts programs to benefit low-income, uninsured and underinsured individuals and families affected by HIV/AIDS. Total appropriations for HRSA-funded CARE Act programs from FY 1991 through FY 1998 was \$4.96 billion.

HRSA's HIV/AIDS Bureau administers HIV/AIDS programs under four titles and Part F of the CARE Act:

- **Title I** HIV emergency relief grant program for eligible metropolitan areas (EMAs)
- **Title II** HIV care grants to States and U.S. territories
- **Title III** HIV early intervention services
- **Title IV** Coordinated HIV services and access to research for children, youth, women, and families
- **Part F** Special Projects of National Significance (SPNS) Program; HIV/AIDS Dental Reimbursement Program; AIDS Education and Training Centers (AETCs) Program

### Title I

Title I funding provides formula and supplemental grants to EMAs that are disproportionately

affected by the HIV epidemic. These areas are eligible for Title I formula grants if they have reported more than 2,000 AIDS cases in the preceding 5 years, and if they have a population of at least 500,000 (this provision does not apply to EMAs funded prior to FY 1997).

Grants are awarded to the chief elected official (CEO) of the city or county that administers the health agency providing services to the greatest number of people living with HIV in the EMA. The CEO must establish an HIV Health Services Planning Council that is representative of the local epidemic and includes representatives from specific groups such as health care agencies and community-based providers. At least 25 percent of voting members must be people living with HIV disease. The planning council sets priorities for the allocation of funds within the EMA, develops a comprehensive plan, and assesses the grantee's administrative mechanism in allocating funds.



Community-based services funded under Title I may include:

- Outpatient health care, including medical and dental care and developmental and rehabilitative services;
- Support services such as case management, home health and hospice care, housing and transportation assistance, nutrition services, and day or respite care; and
- Inpatient case management services that expedite discharge and prevent unnecessary hospitalization.

Providers may include public or nonprofit entities; private for-profit entities are eligible only if they are the only available provider of quality HIV care in the area.

When the first Title I grants were awarded in FY 1991, 16 EMAs were identified; in FY 1998, there were 49 EMAs in 19 States, Puerto Rico, and the District of Columbia. EMAs were appropriated \$464.8 million in FY 1998. Since FY 1991, more than \$2.4 billion in Title I grants has been appropriated.

### Title II

Title II provides formula grants to States, the District of Columbia, Puerto Rico and eligible U.S. territories to provide health care and support services for people living with HIV disease. Grants are awarded to the State agency designated by the governor to administer Title II, usually the health department.

Grants are awarded based on: (a) the estimated number of living AIDS cases in the State or territory; and (b) the estimated number of living AIDS cases within the State or territory but outside of Title I EMAs. States with more than 1 percent of the total AIDS cases reported nationally during the previous 2 years must contribute their own resources to match the Federal grant, based on a yearly formula.

Title II funds may be used to support a wide range of services, including:

- Home and community-based health care and support services;

- Continuation of health insurance coverage through a Health Insurance Continuation Program (HICP);
- Pharmaceutical treatments through an AIDS Drug Assistance Program (ADAP);
- Local consortia that assess needs, organize and deliver HIV services in consultation with service providers, and contract for services; and
- Direct health and support services.

Since FY 1991, more than \$1.9 billion in Title II grants has been appropriated. In FY 1998, \$543 million was appropriated, which includes \$285.5 million in ADAP funding.

### Title III

Title III of the CARE Act supports outpatient HIV early intervention services for low-income, medically underserved people in existing primary care systems. Medical, educational, and psychosocial services are designed to prevent the further spread of HIV/AIDS, delay the onset of illness, facilitate access to services, and provide psychosocial support to people with HIV/AIDS.

Since FY 1991, \$445.8 million has been appropriated under Title III; in FY 1998, \$76.3 million supported 165 facilities in 37 States, Puerto Rico, and the District of Columbia. Nearly one-half was awarded to community and migrant health centers; the other half funded homeless programs, local health departments, family planning programs, comprehensive hemophilia diagnostic and treatment centers, Federally-qualified health centers, and private nonprofits.

### Title IV

Title IV programs focus on the development and operation of systems of primary health care and social services that benefit children, youth, and women living with HIV and their families. These systems aim at building comprehensive, community-based, coordinated programs that include both health and social outreach elements, as well as prevention. Title IV also works to develop new ways to effectively link these care systems with HIV research



supported by the National Institutes of Health (NIH) and other organizations.

Title IV, in collaboration with the Special Projects of National Significance (SPNS) Program, funds the Women's Initiative for HIV Care and Reduction of Perinatal HIV Transmission ("WIN"). In 1997, the WIN entered its third year.

This program aims to improve care for women living with HIV and to reduce rates of HIV transmission to newborns. WIN focuses on efforts to reach women of childbearing age, the enhancement of counseling and testing opportunities for women, engaging and maintaining pregnant women and their children in care, providing broad-based community education to women about HIV, and educating health care and social service providers.

During 1996, the seven WIN project sites reported contact with more than 10,000 women by means of outreach programs, supported HIV counseling activities for more than 12,000 women, and enrolled more than 600 women with HIV and 700 infants in care.

In 1997, approximately \$32 million was awarded under Title IV to improve access to HIV comprehensive care. These funds supported: 44 Comprehensive Care and Access to Research grantees and 7 Women's Initiative for HIV Care and Reduction in Perinatal Transmission projects in 23 States, Puerto Rico, and the District of Columbia. Funding for Title IV activities increased to \$41 million in FY1998. The increased funding will be used to support six to eight new Comprehensive Care and Access to Research projects, as well as a new Adolescent Services Initiative to identify and enroll adolescents into care. Funds also will be used to strengthen current program efforts, especially in the areas of enhanced access to research and expanded women's services.

Beginning in 1988, the Pediatric AIDS Demonstration Program and, since 1994, the CARE Act Title IV program, have provided more than \$241.5 million to States and communities.

## Part F

### Special Projects of National Significance (SPNS) Program

The Special Projects of National Significance (SPNS) Program supports the development of innovative models of HIV/AIDS care, designed to address special care needs of individuals with HIV/AIDS in minority and hard-to-reach populations. These projects are designed to be replicable in other parts of the country, and have a strong evaluation component.

SPNS Program models focus on managed care; infrastructure development; training; access to care through reduction of sociocultural, financial, and transportation barriers for rural residents, women, adolescents, and children; legal advocacy; comprehensive primary care (including managed care); integration of mental health and primary care services; and services for correctional populations. In FY 1996, Integrated Service Delivery Models were funded to create formal linkages to integrate health and support services.

The SPNS Program has collaborated with the Substance Abuse and Mental Health Services Administration and the National Institute of Mental Health, NIH, to co-fund 11 mental health services demonstration projects for people living with HIV/AIDS. Projects are funded for 4 years and received approximately \$4.5 million in FY 1996.

Since FY 1991, \$119.9 million has been set aside for the SPNS Program. In FY 1998, 51 grantees received \$25 million.

### AIDS Education and Training Centers

The AIDS Education and Training Center (AETC) Program is a national network of 15 centers that conduct targeted, multi-disciplinary education and training programs for health care providers in designated geographic areas. The AETCs increase the number of health care providers who are educated and motivated to counsel, diagnose, treat, and manage care for individuals with HIV/AIDS and to help prevent high risk behaviors that may lead to infection.



AETCs collaborate with CARE Act-funded organizations, Area Health Education Centers (AHECs), community-based HIV/AIDS organizations, medical and health professional schools, local hospitals, health departments, community and migrant health centers, medical societies, and other professional organizations.

Since 1991, more than 700,000 providers have been trained by the AETC program. A 1993 study showed that providers trained in AETCs were more competent with regard to HIV issues and more willing to treat persons living with HIV than other primary care providers.

From FY 1987 to FY 1995, \$125.4 million was appropriated to the AETC Program. Starting in FY 1996, AETCs were funded under the CARE Act; from FY 1996 to FY 1998, \$45.6 million was appropriated. In FY 1998, the program received \$17.3 million. The total appropriation through FY 1998 is \$171 million.

#### **HIV/AIDS Dental Reimbursement Program**

HRSA's HIV/AIDS Dental Reimbursement Program assists accredited dental schools and post-doctoral dental programs with uncompensated costs incurred in providing oral health treatment to HIV-positive patients. Eligible applicants must have documented uncompensated costs of oral health care for HIV-positive persons, and must be accredited by the Commission on Dental Accreditation. Funding takes into account the number of patients served by each individual applicant and unreimbursed oral

health costs, as compared to the total number of patients served and total costs incurred by all eligible applicants. In FY 1997, 103 institutions received funding.

In FYs 1994 and 1995, the HIV/AIDS Dental Reimbursement Program received \$13.9 million in funding. Since FY 1996, the program has been funded under the CARE Act and has received \$22.2 million through FY 1998; the FY 1998 appropriation was \$7.8 million. The total appropriation from FY 1994 through FY 1998 was \$36.1 million.

#### **Other HRSA HIV/AIDS Programs**

##### **National HIV Telephone Consulting Service**

Through the Western AIDS Education and Training Center funded by HRSA, an on-line telephone consulting service is available exclusively to primary care providers. Operating out of San Francisco General Hospital, the service offers a toll-free number (800-933-3413) from 10:30 AM-8:00 PM EST Monday through Friday.

A multidisciplinary consulting team of physicians, nurse practitioners, and clinical pharmacists is available to answer HIV-related clinical management questions. After hours, primary care providers may leave a recorded question that is later answered by a consultant. Approximately 1,200 calls are received per quarter. Through Oct. 1, 1997, more than 18,000 calls covering every aspect of HIV disease and treatment were received.

For media inquiries, contact Office of Communications, HRSA  
5600 Fishers Lane, Room 14-43 • Rockville, MD 20857  
(301) 443-3376 • Fax (301) 443-1989

All other inquiries, contact Office of Communications, HIV/AIDS Bureau, HRSA  
5600 Fishers Lane, Room 7-46 • Rockville, MD 20857  
(301) 443-6652 • Fax (301) 443-0791

<http://www.hrsa.dhhs.gov/hab>



# FACT SHEET

HIV/AIDS BUREAU

DIVISION OF SERVICE SYSTEMS

MAY 1998

## Title I

### Ryan White CARE Act

#### The CARE Act

On August 18, 1990, Congress enacted the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Reauthorized in 1996, the CARE Act is designed to improve the quality and availability of care for individuals and families affected by HIV disease. The HIV/AIDS Bureau, Health Resources and Services Administration (HRSA), administers CARE Act programs. Title I is administered by the Bureau's Division of Service Systems.

The CARE Act includes the following major program components:

- **Title I:** funding to eligible metropolitan areas hardest hit by the HIV/AIDS epidemic;
- **Title II:** formula funding to States and territories to improve the quality, availability, and organization of health care and support services for people living with HIV disease;
- **Title III:** funding to public and nonprofit entities for outpatient early intervention services;
- **Title IV:** funding to public and private nonprofit entities for demonstration projects to coordinate services to, and improve access to research for, children, youth, women and families; and
- **Part F:** support for Special Projects of National Significance (SPNS) Program, the Dental Reimbursement Program, and AIDS Education and Training Centers (AETCs).

#### Eligible Services

Title I funds may be used to provide a wide range of community-based services, including the following:

- **Outpatient health care**, including medical and dental care and developmental and rehabilitative services;

- **Support services** such as case management, home health and hospice care, housing and transportation assistance, nutrition services, and day/respite care; and
- **Inpatient case management services** that expedite discharge and prevent unnecessary hospitalization.

Providers may include public or nonprofit entities; private for-profit entities are eligible only if they are the only available provider of quality HIV care in the area.

In 1995, an estimated 300,000 people received services from Title I providers.

#### Title I Eligibility

Title I provides emergency assistance to eligible metropolitan areas (EMAs) most severely affected by the HIV/AIDS epidemic. To be eligible, an area must:

- Have more than 2,000 cumulative AIDS cases reported during the past 5 years; and
- Have a population of at least 500,000. This provision does not apply to any EMA designated and funded prior to Fiscal Year (FY) 1997.

#### Grantee

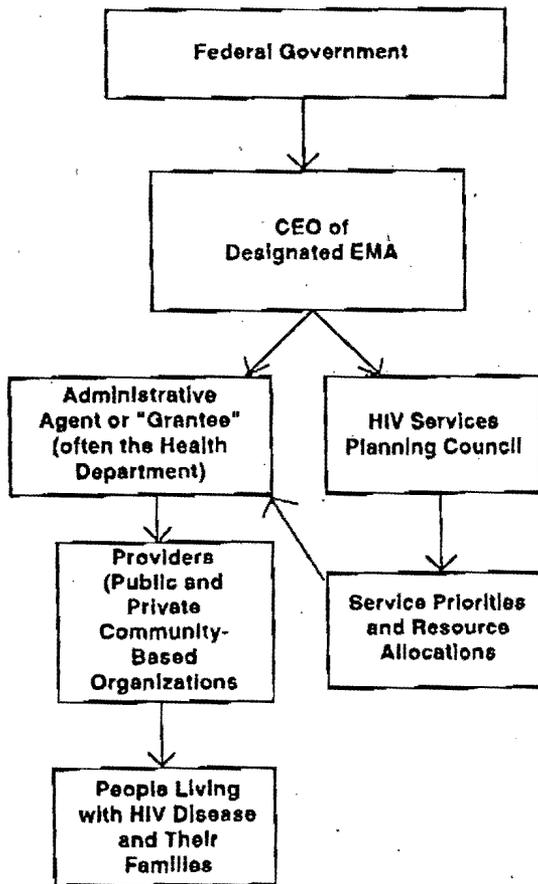
Grants are awarded to the Chief Elected Official (CEO) of the city or county that administers the health agency providing services to the greatest number of people living with HIV in the EMA. The CEO usually designates an administrative agent (most often the local health department) to select service providers and administer contracts. The CEO or grantee establishes intergovernmental agreements with other political subdivisions within the EMA that provide HIV services and include 10 percent or more of the EMA's total AIDS cases.

When the first Title I grants were awarded in FY 1991, 16 EMAs were identified. In FY 1998, there were 49 EMAs in 19 States, Puerto Rico, and the District of Columbia.



FACT SHEET

## Flow of Title I Decision-Making and Funds



## Title I HIV Health Services Planning Councils

The CEO must establish an HIV Health Services Planning Council. The planning council sets service priorities for the allocation of funds within the EMA, develops a comprehensive plan, and assesses the efficiency of the grantee's administrative mechanism for rapidly allocating funds.

Planning councils also work in partnership with the grantee to assess service needs within the EMA and develop a continuum of care for people living with HIV disease and their families. Planning councils also may assess the effectiveness of services in meeting identified needs, and must participate in the development of each State's Statewide Coordinated Statement of Need (SCSN).

Planning councils may not become involved in the selection of particular entities to receive Title I funding, or in the administration of contracts with providers; these are grantee responsibilities.

Planning council membership must be reflective of the local epidemic and include representatives from a variety of specific groups such as health care agencies and community-based providers. At least 25 percent of voting members must be people living with HIV disease. Planning councils must have an open nominations process and grievance procedures.

## Funding

Title I funding includes formula and supplemental components:

- **Formula grants**, awarded based on the estimated number of people living with HIV disease in the EMA; and
- **Supplemental grants**, awarded competitively based on demonstration of severe need and other criteria, including the ability to use funds responsively and cost-effectively; plans to allocate funds in accordance with the local demographics of AIDS; and inclusive planning council membership, with emphasis on affected communities and people living with HIV disease.

Since FY 1991, more than \$2.4 billion in funding has been appropriated to the Title I program; in FY 1998, EMAs received \$445 million in formula and supplemental funds. The attached table shows funding by EMA through FY 1998.

For media inquiries, contact Office of Communications, HRSA  
5600 Fishers Lane, Room 14-43 • Rockville, MD 20857 • (301) 443-3376 • Fax (301) 443-1989

All other inquiries, contact Division of Service Systems, HIV/AIDS Bureau, HRSA  
5600 Fishers Lane, Room 7A-55 • Rockville, MD 20857 • (301) 443-6745 • Fax (301) 443-8143

<http://www.hrsa.dhhs.gov/hab>



### Ryan White CARE Act Title I Grant Awards

EMA	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998
Atlanta GA	\$2,123,775	\$3,111,666	\$5,490,571	\$7,488,801	\$9,091,331	\$9,208,162	\$12,632,117	\$12,021,454
Austin TX	N/E	N/E	N/E	N/E	2,124,274	2,398,671	3,337,861	2,856,752
Baltimore MD	N/E	1,898,561	3,250,343	3,923,438	4,715,150	8,364,074	10,033,688	12,184,481
Bergen-Passaic NJ	N/E	N/E	N/E	2,019,121	2,847,639	3,369,095	4,292,593	4,354,291
Boston MA	2,236,287	2,823,768	4,154,744	6,955,035	7,079,242	8,380,436	9,033,443	9,463,130
Caguas PR	N/E	N/E	N/E	N/E	902,928	1,064,876	1,431,210	1,405,197
Chicago IL	3,229,799	4,327,603	7,390,763	9,625,451	12,099,865	13,164,930	15,741,071	15,995,512
Cleveland-Lorain-Elyria OH	N/E	N/E	N/E	N/E	N/E	1,384,956	1,877,513	2,459,443
Dallas TX	1,379,434	3,119,688	4,542,034	6,935,644	8,176,385	7,820,653	8,129,583	9,082,217
Denver CO	N/E	N/E	N/E	3,375,884	3,092,041	3,549,707	4,668,572	4,278,161
Detroit MI	N/E	N/E	2,081,739	2,849,559	2,406,902	4,405,380	6,087,121	5,628,350
Dutchess Co. NY	N/E	N/E	N/E	N/E	609,583	581,761	776,847	854,481
Ft. Lauderdale FL	1,807,299	3,065,827	4,591,215	6,814,599	5,091,994	6,584,204	8,312,185	10,128,631
Ft. Worth-Arlington TX	N/E	N/E	N/E	N/E	N/E	2,255,398	1,902,232	2,618,024
Hartford CT	N/E	N/E	N/E	N/E	N/E	3,048,467	2,661,473	3,613,029
Houston TX	3,710,210	5,803,011	7,820,319	10,133,592	10,233,981	10,312,524	10,768,697	12,722,479
Jacksonville FL	N/E	N/E	N/E	N/E	2,418,868	2,725,251	3,762,713	3,443,168
Jersey City NJ	1,562,728	2,181,853	3,618,220	4,140,141	3,770,366	3,767,874	4,600,103	5,320,300
Kansas City MO	N/E	N/E	N/E	2,855,564	2,726,195	2,514,291	2,884,537	2,622,409
Los Angeles CA	7,848,314	9,788,087	19,180,269	25,441,211	31,037,580	26,313,561	30,227,298	30,637,106
Miami FL	3,044,301	5,923,065	9,716,264	15,258,563	19,195,347	15,158,078	18,863,208	18,472,153
Middlesex-Somerset-Hunterdon NJ	N/E	N/E	N/E	N/E	N/E	2,198,883	1,919,076	2,597,923
Minneapolis-St. Paul MN	N/E	N/E	N/E	N/E	N/E	1,370,726	1,990,700	2,570,712
Nassau-Suffolk NY	N/E	N/E	2,012,809	2,886,868	3,895,849	3,683,885	4,697,795	4,939,871
Newark NJ	4,111,603	5,363,563	3,542,848	7,009,180	11,791,405	9,725,848	11,612,530	12,630,257
New Haven CT	N/E	N/E	N/E	2,136,872	2,711,634	4,002,182	5,336,678	5,348,730
New Orleans LA	N/E	N/E	1,796,972	3,243,332	3,503,009	2,087,199	4,727,682	4,921,857
New York NY	33,457,519	35,894,688	44,489,219	100,054,267	93,587,184	92,241,697	92,459,373	95,325,334
Oakland CA	N/E	2,123,466	2,602,816	3,928,287	4,148,289	4,741,595	5,905,961	5,928,194
Orange County CA	N/E	N/E	1,839,726	2,627,947	3,175,288	3,492,993	4,401,330	3,810,759
Orlando FL	N/E	N/E	N/E	2,615,587	3,194,835	3,599,489	4,319,349	4,608,839
Philadelphia PA	2,323,850	3,571,035	4,729,230	7,374,936	9,836,096	10,345,478	13,465,328	14,081,773
Phoenix AZ	N/E	N/E	N/E	2,217,471	2,447,784	2,801,602	3,380,053	3,412,037
Ponce PR	N/E	N/E	1,280,364	1,176,793	1,908,071	1,685,036	2,183,463	2,200,114
Portland OR	N/E	N/E	N/E	N/E	2,402,734	2,688,924	3,472,480	3,057,466
Riverside-San Bernardino CA	N/E	N/E	N/E	2,402,010	2,656,331	4,687,432	5,986,979	5,634,427
Sacramento CA	N/E	N/E	N/E	N/E	N/E	2,463,814	2,038,827	2,389,370
St. Louis MO	N/E	N/E	N/E	2,248,247	2,581,330	2,587,364	3,506,350	3,561,850
San Antonio TX	N/E	N/E	N/E	N/E	1,731,222	2,396,426	3,014,191	2,952,239
San Diego CA	1,460,205	2,778,724	3,761,979	5,233,574	5,628,252	6,592,104	8,198,109	8,452,437
San Francisco CA	12,713,831	12,713,831	18,944,229	27,217,076	39,210,400	35,172,274	37,194,634	36,394,914
San Jose CA	N/E	N/E	N/E	N/E	N/E	2,275,044	1,992,602	2,445,480
San Juan PR	1,681,081	3,579,982	4,679,777	8,456,057	10,269,418	8,199,506	10,550,845	11,658,912
Santa Rosa-Petaluma CA	N/E	N/E	N/E	N/E	1,207,605	1,142,456	1,330,630	1,225,807
Seattle WA	N/E	N/E	2,824,570	3,233,903	4,048,484	4,289,545	5,481,431	5,060,533
Tampa-St. Petersburg FL	N/E	N/E	2,285,553	3,304,312	4,231,119	4,610,201	6,548,952	6,536,189
Vineland-Milville-Bridgeton NJ	N/E	N/E	N/E	N/E	340,644	454,338	677,001	594,001
Washington DC	3,392,784	5,127,184	7,447,578	9,328,712	10,713,183	12,763,696	15,838,868	16,710,728
West Palm Beach FL	N/E	N/E	N/E	3,582,542	3,770,641	3,380,914	5,122,618	5,985,481
<b>TOTALS</b>	<b>\$86,083,000</b>	<b>\$119,426,000</b>	<b>\$182,326,998</b>	<b>\$319,989,000</b>	<b>\$349,370,000</b>	<b>\$372,141,000</b>	<b>\$429,377,900</b>	<b>445,176,000</b>

"N/E" means "not eligible." The EMA was not eligible to receive funding in that fiscal year.



# FACT SHEET

HIV/AIDS BUREAU • DIVISION OF SERVICE SYSTEMS • MAY 1998

## Title II Ryan White CARE Act

### The CARE Act

On August 18, 1990, Congress enacted the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Reauthorized in 1996, the CARE Act is designed to improve the quality and availability of care for individuals and families affected by HIV disease. The HIV/AIDS Bureau, Health Resources and Services Administration (HRSA), administers CARE Act programs. Title I is administered by the Bureau's Division of Service Systems.

The CARE Act includes the following major program components:

- **Title I:** funding to eligible metropolitan areas hardest hit by the HIV/AIDS epidemic;
- **Title II:** formula funding to States and territories to improve the quality, availability, and organization of health care and support services for people living with HIV disease;
- **Title III:** funding to public and nonprofit entities for outpatient early intervention services;
- **Title IV:** funding to public and private nonprofit entities for demonstration projects to coordinate services to, and provide enhanced access to research for, children, youth, women and families; and
- **Part F:** support for the Special Projects of National Significance (SPNS) Program, the Dental Reimbursement Program, and AIDS Education and Training Centers (AETCs).

### Grants

Title II grants are awarded on a formula basis to States, the District of Columbia, Puerto Rico, and eligible U.S. territories to provide health care and support services for people living with HIV disease. Grants are awarded to the State agency designated by the governor to administer Title II, usually the health department.

States with more than one percent of the total AIDS cases reported nationally during the previous 2 years must contribute their own resources to match the Federal grant, based on a yearly formula. Under Title II, in addition to a base award, States receive earmarked funds to support AIDS Drug Assistance Programs (ADAPs). ADAPs provide medications to low-income individuals with HIV disease who have limited or no coverage from private insurance or Medicaid, in all 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, and Guam. States also may use Title II base funds for their ADAP Programs.

### Eligible Services

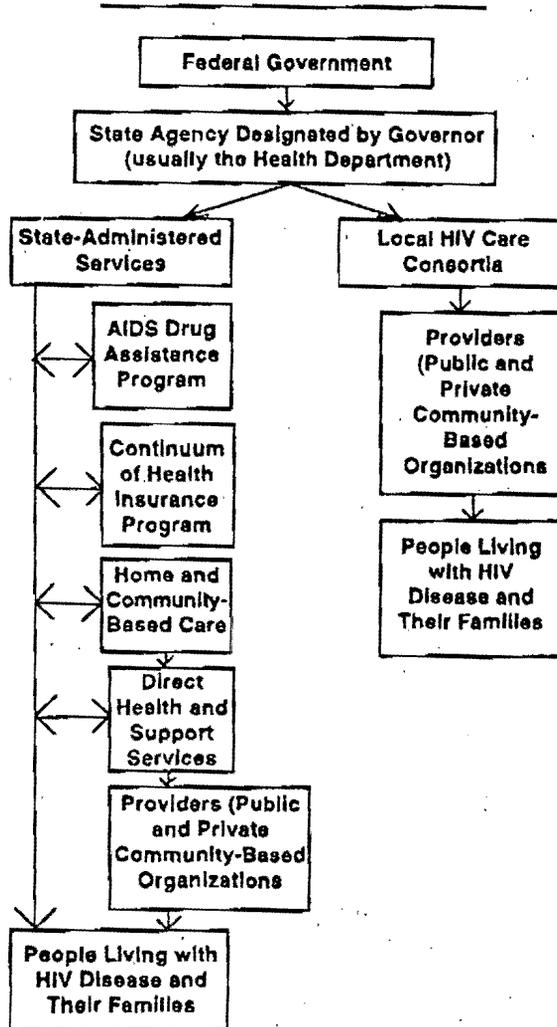
Title II funds may be used to support a wide range of services:

- **Home and community-based health care and support services;**
- **Continuum of health insurance coverage,** through either a Health Insurance Continuation Program (HICP), or provision of medical benefits under a health insurance program including high risk pools;
- **Pharmaceutical treatments,** through the ADAP Program;
- **HIV care consortia** that assess needs, organize and deliver HIV services in consultation with service providers, and contract for services; and
- **Direct health and support services.**

States are required to spend a portion of their Title II award to provide medications to treat HIV disease, including drugs for the prevention and treatment of opportunistic infections. States also must document their progress in making therapeutics available to people with HIV disease who are eligible for assistance.



## Flow of Title II Decision-Making and Funds



Providers may include public or nonprofit entities; private for-profit entities are eligible only if they are the only available provider of quality HIV care in the area.

### Title II Care Consortia

Most States provide some services directly and others through subcontracts with Title II HIV care consortia. A consortium is an association of public and nonprofit health care and support service providers and community-based

organizations that plans, develops, and delivers services for people living with HIV disease.

A consortium must submit an application to the State assuring that it has:

- Conducted a needs assessment;
- Developed a plan and set service priorities to meet identified needs;
- Promoted coordination and integration of community resources, addressing the needs of all affected populations;
- Assured the provision of comprehensive outpatient health and support services; and
- Arranged to evaluate the success and cost-effectiveness of the consortium in responding to service needs.

### Statewide Coordinated Statement of Need

States are required to have a process in place that periodically convenes people living with HIV disease, representatives of other CARE Act grantees, providers, and public health agencies to develop a Statewide Coordinated Statement of Need (SCSN).

### Funding and Services

Since FY 1991, more than \$1.9 billion in Title II funding has been appropriated; starting in FY 1996, special earmarked funds were made available in response to the rapid growth in ADAP clients and costs, and to expand access to newly available treatments. The total Title II appropriation for FY 1998 is \$520 million, which includes \$285.5 million for ADAP funding. The attached table shows funding by State through FY 1998.

In 1995, an estimated 284,000 people received Title II services. In 1995, 44 States and territories funded consortia, 23 funded home and/or community-based care programs, 18 allocated funds for health insurance continuation programs, and 46 ran drug assistance programs. In FY 1998, all States have ADAPs.

For media inquiries, contact Office of Communications, HRSA  
5600 Fishers Lane, Room 14-43 • Rockville, MD 20857 • (301) 443-3376 • Fax (301) 443-1989

All other inquiries, contact Division of Service Systems, HIV/AIDS Bureau, HRSA  
5600 Fishers Lane, Room 7A-55 • Rockville, MD 20857 • (301) 443-6745 • Fax (301) 443-8143

<http://www.hrsa.dhhs.gov/hab>



## Ryan White CARE Act Title II Grant Awards

STATE	FY 1991	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996	FY 1997	FY 1998 FORMULA	FY 1998 ADAP	FY 1998 TOTAL
ALABAMA	483,388	5636,291	5938,176	\$1,421,553	\$1,349,942	\$2,756,823	\$4,167,971	\$2,844,372	\$2,265,704	\$5,110,076
ALASKA	100,000	100,000	100,000	100,000	100,000	288,443	362,917	250,000	194,562	444,562
ARIZONA	653,285	687,616	751,528	1,855,383	1,759,313	2,260,259	3,496,214	2,084,451	2,469,052	4,553,503
ARKANSAS	276,192	440,564	528,077	821,978	753,038	1,389,814	2,050,008	1,394,809	1,110,885	2,505,494
CALIFORNIA	12,953,753	15,559,171	17,183,378	28,172,762	27,867,193	36,282,354	57,920,029	30,612,837	43,084,687	73,877,524
COLORADO	727,458	832,808	937,655	1,794,570	1,980,899	2,509,154	3,734,969	2,028,264	2,585,789	4,614,053
CONNECTICUT	763,464	915,334	1,088,399	2,246,095	2,404,858	3,651,778	6,120,430	3,430,779	4,836,430	8,267,209
DELAWARE	151,980	173,168	229,208	515,066	585,604	1,259,006	1,942,410	1,352,061	1,076,994	2,429,055
DIST. OF COLUMBIA	1,094,364	1,385,438	1,441,594	2,155,767	2,532,524	3,332,588	5,490,772	3,055,111	4,664,462	7,719,573
FLORIDA	7,397,516	9,856,630	11,228,316	16,361,686	17,780,752	25,220,349	41,314,998	23,591,403	30,253,733	53,845,138
GEORGIA	2,366,100	2,885,813	3,124,415	4,527,285	4,731,696	7,394,151	12,340,139	7,393,756	8,818,043	16,211,799
HAWAII	329,429	366,974	371,756	545,494	499,350	1,180,678	1,701,733	1,076,291	857,327	1,933,618
IDAHO	100,000	100,000	100,000	130,115	138,867	285,657	362,917	250,000	194,562	444,562
ILLINOIS	2,289,116	2,829,336	3,598,455	5,383,821	5,577,650	7,260,236	12,033,969	6,516,058	8,962,398	16,478,545
INDIANA	621,522	728,781	753,940	1,394,908	1,536,770	2,762,555	4,301,051	2,984,620	2,377,420	5,362,040
IOWA	110,588	164,436	215,475	333,799	333,380	613,264	917,406	614,573	489,543	1,104,116
KANSAS	245,985	256,907	324,039	605,134	568,263	1,050,840	1,565,364	959,605	928,876	1,888,481
KENTUCKY	299,687	406,244	467,575	641,709	643,697	1,344,978	2,078,323	1,804,194	1,277,832	2,882,026
LOUISIANA	1,308,109	1,672,604	1,844,076	2,494,411	2,785,044	4,080,447	6,969,329	4,430,983	4,768,647	9,199,630
MAINE	118,205	136,527	121,410	205,421	228,492	536,845	719,201	449,111	357,743	806,854
MARYLAND	1,554,569	2,027,034	2,130,393	3,625,966	4,684,012	6,521,685	10,948,524	6,088,935	8,759,047	14,847,982
MASSACHUSETTS	1,454,614	1,793,707	1,837,845	3,501,905	3,776,077	4,836,051	7,628,256	4,217,320	5,563,213	9,780,533
MICHIGAN	1,046,092	1,213,083	1,486,048	2,874,019	2,675,843	3,897,084	5,814,246	3,533,167	4,157,347	7,690,514
MINNESOTA	357,781	417,361	501,656	970,420	973,550	1,249,617	1,878,085	997,137	1,368,209	2,365,346
MISSISSIPPI	488,542	590,409	546,105	900,115	954,192	1,868,450	2,780,714	2,017,062	1,606,704	3,623,766
MISSOURI	1,043,394	1,330,744	1,459,224	2,716,091	2,504,335	3,131,126	4,586,448	2,652,631	3,326,379	5,952,010
MONTANA	100,000	100,000	56,197	100,000	100,000	128,912	201,037	250,000	125,524	375,524
NEBRASKA	100,000	117,188	146,689	292,135	267,083	506,277	733,358	518,448	412,973	931,421
NEVADA	330,545	443,483	531,149	924,894	984,174	2,049,946	3,001,392	2,169,918	1,728,462	3,898,380
NEW HAMPSHIRE	100,000	104,655	102,372	160,060	175,763	332,092	529,197	300,979	350,211	651,190
NEW JERSEY	4,215,417	4,711,438	4,505,948	6,650,657	8,958,831	13,135,111	21,380,789	12,119,471	18,226,455	28,345,926
NEW MEXICO	203,312	254,732	259,454	485,763	479,074	882,841	1,183,568	939,194	748,122	1,687,316
NEW YORK	13,802,740	16,909,338	17,618,806	26,126,095	29,093,044	38,324,520	64,354,160	36,592,849	51,291,513	87,884,362
NORTH CAROLINA	986,337	1,253,338	1,366,084	1,986,053	2,414,668	4,810,589	7,053,271	4,818,886	3,838,516	8,657,402
NORTH DAKOTA	100,000	100,000	19,872	100,000	100,000	107,243	124,390	100,000	45,189	145,189
OHIO	1,117,823	1,373,30	1,476,544	2,518,172	2,623,138	4,688,106	7,316,497	4,648,401	4,305,465	8,953,866
OKLAHOMA	393,500	490,547	512,925	1,133,726	1,050,788	1,658,387	2,282,191	1,808,921	1,281,597	2,890,518
OREGON	513,063	658,551	675,020	1,170,946	1,300,587	1,684,631	2,749,308	1,559,364	1,879,091	3,438,455
PENNSYLVANIA	2,241,191	2,536,897	2,849,781	4,421,998	6,177,510	7,991,487	12,944,847	7,863,699	9,074,112	16,937,81
RHODE ISLAND	173,200	194,400	210,219	452,600	554,753	1,083,242	1,548,831	1,025,865	817,160	1,843,025
SOUTH CAROLINA	888,747	795,067	763,896	2,091,875	2,679,771	4,516,376	6,622,683	4,543,116	3,818,850	8,181,986
SOUTH DAKOTA	100,000	100,000	100,000	100,000	100,000	112,536	138,843	100,000	61,507	161,507
TENNESSEE	605,992	737,498	905,045	1,675,354	1,846,877	3,767,915	5,736,623	4,024,869	3,205,877	7,230,546
TEXAS	5,731,924	7,329,198	7,078,303	11,813,825	12,636,414	16,132,517	25,697,515	15,497,405	19,851,998	35,149,403
UTAH	199,022	234,917	304,258	511,096	428,266	810,043	1,261,524	858,827	684,104	1,542,931
VERMONT	100,000	100,000	100,000	100,000	103,727	278,529	342,140	250,000	154,394	404,394
VIRGINIA	970,120	1,351,047	1,430,800	2,403,511	2,642,609	5,365,718	8,116,878	5,436,313	5,015,929	10,452,242
WASHINGTON	1,025,356	1,322,995	1,270,740	2,262,586	2,310,797	3,154,250	4,898,005	2,877,763	3,527,217	6,404,980
WEST VIRGINIA	127,689	153,234	135,148	173,904	184,768	446,290	740,356	508,594	430,546	937,140
WISCONSIN	354,601	459,433	481,719	1,089,752	1,063,650	1,840,433	2,579,528	1,698,881	1,355,656	3,054,537
WYOMING	100,000	100,000	44,037	100,000	100,000	113,650	137,940	100,000	69,038	169,038
GUAM	2,954	4,323	3,379	3,379	2,902	4,970	11,608	11,052	0*	11,052
PUERTO RICO	4,716,952	5,681,717	6,121,433	7,521,643	7,682,087	9,376,181	12,920,475	7,528,445	9,264,906	18,793,353
VIRGIN ISLANDS	38,397	27,019	36,048	68,703	0*	197,380	191,525	222,610	0*	222,610
<b>TOTALS</b>	<b>77,474,015</b>	<b>\$95,151,000</b>	<b>\$102,394,599</b>	<b>\$162,705,300</b>	<b>\$174,766,500</b>	<b>\$250,405,164</b>	<b>\$397,895,000</b>	<b>\$234,574,000</b>	<b>\$285,500,000</b>	<b>\$520,074,000</b>

\*Did not request funding

July 10, 1996



# Health Division



Office of Management and Budget  
Executive Office of the President  
Washington, DC 20503

Please route to:

Richard Turman  
Barry Clendenin  
Nancy-Ann Min

*Handwritten initials: RT, BC*

Decision needed \_\_\_\_\_  
Please sign \_\_\_\_\_  
Per your request X  
Please comment \_\_\_\_\_  
For your information \_\_\_\_\_

Subject: **Alternatives to the ADAP Working Group Proposal for a FY97 Budget Amendment for Protease Inhibitors**

With informational copies for  
HPS and HD Chrons  
H.M.M.M.: *Ms. Minny*  
Phone: 202/395-7791  
Fax: 202/395-3910  
Room: #7026

From: <sup>GW</sup> Greg White and Maria Gutierrez *MG*

Attached is a package of background materials which outlines some alternatives to the ADAP Working Group Proposal for a FY 1997 Budget Amendment for Ryan White to purchase protease inhibitor (PI) medications. Also included in the package are (1) some charts that outline the basic demographics of the epidemic and 3rd party coverage for people with HIV; (2) a summary of the uncertainties in estimating the impact of PI drugs on Ryan White; (3) outstanding policy issues concerning a possible budget amendment; and (4) a package of offsets.

Given that HRSA generally does not have good data for the Ryan White programs and that these drugs have only been on the market for a very short time, it was very difficult for HD to construct an estimate for a possible FY 1997 Budget Amendment. The HD estimate that we have outlined in the package is in the range of \$53 million to \$71 million in additional spending above the \$52 million that is already in the FY 1997 Budget.

Please let us know if you have any questions. It may be helpful for us to meet to walk you through this package.

Attachments

*Handwritten:*  
AIDS DRUG ASSISTANCE  
PROGRAM (ADAP)  
RYAN WHITE  
CARE.

**Ryan White and Protease Inhibitors in FY97  
Alternatives to the \$52 M + \$195 M Proposal  
Offered by the ADAP Working Group**

**DRAFT**

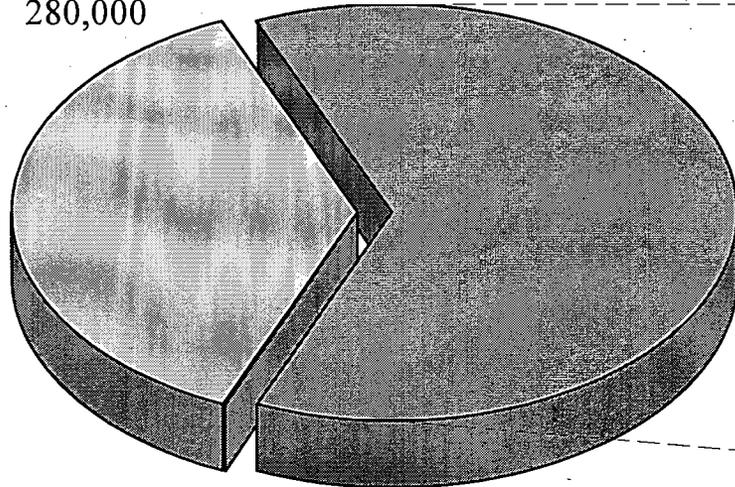
<u>Table of Contents</u>	<u>Page #</u>
I. Demographics of the Epidemic and 3rd Party Coverage for those with HIV.	2
II. Complexities and Uncertainties in Estimating the Impact of Protease Inhibitors on Ryan White.	4
III. Alternative Estimates to the ADAP Working Group	6
IV. Outstanding Policy Issues	13
V. Offsets	17

# An Estimated 63% of the Estimated 750,000 People Infected With HIV in the U.S. Know They Are Infected

**DRAFT**

**Number of HIV Positive  
People  
750,000**

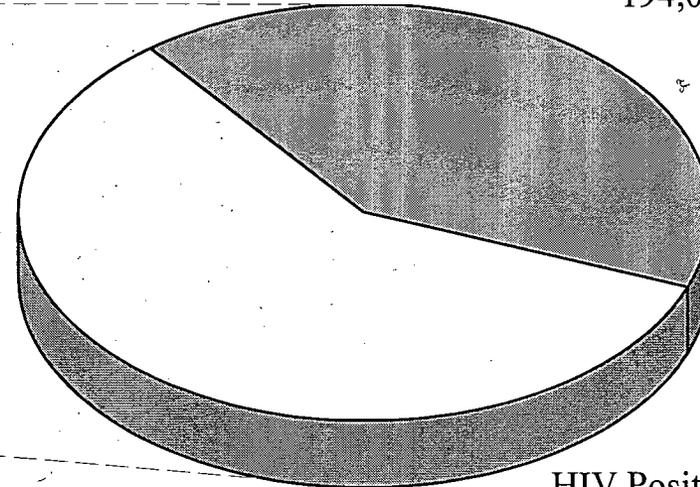
People Unaware They  
Have HIV  
280,000



People Aware They Have HIV  
470,000

**Number of HIV Positive  
People Who Know They are  
Infected  
470,000**

People With AIDS  
194,000

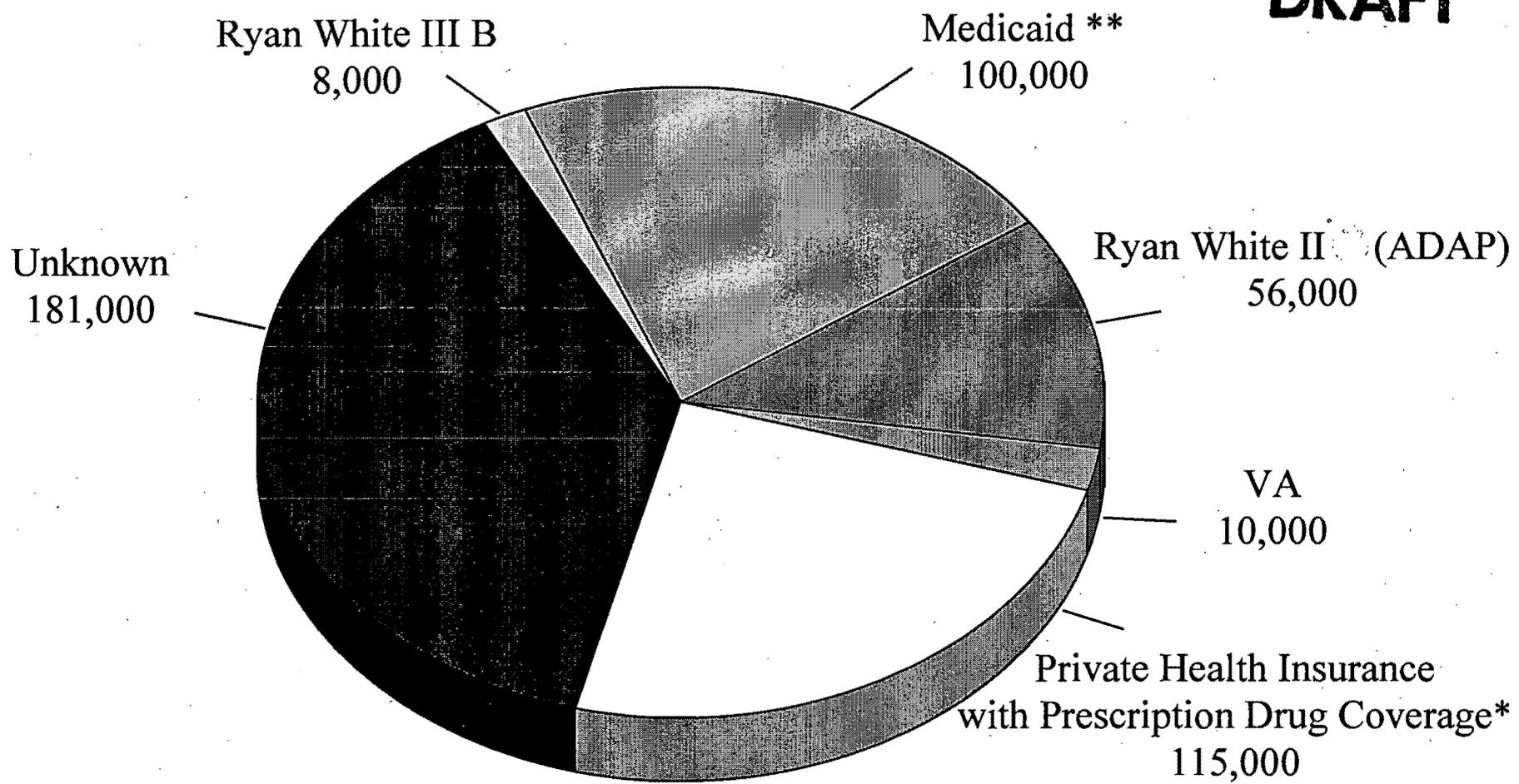


HIV Positive People  
Without AIDS Yet  
276,000

Source: Published and unpublished CDC staff estimates; Rosenberg, JAMA, Dec. 1995; CDC HIV Surveillance Report; Mid-Year edit, vol. 7, No. 1; where estimates have ranges, we have used the mid-point.

**Of the 470,000 Estimated to Know, About 289,000 Receive AIDS Drugs Through Public or Private Sources. The Status of the Remaining 181,000 is Unknown.**

**DRAFT**



Source: \*HD estimates based on AHCPR 1991 Data from the Screener Questionnaire AIDS Costs and Services Utilization Survey.

\*\*HCFA estimates half of the people who have AIDS are on Medicaid.

## Complexities and Uncertainties Surrounding All Estimates

- 1. The Price of Protease Inhibitors (PI)** -- PI medications are currently expensive as compared to other AIDS medications. As more PI medications are approved by the FDA, we could see the price fall significantly -- similar to the market reaction to AZT.
- 2. How many should or will use PI medications?** Since these drugs have been on the market for only a few months, we know very little about how many people will or should take these drugs. In addition, PI combination therapy involves taking 14 to 20 pills a day, often with strict dietary restrictions. To avoid developing resistance to these medications, patients must follow a rigorous and disciplined dosage schedule. Given these requirements, it is not clear to what percentage of people with HIV that doctors will prescribe these drugs. In addition, Ryan White clients are often homeless, sick, or have drug addiction or mental problems. It is not clear how many in this population would follow this disciplined therapeutic regimen.
- 3. How Many Will Seek PI Therapy?** The recent press attention to these drugs may also generate increased demand for PI drugs and AIDS medications in general. With this new optimism, more individuals at-risk for HIV may get tested and/or seek government-financed therapies through State ADAP programs.

**DRAFT**

**4. What did the \$52 million set-aside in FY 1996 buy?** HRSA generally does not have good data. Even if the agency did, we would still not have reports from the State on how they spent this \$52 million. As a result, it is very difficult to predict what any additional budget amendment would purchase given we don't know what the first one bought.

### **3 Approaches to Estimating the FY 97 Budget Impact of Protease Inhibitors on Ryan White**

- (1) ADAP Working Group: + \$195 Million
- (2) Jeff Levi Rough Approach: + \$147 Million
- (3) HD Alternative Approach: + \$53-\$71 Million

	<u>ADAP Group Proposal</u>	<u>Jeff Levi Rough Est.</u>	<u>HD Est.</u>
<u>Assumptions</u>			
1) '97 ADAP Population	86,000	55,000	62,000
2) % Covered for Protease Inhibitors	62%	100%	52%
3) Annual Price of 3 Drugs	\$10,706	\$7,100	-----
Annual Price of 1 PI Drug	-----	-----	\$3,200 - \$3,800
Annual Price of OI Drugs	\$1,305	\$900	-----

**DRAFT**

	<u>ADAP Group Proposal</u>	<u>Jeff Levi Rough Est.</u>	<u>HD Est.</u>
Total for PI Drugs	\$287 M	\$390 M	\$105 - \$123 M
<u>Total for OI Drugs</u>	<u>\$113 M</u>	<u>\$50 M</u>	-----
Total Drug Costs	\$400 M	\$440 M	-----
Less Current Fed. & <u>State Funds (including \$52 M)</u>	<u>-\$144 M</u>	<u>-\$146 M</u>	-----
Total Requested	\$256 M	\$294 M	-----
Less State Share	-\$59 M	-\$147 M	-----
Less \$52 M in FY97 Budget	-----	-----	-\$52 M
<b>Total for Amendment</b>	<b>\$195 M</b>	<b>\$147 M</b>	<b>\$53 - \$71 M</b>

## **Basis for Assumption # 1: Why Assume a Total ADAP Population of 62,000 in FY 1997?**

### Recent Estimates

HRSA '94 Estimate: 50,000  
NASTAD '95 Estimate: 60,000  
HHS '96 Estimate: 52,000 - 60,000 (56,000 Midpoint)

### ADAP Working Group -- Assume 20% Annual Growth

NASTAD '95 Estimate: 60,000  
ADAP Group '96 Estimate: 72,000  
ADAP Group '97 Estimate: 86,000

### HD Assumes a More Moderate Growth Rate

Assuming that 56,000 (mid-point of HHS estimate) were enrolled in ADAP in FY 1996, you could assume a more moderate 10% growth for FY96-FY97, and project that 62,000 would be in ADAP in FY97.

**Basis for Assumption #2: Why Assume that the Percentage of Enrollees who Could Benefit from Protease Inhibitor Combination Therapy in FY 1997 is 52%?**

According to national 1994 HRSA data, 52% of total ADAP clients (26,060 of 49,990) used AZT in 1994. If we assume that many of these individuals are already receiving double combination therapy (i.e. receiving AZT in combination with some other older nucleoside analogs like 3TC and DDI) which has already become the standard of care even before the introduction of Protease Inhibitors, we could expect that this same group could also benefit from a third drug, one of the 3 protease inhibitors.

Based on AZT usage in the New York ADAP program from January-May, 1996, the ADAP Working Group assumes that 62% of the total ADAP population could benefit from Protease Inhibitor combination therapy.

HD Recommendation: Use the 1994 national ADAP data compiled by HRSA, rather than the AZT usage level from a single State over a six-month period.

**Basis for Assumption #3: Why Assume the Annual Cost of A Single Protease Inhibitor at \$3,200 - \$3,800?**

The statistics usually cited by the media include the price of all three drugs in the protease inhibitor/nucleoside analog cocktail (AZT, 3TC and a Protease Inhibitor). These estimate usually range from \$12,000-\$16,000 and do not include the PHS drug-pricing discount of which most States take advantage. With the PHS drug discount, Ryan White grantees can expect to receive roughly a 33% discount on protease inhibitors from the catalog price.

<u>PI Drug</u>	<u>Avg. Current Annual Price /2</u>	<u>Avg. Annual Price Less 33%</u>	<u>VA Price w/ similar Drug-Pricing Discount /3</u>
Norvir (ritonavir) Abbot Laboratories	\$7,500-\$8,000	\$5,025-\$5,360	\$4,860
Invirase (saquinavir) Hoffman-LaRoche	\$7,200	\$4,824	\$4,320
Crixivan (indinavir) Merck	\$4,800 - \$5,200	\$3,216 - \$3,484	\$3,263

HD Recommendation: HD recommends basing the estimate on the price of Merck's indinavir (\$3,216 - \$3,484) as the basis of an estimate. This is the newest and now the least expensive PI drug approved by the FDA, which suggests that the price of these medications may be decreasing due to market pressures. It is also the drug that NIH scientists suggested were shown to be the most effective of the 3 PIs on the market to date. Given the uncertainty in predicting future prices and the fact that not all States participate in the PHS Drug-Pricing program, we have used a range of \$3,200 - \$3,800.

1/Under the PHS Drug Pricing Program, PHS grantees receive roughly a 33% savings on Saquinavir from the average wholesale price.

2/ Source: New York Times Article (7/5/96)

3/ 1996 Veterans Health Administration estimates. VA hospitals receive a similar type of drug discount that PHS grantees have access to.

## The HD Estimate

This leads us to the following calculation.

62,000 (Assumption #1) x 52% (Assumption #2) = 32,240 individuals.

Assuming that we use a range of \$3,200-\$3,800 as the average annual cost of a protease inhibitor (Assumption #3) as the base, we calculate the following range for a possible FY97 Budget Amendment:

32,240 x \$3,200 = \$105 million

32,240 x \$3,800 = \$123 million

In the FY97 Budget, the Administration requested a \$52 million set-aside for the purchase of PI drugs and other medications.

\$105 m - \$52 m = \$53 million.

\$123 m - \$52 m = \$71 million.

Bottom Line Range: \$53 - \$71 million.

## Outstanding Policy Issues

**1. Means-Testing?** Based on 1993 HRSA data, several States appear to have very generous financial eligibility limits for their ADAP program. For example, California, New York and Idaho ADAP enrollees with incomes up to 400% of poverty can receive ADAP drugs at no charge. Several other States allow individuals with incomes up to 300% of poverty to receive ADAP drugs at no charge, including Hawaii, Maryland, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, South Dakota, Wisconsin and Wyoming.

HD recommendation: If a Budget Amendment for PI drugs is introduced, we recommend that HHS establish some means-testing criteria for all States, so that these resources can be used only for those who can not afford to pay for these drugs. In addition, current data suggest that even in States with generous income eligibility standards, most ADAP enrollees have lower incomes. For example, of all New York ADAP enrollees, 74% have annual incomes below 20,000 or about 250% of poverty. (Current annual poverty level used by HHS for an individual is \$7,740.)

A means-testing standard, therefore, should not likely result in forcing many current ADAP enrollees to purchase these drugs with their own resources.

**2. Should the potential Budget Amendment be a set-aside solely for ADAP activities or all of Title II?** Given the rigorous protocols for these drugs, Jeff Levi feels strongly that a potential amendment should be for all of Title II. This could allow individuals to receive enhanced counseling, support and viral-load monitoring services while receiving the drugs from their ADAP program. The ADAP working group is seeking a \$247 million set-aside (\$52 M + \$195 M) just for Title II ADAP activities.

HD Recommendation: At this time, HD staff concur with Jeff Levi. These drugs should be administered within a full continuum of medical care services, all of which are not offered through ADAP programs. In addition, the Ryan White CARE Act Amendments of 1996 (P.L.) gives States new flexibility in how they can spend their funds. By funneling the money through the standard Title II formula, we would give States the discretion on how to spend these additional funds. However, we would still maintain the \$52 million set-aside that we have requested in the FY 1997 Budget.

The one major drawback with this approach is that it could make means-testing this additional money more difficult.

**3. Should the Budget Amendment be used to finance Opportunistic Infection (OI) drugs and other AIDS medications?** Both the ADAP Working Group and the Jeff Levi

estimates include funds to finance OI and other AIDS medications. The HD estimate does not.

HD Recommendation: At this time, HD staff believe that any Budget Amendment be used strictly to finance the new Protease Inhibitors. States have been purchasing the older nucleoside analogs (AZT and 3TC) for quite some time, and there is likely sufficient money within the current ADAP system (estimated to be \$144 million in FY 1996) to purchase these older drugs.

**4. What will other public (Medicaid) and private insurers do in response to the introduction of these drugs? What role should Ryan White play in relation to other financing mechanisms?**

HD Recommendation: At this time, HD staff recommend maintaining Ryan White's current "gap-filling" Federal role, rather than allowing it to be transformed to cover everyone infected with HIV.

It may make sense to propose a moderately-sized budget amendment (it needn't be large now, given all the uncertainties; if more is needed later, it can be requested) at this time.

However, a large budget amendment could possibly encourage private insurance companies not to cover protease inhibitors because it is covered by the Federal government and could even discourage drug companies from lowering their price, because we're paying for it -- leading to counter-productive results!

**FY 1997 POTENTIAL OFFSETS**  
(\$ in millions)

	<u>FY 1996</u> <u>Enacted</u>	<u>FY 1997</u> <u>Pres. Budget</u>	<u>Offsets</u> <u>Delta</u>
<b><u>HRSA Health Professions Facility Construction</u></b>			
BA	0	0	-2
OL	0	0	0

*Comments*            Rescind the remainder of an unobligated balance in HRSA.

**CDC--Shift NCHS BA to 1%**

BA	38	35	-19
OL	34	33	-18

*Comments*            Fund more of NCHS with 1% evaluation funding. 1% funds already provide more than half of NCHS's budget.

**CDC--Reduce Chronic Disease/Breast Cancer Program Funding**

BA	269	268	-25
OL	245	248	-23

*Comments*            Many of these programs provide "secondary prevention" of death and illness caused by primary disease -- similar to the effect of ADAP funded protease inhibitors. It may be appropriate to shift CDC funds to focus on an infectious disease.

**NIH--Reduce Administrative Costs by 2%**

BA	1,836	1,848	-37
OL	1,285	1,294	-26

*Comments*            Reduce by 2% NIH's nearly \$2 billion in FY 1997 administrative costs.

	FY 1996 Enacted	FY 1997 Pres. Budget	Offsets Delta
<b><u>NIH--Reduce Funding for Training by 5%</u></b>			
BA	446	456	-23
OL	408	439	-10

*Comments*            Reduce the FY 1997 request for NIH training programs by 5%.

<b><u>HHS--Reduce Administrative Costs by 1%</u></b>			
BA	1,100 to 1,300	1,265	-13
OL	880 to 1,040	1,012	-10

*Comments*            Reduce administrative costs in CDC, HRSA, SAMHSA, AHCPR, HCFA, and Departmental Management by 1%.  
FY 1996 BA and OL are rough estimates.

<b><u>Government-Wide--Reduce Printing &amp; Reproduction Costs</u></b>			
BA	774	785	-39
OL	751	761	-39

*Comments*            Reduce agency funding for printing and reproduction services by 5% government-wide. Rough estimate.  
Source: FY 1997 Object Class Analysis.

**TOTAL FY 1997 SAVINGS FROM PROPOSED OFFSETS:**

BA	-158
OL	-126

July 12, 1996



# Health Division



Office of Management and Budget  
Executive Office of the President  
Washington, DC 20503

Please route to:

Nancy-Ann Min

Decision needed \_\_\_\_\_  
Please sign \_\_\_\_\_  
Per your request   X    
Please comment \_\_\_\_\_  
For your information \_\_\_\_\_

Subject: **State Distribution of \$52 Million  
ADAP Set-Aside in FY96**

With informational copies for  
HPS and HD Chrons, RT, BC

Phone: 202/395-7791  
Fax: 202/395-3910  
Room: #7026

From: Greg White <sup>GW</sup>

Per your request, attached is the table (**Tab A**) that summarizes how the \$52 million ADAP set-aside will be distributed to the States in FY 1996. In addition, we have included a copy of a letter that HRSA sent out to the States on May 16th, which offers guidance and asks States to fill out a set of questions on their individual ADAP programs (**Tab B**). Once the State completes this questionnaire and provides additional information, HRSA then sends that State its portion of the \$52 million set-aside. HRSA staff advise that all but four of the grantees have now completed this package and received their FY 1996 ADAP set-aside grants.

The standard Title I and II grants were distributed to the States on May 20, 1996, the day that POTUS signed the Ryan White CARE Act Amendments of 1996 (P.L. 104-146). The distribution of these grant awards are included in **Tab C**.

Attachments

**TAB A**

## Attachment I

## Estimated Amounts of Awards

\$52 Million Set-aside for State AIDS Drug Assistance Programs  
in FY 1996 Appropriation for Title II of the Ryan White CARE Act

	Estimated Living Cases	Relative Estimated Living Cases	Grant Amount
ALABAMA	1,443	0.77%	\$401,982
ALASKA	138	0.07%	\$38,443
ARIZONA	1,690	0.91%	\$470,790
ARKANSAS	717	0.38%	\$199,737
CALIFORNIA	30,308	16.18%	\$8,415,161
COLORADO	1,997	1.02%	\$528,455
CONNECTICUT	3,093	1.66%	\$861,629
DELAWARE	659	0.35%	\$183,580
DISTRICT OF COLUMBIA	2,872	1.54%	\$800,064
FLORIDA	19,756	10.58%	\$5,503,506
GEORGIA	5,441	2.91%	\$1,515,721
HAWAII	618	0.33%	\$172,159
IDAHO	128	0.07%	\$35,657
ILLINOIS	6,040	3.24%	\$1,682,586
INDIANA	1,446	0.77%	\$402,818
IOWA	321	0.17%	\$89,422
KANSAS	657	0.35%	\$183,023
KENTUCKY	704	0.38%	\$196,116
LOUISIANA	2,778	1.49%	\$773,878
MAINE	281	0.15%	\$78,279
MARYLAND	5,557	2.98%	\$1,548,035
MASSACHUSETTS	3,805	2.04%	\$1,059,974
MICHIGAN	2,846	1.52%	\$792,821
MINNESOTA	991	0.53%	\$276,067
MISSISSIPPI	978	0.52%	\$272,445
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MONTANA	68	0.04%	\$18,943
NEBRASKA	265	0.14%	\$73,822
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NEW JERSEY	10,601	5.68%	\$2,953,162
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NORTH DAKOTA	26	0.01%	\$7,243
OHIO	2,808	1.50%	\$782,236
OKLAHOMA	867	0.46%	\$241,524
OREGON	1,273	0.68%	\$354,625
PENNSYLVANIA	5,742	3.08%	\$1,599,571
PUERTO RICO	6,049	3.24%	\$1,685,094
RHODE ISLAND	567	0.30%	\$157,951
SOUTH CAROLINA	2,364	1.27%	\$658,549
SOUTH DAKOTA	45	0.02%	\$12,536
TENNESSEE	1,967	1.05%	\$547,955
TEXAS	12,550	6.72%	\$3,496,103
UTAH	424	0.23%	\$118,115
VERMONT	106	0.06%	\$29,529
VIRGINIA	3,231	1.73%	\$900,072
WASHINGTON	2,396	1.28%	\$667,463
WEST VIRGINIA	249	0.13%	\$69,365
WISCONSIN	965	0.52%	\$268,824
WYOMING	49	0.03%	\$13,650
GUAM	3	0.00%	\$836
VIRGIN ISLANDS	102	0.05%	\$28,415
TOTAL U.S.	186,665	100.00%	\$52,000,000

**TAB B**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Bureau of Health Resources Development

Rockville MD 20857

MAY 16 1996

*Similar letter sent to each STATE! (List attached)*

Ms. Jane Cheeks  
Director, Division of HIV/AIDS Prevention and Control  
Alabama Department of Public Health  
434 Monroe Street  
Montgomery, Alabama 36130-3017

Dear Ms. Cheeks:

Enclosed are the materials to be used to apply for your State's share of the \$52 million in the Ryan White CARE Act Amendments of 1996 appropriation which was designated exclusively for State AIDS Drug Assistance Programs (ADAP).

Based on the formula proposed in the CARE Act reauthorization recently passed by Congress, we estimated that the awards will equal the amounts on the table in Attachment I to this letter. We will be prepared to award these additional funds upon receipt of the signed assurances found in Attachment II, the five to seven page narrative outlined in Attachment III, and the completion of the Table of Estimated Funds Available for ADAP Programs from All Sources in Attachment IV. An original and two copies of these materials are to be submitted at your earliest convenience, but not later than 30 days from the date of this letter, to:

Grants Management Branch  
Bureau of Health Resources Development  
5600 Fishers Lane, Room 7-27  
Rockville, MD 20857

These additional funds were requested by the Administration and approved by Congress in direct response to promising new developments in pharmacological management of HIV disease, including newly-approved therapeutics, and combination therapies involving multiple drugs. The appropriations language for these awards requires that they be used only for the provision of Food and Drug Administration (FDA)-approved therapeutics to treat HIV disease or prevent the serious deterioration of health arising from HIV disease eligible individuals, including measures for the prevention and treatment of opportunistic infections.

Therefore, States may use these funds to:

- > provide FDA-approved pharmaceuticals to eligible individuals in newly-established ADAP programs, and/or

PREPARED BY: HRSA/BHRD/DHS/PTAB/MDICLEMENTE/CAH/5/15/96  
J:\GENERAL\PTAB\HOLLAND\ADAPCOVER.LTR

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
.....	.....	.....	.....	.....	.....	.....	.....	.....
.....	.....	.....	.....	.....	.....	.....	.....	.....

Page 2 - Ms. Jane Cheeks

- > maintain expansion of existing ADAP programs initiated to add FDA-approved pharmaceuticals or sustain increased use of combination therapies, and/or
- > provide FDA-approved pharmaceuticals to more people than are currently served through an existing ADAP program, and/or
- > increase the number of FDA-approved pharmaceuticals available through an existing ADAP program (with or without an increase in the number of people served), and/or
- > provide for an increase in the number of concurrent prescriptions an enrolled individual may receive (e.g., to accommodate the increasing trend toward combination therapies).

In planning for the use of these funds, you are reminded that CARE Act funds have always been intended to supplement, rather than supplant existing allocations to AIDS programs. In this instance, the Bureau is confident that the intent of Congress was to extend this requirement to other CARE Act funds, as well. In other words, you are expected to add these funds to the percent of your anticipated total award proposed for expenditure on ADAP in your fiscal year (FY) 1996 Title II application. By the same token, if one or more Title I Eligible Metropolitan Areas in your State had committed funds to support the State ADAP program in FY 1996, those funds should not be diverted from ADAP support to some other use as a result of this increase in your award. We will reinforce this expectation in a separate communication to all Title I grantees.

While the President's FY 1997 budget includes these designated funds, the Bureau cannot guarantee the future level of funding for Title II. You will have to be particularly careful not to annualize these additional funds as you plan for your ADAP program in FY 1997.

While the new statute applies the same limitations regarding use of administrative funds to these ADAP supplemental funds as to all Title II funds, States are strongly encouraged to maximize use of these funds on the provision of FDA-approved therapeutics to treat HIV disease or prevent opportunistic infections.

We will process applications and make awards as they are received, so early submission of your ADAP supplemental application is encouraged. Ms. Margaret DiClemente has been designated as the Division of HIV Services contact for questions about the supplemental application. She can be

Page 3 - Ms. Jane Cheeks

reached at 301-443-4268. Please call Mr. Neal Meyerson of this office at 301-443-5906 if you have any grants management questions.

Sincerely,

Glenna Wilcom  
Grants Management Officer  
Grants Management Branch

Enclosures:

- Attachment I:           **Estimated Amounts of Awards, \$52 Million Set-aside for State AIDS Drug Assistance Programs in FY 1996 Appropriation for Title II of the Ryan White CARE Act**
- Attachment II:           **Required Assurances Related to Supplemental Awards for State AIDS Drug Assistance Programs**
- Attachment III:           **Outline for Application Narrative**
- Attachment IV:           **Table of Estimated Funds Available for ADAP Programs from All Sources**

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NORTH DAKOTA	26	0.01%	\$7,243
OHIO	2,808	1.50%	\$782,236
OKLAHOMA	867	0.46%	\$241,524
OREGON	1,273	0.68%	\$354,625
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VIRGIN ISLANDS	102	0.05%	\$28,415
TOTAL U.S.	186,665	100.00%	\$52,000,000

**Attachment II****Required Assurances Related to Supplemental Awards for  
State AIDS Drug Assistance Programs**

I, the director of the health department/agency of the State or Territory of \_\_\_\_\_, hereinafter referred to as

"State, " assure that:

- I. All funds received by this State which are identified as "ADAP Supplemental" under an amendment to the original Notice of Grant Award issued by the Grants Management Branch on March 1, 1996, will be separately accounted for and their use reported through the OMB-approved ADAP Annual Administrative Report.
- II. In cases where the ADAP is not centrally managed, the State will require every entity operating an AIDS drug assistance program supported with Federal funds to submit an ADAP Annual Administrative Report using the form prescribed by the Division of HIV Services.
- III. All Title II funds received by this State which are identified as "ADAP Supplemental" will be used exclusively for the provision of FDA-approved therapeutics to treat HIV-disease or prevent opportunistic infections.
- IV. No individual will receive benefits under this program who could have received complete covered benefits paid for by another public or private third-party payor (e.g., Medicaid, Medicare, private insurance with pharmaceutical benefit, etc.)
- V. The State will participate in the U.S. Public Health Service Office of Drug Pricing discount program, and/or will negotiate rebates from manufacturers/wholesalers, and/or will (as described in the attached narrative) otherwise seek the lowest possible price and reduced costs for each FDA-approved therapeutic on its formulary.
- VI. The State will develop a plan to coordinate with other grantees under Title II to reduce barriers to the expanded availability of the FDA-approved therapeutics to treat HIV-disease or prevent opportunistic infections.

Typed or Printed Name \_\_\_\_\_

Title \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

**Attachment III**  
**Outline for Application Narrative (not to exceed five to seven pages)**

- I. Name of State and agency within the State responsible for administering the AIDS Drug Assistance Program (ADAP).
- II. Brief description of how the program is administered in the State, including:
  1. How are therapeutics added to or dropped from the formulary?
  2. How are individual eligibility criteria established and/or modified (see also Section III. below)?
  3. Does the State directly administer each aspect of the program listed below, and if not, which entities do?
    - > enrollment
    - > certification of individual eligibility
    - > re-certification of already-enrolled individuals
    - > contracting with manufacturers/wholesalers for specific medications
    - > contracting with dispensaries/pharmacies
  4. How are medications dispensed to patients (e.g., mail order, centralized pharmacy, regional/local health clinic dispensaries, private pharmacies)?
- III. Brief description or reference to an attachment which defines ADAP eligibility in terms of the following (at a minimum):
  1. the State's definition of "low income" for purposes of the ADAP
  2. Medical/health status (e.g., CD<sub>4</sub> count, AIDS diagnosis, etc.)
  3. frequency of re-certification
  4. proof of income required
  5. co-payments or other cost-sharing requirements
- IV. Indicate which of the following the State/its sub-entities uses to seek the lowest possible price and reduced costs for each medication on the formulary:
  1. Office of Drug Pricing Veteran's Health Care Act Discount Program
  2. Voluntary manufacturers' rebates
  3. Using HCFA Medicaid rebate mechanisms
  4. Directly negotiated discounts with manufacturers and/or wholesalers
  5. Directly negotiated discounts with dispensing pharmacies
  6. Other (please describe)
- V. Brief description of the *specific* ways in which the State intends to:
  1. Maintain recent expansion of existing ADAP programs initiated to add FDA-approved pharmaceuticals or sustain increased use of combination therapies, and/or
  2. Provide FDA-approved therapeutics to more people than are currently served in any existing ADAP program, and/or
  3. Add new FDA-approved therapeutics to an existing formulary (with or without an increase in the number of people served), and/or
  4. Provide for an increase in the number of concurrent prescriptions (e.g., to accommodate the increasing trend toward combination therapies), and/or
  5. Coordinate with other Title II grantees to reduce barriers to the expanded availability of the FDA-approved therapeutics to treat HIV-disease or prevent opportunistic infections.

## Attachment IV

**TABLE OF ESTIMATED FUNDS AVAILABLE  
FOR ADAP PROGRAMS FROM ALL SOURCES**

State/Territory: ALABAMA

State ADAP Program Contact: \_\_\_\_\_

Phone Number \_\_\_\_\_

## Resources:

I. Title II- FY 1996 ADAP request reported in Title II  
Application (Table 4: FY 1996 Implementation Plan)\*:Amount \$1,135,212Percent 60.0%

Title II- Revised estimate of ADAP request based on final FY 1996  
Formula Award (this does not include the \$52 million ADAP  
supplement; see II. below, and should be equal to or greater than  
the proportion of the final award using the percent in I., above):

\$ \_\_\_\_\_

II. ADAP Supplemental- Share of \$52 million appropriated  
exclusively for carrying out Section 2616:\$401,982III. Estimate of Title I funds to be provided to the State ADAP  
program in FY 1996:

\$ \_\_\_\_\_

IV. Estimate of State funds (excluding Medicaid) available for HIV drug  
or pharmaceutical programs in FY 1996:

\$ \_\_\_\_\_

V. Estimate of other ADAP resources available in FY 1996  
(for example, rebate and/or discount programs):

\$ \_\_\_\_\_

VI. Total ADAP resources in FY 1996:

\$ \_\_\_\_\_

\* Include an estimate of funds allocated to consortia for pharmaceuticals.

**ESTIMATED 1996 TITLE II GRANT AWARDS**

*Pending Enactment of the Ryan White CARE Act Amendments of 1996  
as passed by the House May 1, 1996 and by the Senate, May 2, 1996 -  
assumes set-asides for SPNS, technical assistance and evaluation*

May 15, 1996	Estimated 1996 Grant Amount
ALABAMA	\$2,343,975
ALASKA	\$250,000
ARIZONA	\$1,781,212
ARKANSAS	\$1,184,878
CALIFORNIA	\$27,887,193
COLORADO	\$1,980,899
CONNECTICUT	\$2,777,274
DELAWARE	\$1,070,464
DISTRICT OF COLUMBIA	\$2,532,624
FLORIDA	\$19,825,887
GEORGIA	\$5,851,305
HAWAII	\$1,003,865
IDAHO	\$250,000
ILLINOIS	\$5,577,850
INDIANA	\$2,348,848
IOWA	\$521,425
KANSAS	\$883,813
KENTUCKY	\$1,143,561
LOUISIANA	\$3,281,312
MAINE	\$458,450
MARYLAND	\$4,950,700
MASSACHUSETTS	\$3,778,077
MICHIGAN	\$3,089,940
MINNESOTA	\$973,560
MISSISSIPPI	\$1,588,640
MISSOURI	\$2,504,335
MONTANA	\$110,457
NEBRASKA	\$430,460
NEVADA	\$1,742,958
NEW HAMPSHIRE	\$284,010
NEW JERSEY	\$10,134,868
NEW MEXICO	\$750,462
NEW YORK	\$29,178,896
NORTH CAROLINA	\$4,090,180
NORTH DAKOTA	\$100,000
OHIO	\$3,867,940
OKLAHOMA	\$1,408,334
OREGON	\$1,323,869
PENNSYLVANIA	\$6,362,404
PUERTO RICO	\$7,682,087
RHODE ISLAND	\$921,022
SOUTH CAROLINA	\$3,840,028
SOUTH DAKOTA	\$100,000
TENNESSEE	\$3,195,149
TEXAS	\$12,636,414
UTAH	\$688,735
VERMONT	\$250,000
VIRGINIA	\$4,445,040
WASHINGTON	\$2,475,313
WEST VIRGINIA	\$375,186
WISCONSIN	\$1,564,357
WYOMING	\$100,000
GUAM	\$4,954
VIRGIN ISLANDS	\$188,425
total	\$197,798,000

**TAB C**

# HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE  
Monday, May 20, 1996

Contact: HRSA Press Office  
(301) 443-3376

## CLINTON ADMINISTRATION AWARDS \$350 MILLION IN GRANTS FOR HIV SERVICES UNDER THE RYAN WHITE CARE ACT

President Clinton today announced the award of \$350 million in Ryan White CARE Act grants to complete FY 1996 funding to cities and states to provide emergency medical and support services for low-income or uninsured Americans living with HIV and AIDS. With partial awards made earlier in the fiscal year, this brings the total amount of awards made under under Titles I and II of the CARE Act in FY 1996 to \$569 million.

The President made the announcement as he signed the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 1996.

"This money is a lifeline of support for the thousands of men, women and children across this country who struggle, day to day, with the virus in their body," President Clinton said.

The grants announced today include:

- Title I formula and supplemental grants totaling \$235 million for 49 eligible metropolitan areas (EMAs) for the rest of FY 1996. A list of the EMAs and grant amounts follow.

- Title I formula and supplemental awards of \$5 million to seven new EMAs for the first part of FY 1996. (While 42 already-established EMAs received partial formula and supplemental grants earlier in the fiscal year, the seven new EMAs could not be funded until the FY 1996 budget was passed.)

Title I grants include both formula grants and competitive supplemental grants, which are awarded based on applications demonstrating additional critical needs. Funds pay for such services as medical and dental care, prescription drugs, transportation, case management, counseling and home and hospice care for underinsured and uninsured Americans living with HIV. A list of the seven new EMAs and their grant awards follow.

- Title II formula grants of \$110 million to all 50 states, Puerto Rico and Guam to complete Title II funding for FY 1996. The states, like the cities, received partial funding earlier in the fiscal year.

Title II grants are used to provide home and community-based care, assistance in continuing private health insurance coverage, and treatments and drugs that prolong life and/or prevent hospitalization. A list of these grants follows.

President Clinton also announced the availability of \$52 million in FY 1996 funds to states for the AIDS Drug Assistance Program, which will help states increase the number of HIV patients receiving drugs, including combination therapies and new drugs, and help pay for their increasing costs. The funds will be distributed within 30 days.

Under the reauthorized CARE Act, the Congress revised the formulas for calculating Title I and II grant amounts to reflect changes in the epidemic since 1990.

Since 1991, when the first CARE Act grants were awarded, nearly \$2.8 billion in federal funds has been appropriated under all four titles of the Act, providing care to more than 500,000 low-income Americans living with HIV and AIDS.

The CARE Act is administered by the Health Resources and Services Administration, an agency of the Department of Health and Human Services.

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NOTE: Charts attached

**NEW TITLE I FORMULA AND SUPPLEMENTAL AWARDS TO ELIGIBLE  
METROPOLITAN AREAS FOR FY 1996**

<b>Eligible Metropolitan Area</b>	<b>Formula Award</b>	<b>Supplemental Award</b>
Cleveland-Lorain-Elyria, Ohio	\$ 402,911	\$ 66,666
Fort Worth-Arlington, Texas	426,344	370,430
Hartford, Conn.	432,848	373,300
Middlesex-Somerset- Hunterdon, N.J.	466,503	351,999
Minneapolis-St. Paul, Minn.	417,063	69,054
Sacramento, Calif.	437,619	391,124
San Jose, Calif.	432,124	378,193
<b>Totals</b>	<b>\$ 3,015,412</b>	<b>\$ 2,000,766</b>

**TITLE I FORMULA AND SUPPLEMENTAL GRANTS TO ELIGIBLE METROPOLITAN  
AREAS FOR FY 1996**

<b>Eligible Metro Area</b>	<b>Today's award formula</b>	<b>Today's award supplemental</b>	<b>Total FY96* awards</b>
Atlanta, Ga.	\$ 3,085,678	\$ 3,066,231	\$ 9,168,453
Austin, Texas	780,087	797,407	2,388,429
Baltimore, Md.	3,725,949	2,577,584	8,329,265
Bergen-Passaic, N.J.	1,148,421	1,116,719	3,354,601
Boston, Mass.	2,781,286	2,923,043	8,324,071
Caguas, Puerto Rico	405,367	315,763	1,060,499
Chicago, Ill.	4,620,257	4,640,136	13,107,616
Cleveland-Lorain- Elyria, Ohio	778,412	133,334	1,381,323
Dallas, Texas	2,624,006	2,636,652	7,786,911
Denver, Colo.	1,204,907	1,122,521	3,534,616
Detroit, Mich.	1,754,003	1,413,576	4,386,879
Dutchess City, N.Y.	187,125	148,737	579,401
Fort Lauderdale, Fla.	2,296,631	1,711,123	6,557,146
Fort Worth-Arlington, Texas	665,975	782,184	2,244,933
Hartford, Conn.	1,049,199	1,178,991	3,034,338
Houston, Texas	2,901,628	3,125,533	10,299,874
Jacksonville, Fla.	890,788	908,721	2,713,601
Jersey City, N.J.	1,203,146	895,464	3,764,055
Kansas City, Mo.	769,153	859,220	2,503,314
Los Angeles, Calif.	7,714,390	8,643,407	26,199,164
Miami, Fla.	4,392,543	4,472,395	15,090,877
Middlesex-Somerset- Hunterdon, N.J.	675,712	694,702	2,188,916

(more)

**TITLE I FORMULA AND SUPPLEMENTAL GRANTS TO ELIGIBLE METROPOLITAN  
AREAS FOR FY 1996**

<b>Eligible Metro Area</b>	<b>Today's award formula</b>	<b>Today's award supplemental</b>	<b>Total FY96* awards</b>
Minneapolis-St. Paul, Minn.	\$ 752,123	\$ 128,891	\$ 1,367,131
Nassau-Suffolk, N.Y. 3,668,087	1,229,132	1,204,978	
New Haven, Conn.	1,604,349	1,320,915	3,985,302
New Orleans, La.	1,181,554	0	2,080,800
New York, N.Y.	24,318,013	29,838,339	92,119,368
Newark, N.J.	2,779,936	2,840,028	9,710,001
Oakland, Calif.	1,591,555	1,438,419	4,721,519
Orange Co., Calif.	1,152,388	1,202,005	3,477,837
Orlando, Fla.	1,437,504	1,196,980	3,584,223
Philadelphia, Penn.	3,934,947	3,348,091	10,301,649
Phoenix, Ariz.	1,094,348	992,946	2,889,198
Ponce, Puerto Rico	514,698	451,369	1,678,032
Portland, Ore.	894,393	995,328	2,677,185
Riverside-San Bern, Calif.	1,841,288	1,677,348	4,667,199
Sacramento, Calif.	738,309	885,275	2,452,327
St. Louis, Mo.	992,683	789,466	2,576,576
San Antonio, Texas	916,699	780,709	2,386,397
San Diego, Calif.	2,150,769	2,241,896	6,563,505
San Francisco, Calif.	9,563,339	11,121,771	
35,127,261			
San Jose, Calif.	665,589	788,568	2,264,474
San Juan, Puerto Rico	2,641,018	2,262,756	8,165,382

(more)

**TITLE I FORMULA AND SUPPLEMENTAL GRANTS TO ELIGIBLE METROPOLITAN  
AREAS FOR FY 1996**

<b>Eligible Metro Area</b>	<b>Today's award formula</b>	<b>Today's award supplemental</b>	<b>Total FY96* awards</b>
Santa Rosa-Petaluma, Calif.	\$ 319,554	\$ 376,614	\$ 1,137,515
Seattle, Wash.	1,333,755	1,467,576	4,270,832
Tampa-St. Pete, Fla.	1,625,649	1,415,744	4,590,780
Vineland, N.J.	153,229	150,736	452,401
Washington, D.C. 12,708,965	4,353,155	4,120,758	
West Palm Beach, Fla.	1,420,953	709,788	3,377,772
<b>Totals</b>	<b>\$116,855,592</b>	<b>\$117,910,737</b>	<b>\$371,000,000</b>

**\*Please note: The total FY 1996 award amounts include the partial Title I funding that the cities received earlier in the fiscal year.**

## TITLE II FORMULA AWARDS TO STATES FOR FY 1996

State	Today's award	Total FY 1996 grants*
Alabama	\$ 1,665,137	\$ 2,343,975
Alaska	181,545	250,000
Arizona	1,083,209	1,781,212
Arkansas	810,796	1,164,678
California	15,109,970	27,867,193
Colorado	1,188,170	1,980,699
Connecticut	1,587,888	2,777,274
Delaware	754,712	1,070,464
Florida	10,090,179	19,625,867
Georgia	3,256,765	5,851,305
Hawaii	747,647	1,003,865
Idaho	184,976	250,000
Illinois	2,635,478	5,577,650
Indiana	1,662,200	2,348,848
Iowa	379,455	521,425
Kansas	561,980	863,813
Kentucky	783,015	1,143,561
Louisiana	1,852,249	3,291,312
Maine	322,878	456,450
Maryland	2,149,874	4,950,700
Massachusetts	2,172,436	3,776,077
Michigan	1,925,518	3,089,940
Minnesota	560,685	973,550
Mississippi	1,073,173	1,588,640
Missouri	1,693,656	2,504,335
Montana	60,457	110,457
Nebraska	319,931	430,460
Nevada	1,291,804	1,742,956
New Hampshire	150,284	264,010
New Jersey	5,237,000	10,134,968

(more)

## TITLE II FORMULA AWARDS TO STATES FOR FY 1996

State	Today's award	Total FY 1996 grants*
New Mexico	\$ 521,769	\$ 750,462
New York	14,500,593	29,179,895
North Carolina	2,746,136	4,090,180
North Dakota	50,000	100,000
Ohio	2,522,038	3,867,940
Oklahoma	1,073,432	1,408,334
Oregon	718,518	1,323,869
Pennsylvania	3,487,424	6,362,404
Puerto Rico	3,389,616	7,682,087
Rhode Island	620,926	921,022
South Carolina	2,621,192	3,840,026
South Dakota	50,000	100,000
Tennessee	2,169,536	3,195,149
Texas	6,528,690	12,636,414
Utah	512,097	688,735
Vermont	200,000	250,000
Virginia	3,030,038	4,445,040
Washington	1,429,738	2,475,313
West Virginia	242,011	375,186
Wisconsin	1,165,142	1,564,357
Wyoming	50,000	100,000
Washington, D.C.	1,177,372	2,532,524
Guam	4,391	4,954
<b>Totals</b>	<b>\$110,303,726</b>	<b>\$197,629,575</b>

\*Please note: The total FY 1996 award amounts include the partial Title II funding that the states received earlier in the fiscal year.

###

July 25, 1996



# Health Division



Office of Management and Budget  
Executive Office of the President  
Washington, DC 20503

Please route to:

Barry Clendenin *BC*  
Nancy-Ann Min

Decision needed   
Please sign   
Per your request   
Please comment   
For your information

With informational copies for:

Subject: Two ADAP Items

HD Chron, HPS Chron,

From: Richard Turman *RT*

Phone: 202/395-4926  
Fax: 202/395-3910  
Room: #7002

- 1) HRSA set us the attached note that concerns ADAP and the concern about states "running out of money."
- 2) AIDS Action sent the attached letter from 10 Senators to Chairman Specter urging increased funding for Ryan White, as well as for AIDS research and AIDS prevention.

Attachments

**C O V E R****FAX****S H E E T**

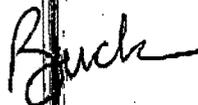
**To:** Bill Beldon and Richard Turman  
**Fax #:** 202-690-7846 / 202-395-3910  
**Subject:** ADAP and States "running out of money"  
**Date:** July 25, 1996  
**Pages:** 2, including this cover sheet.

**COMMENTS:**

I was able to confirm through AIDS Action that the four States they had named in conversation with Nancy Ann Min were Pennsylvania, Washington, Illinois, and *North Carolina*. The attached fact sheet summarizes our findings on the status of ADAP in the four.

I took the opportunity to request that AIDS Action bring speculative reports to our attention so that we could clarify things before they elevated them to the level they did yesterday -- but don't have great expectations that they'll cooperate.

Please feel free to call me with any questions.



From the desk of...

Warren W. Buckingham III  
Deputy Director  
Division of HIV Services/BHRD/HRSA  
6600 Fishers Lane, Room 7A-55  
Rockville, MD 20857

301-443-6747  
Fax: 301-443-8143 [FAX]

**Status Report:**  
**State AIDS Drug Assistance Programs in**  
**North Carolina, Washington, Illinois, and Pennsylvania**

It was reported to Nancy Ann Min of OMB on 7/23/96 by AIDS Action that the four States named above were "running out of money" or were "out of money" for their AIDS Drug Assistance Programs (ADAP). The Division of HIV Services (DHS), which is responsible for implementing Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, contacted the grantee in each State and offers the following information to clarify the status of these ADAP programs.

**North Carolina:** This State has seen a four-fold increase in ADAP expenditures from 1995 to 1996 (from \$26K/month to \$100K/month). Based on the supplemental application just received in our offices, they should be able to manage this increase as they have a \$702K ADAP supplemental award, and received a \$1.6M increase in their formula award and have dedicated up to \$1.3M of the increase to pharmaceuticals. In addition, their ADAP was entirely State funded up to this fiscal year and they have an appropriation of \$350K in State funds for further ADAP support.

**Washington State:** on 7/17 the State Health Department stopped accepting new enrollments and restricted coverage of protease inhibitors to those who had already begun treatment with them. These decisions were precipitated by rapid escalation of both enrollment and monthly costs to the program. Monthly costs had increased from \$53,000/month in 1995 to \$143,803 in June, 1996. Enrollment increased from 475 to 835 (a 75% rise) between December of 1995 and June of 1996 [actual program utilization increased less dramatically, from 206 to 335 people (still a 62% increase)]. Restricting protease inhibitors to those who had already initiated treatment was done because future funding at the greatly increased level of expenditures could not be assured, and interrupting the therapies can lead to rapid development of drug resistant strains of HIV. Plans for longer-term stabilization of funding are being developed. The State is not "out of money" and has taken responsible steps to seek to ensure that it doesn't run out within the fiscal year.

**Illinois:** Illinois' ADAP is incurring expenses at an annualized rate of approximately \$10.3M but has identified resources of just \$7M for the year. Recent formulary changes (effective 7/1) are expected to reduce expenses by 15-20%, and aggressive efforts will be made to shift more people (and expenses) to Medicaid. All Title II ADAP funds (\$1.7 supplemental award and \$600K from formula award) were spent in the first quarter for cash flow purposes prior to start of the State FY on 7/1. It is hoped that the State legislature will award emergency supplemental funds, but the Fall session will not take place until after the November elections, and prospects are considered mixed.

**Pennsylvania:** This program was entirely State-funded in FY 1994 and 95. The State reports no imminent shortfall in either Federal or State funding, and in the current FY they plan to use CARE dollars (via ADAP Supplement) plus State dollars for a total of \$6,325,571. According to the State, they expect to add all three protease inhibitors and have not run out of money.

**URGENT**  
**FAX**

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**RUSH TO:** Greg White, OMB, Health Division

---

**FAX:** 395-3910

---

**FROM:** The ADAP Working Group, Washington,DC

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**PAGES (INCLUDING THIS COVER):** 4

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FYI and self explanatory.

- Bill Arnold, The ADAP Working Group Washington,DC

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Wednesday, July 24, 1996

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•• Please see comment on page

## United States Senate

WASHINGTON, DC 20510

July 18, 1996

The Honorable Arlen Specter  
Chairman  
Subcommittee on Labor, HHS  
184 Dirksen Senate Office Bldg.  
Washington, D.C. 20510

Dear Mr. Chairman:

We are writing to express our strong support for funding increases for fiscal year 1997 in HIV/AIDS prevention, care and research programs.

AIDS is the leading killer of young men and women ages 25 through 44. It is spreading most rapidly among women, adolescents, and within minority communities. In the coming year, some 40,000 Americans will become infected with HIV, a quarter of whom will be between the ages of 13 and 25. By the end of the decade, more Americans will have lost their lives to AIDS than in all wars in U.S. history.

This worsening situation demands strong federal leadership. While the Congress provided welcome increases for HIV/AIDS research and care in FY 1996, more funding is needed if we are to keep pace with new scientific opportunities and ensure that medical advances translate into affordable health care and treatment for an increasing patient population.

We are requesting funding increases in three areas: prevention, the Ryan-White CARE Act, and National Institute of Health research. Additional funding is urgently needed to support HIV/AIDS prevention programs which received a \$6 million cut in FY 1996. State and local health departments have identified over \$60 million in unfunded prevention programs for populations at greatest risk for HIV. Our failure to provide adequate funding will doom these vital community-based efforts. An investment of \$33 million over FY 1996 levels would begin to fill critical gaps in our prevention efforts.

The second area needing a funding increase is the Ryan-White CARE Act, which provides resources to local communities for medical treatment and ancillary services and training for health care providers. This program also helps people with HIV/AIDS to live longer and avoid expensive treatment in emergency rooms. Programs funded under Ryan-White have struggled to keep pace with increasing case loads since the Act's inception. These growing case loads and the availability of several promising, yet costly, treatments require a further increase of at least \$125 million over FY 1996 funding levels. These funds would include a \$4.3 million increase for the AIDS Education and Training Centers (AETCs) now funded under Title V of the CARE Act.

1000 18th ST. N.W., SUITE 1117  
WASHINGTON DC 20009

Joseph I. Lieberman  
United States Senator

Carol Moseley-Braun  
United States Senator

John H. Chafee  
United States Senator

Ron Wyden  
United States Senator

John F. Kerry  
United States Senator

Daniel K. Akaka  
United States Senator

Carl Levin  
United States Senator

Paul Wellstone  
United States Senator

Patty Murray  
United States Senator

Jeff Bingaman  
United States Senator

Bob Graham  
United States Senator

Olympia Snowe  
United States Senator

•• Note - The CARE Act issue and ADAP (drug access) issues - in particular. As States proceed with their ADAP planning and the inadequacy of current ADAP resource levels become apparent - all should expect even more "crisis" driven letters from States, Governors, Senators, and Representatives. The "good news" from the Vancouver AIDS meeting makes the issue of lack of access even more painful, and politically sensitive. • Bill Arnold, The ADAP Working Group Washington, DC

1929 18th ST. N.W., SUITE 1117  
WASHINGTON DC 20009