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Report to Congressional Requesters

April 2006

RYAN WHITE CARE ACT

Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs

GAO-06-646

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Highlights

Highlights of GAO-06-646, a report to congressional requesters

RYAN WHITE CARE ACT

Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs

Why GAO Did This Study

The CARE Act authorized grants to the states and certain territories for AIDS Drug Assistance Programs (ADAP) to purchase and provide HIV/AIDS drugs to eligible individuals. An ADAP's coverage—who and what is covered—is determined by each ADAP's eligibility and other program criteria, and ADAPs may establish waiting lists for eligible individuals. ADAPs may purchase their drugs through the 340B federal drug pricing program, which provides discounts on certain drugs to covered entities. The Health Resources and Services Administration (HRSA) oversees ADAPs and is responsible for monitoring the prices they pay.

GAO was asked to examine (1) coverage differences among ADAPs, (2) how the prices ADAPs reported paying for HIV/AIDS drugs compare to 340B prices, (3) how HRSA monitors the drug prices ADAPs pay, and (4) how the 340B prices compare to other selected federal drug pricing programs.

What GAO Recommends

GAO recommends that HRSA require ADAPs to report the final prices they paid for drug purchases, net of rebates, and that HRSA routinely determine whether these prices paid are at or below the 340B prices. HRSA stated that these steps would be labor intensive and it lacks capacity to carry out such oversight. We believe there are cost-effective processes HRSA could use.

www.gao.gov/cgi-bin/getrpt?GAO-06-646.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or crossem@gao.gov.

What GAO Found

Variation in each ADAP's program design and funding from various sources contributes to differences in coverage among the 52 ADAPs GAO reviewed. Each ADAP has considerable flexibility in designing eligibility and other program criteria to determine who will be covered by the program. Consequently, an individual eligible for ADAP services in one state may not be eligible for services in another. ADAPs varied in the extent to which they received funding from sources in addition to the CARE Act ADAP base grants, such as state funds or transfers of funds from other CARE Act grants. Eligibility and other program design criteria also varied among ADAPs that had waiting lists of eligible individuals in fiscal year 2004, as did the amount and sources of additional funding for those ADAPs.

In their quarterly reports to HRSA, some ADAPs reported prices that were above the 340B price for some of the 10 drugs GAO compared. These 10 drugs accounted for 73 percent of ADAP drug spending. If ADAPs choose to use the 340B program, they may purchase drugs from manufacturers either through the direct purchase option, receiving the 340B price up front, or through the 340B rebate option, paying full price and receiving a rebate later. The 340B prices are not disclosed to ADAPs, but participating manufacturers agree to sell at the 340B prices. However, all 25 ADAPs that used the 340B direct purchase option reported a price that was above the 340B price. All but 3 of the 27 ADAPs using the 340B rebate option reported prices higher than the 340B price for one or more drugs. These prices may not have been the final prices these ADAPs paid, however, because they may not have included all rebates eventually received.

HRSA is responsible for monitoring whether ADAPs obtain the best prices available for drugs. HRSA has identified the 340B prices as a measure of an ADAP's economical use of grant funds. However, HRSA does not routinely determine whether the prices ADAPs report are no higher than the 340B prices. Also, quarterly reports do not reflect the rebates eventually received by ADAPs using the rebate option to purchase drugs. Without considering the final ADAP rebate amount on a drug purchase, HRSA cannot determine whether the final drug prices paid were at or below the 340B price.

ADAPs that purchase drugs at 340B prices paid more for some drugs than certain federal agencies did for the same drugs under the federal ceiling price program. ADAPs do not have access to this program. The 340B prices were also higher than some of the prices available through the 340B prime vendor program, which negotiates drug prices on behalf of participating 340B entities including ADAPs. The 340B prices, including the 340B prime vendor prices, were lower than the Medicaid rebate program prices available to state Medicaid programs, for each of the drugs GAO could compare.

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Abbreviations

ADAP	AIDS Drug Assistance Program
AIDS	acquired immunodeficiency syndrome
AMP	average manufacturer price
CARE Act	Ryan White Comprehensive AIDS Resources Emergency Act of 1990
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
ELC	estimated living AIDS case
EMA	eligible metropolitan area
FCP	federal ceiling price
FDA	Food and Drug Administration
FSS	federal supply schedule
HAART	highly active antiretroviral therapy
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
IOM	Institute of Medicine
NASTAD	National Alliance of State and Territorial AIDS Directors
NDC	national drug code
OIG	Office of Inspector General
OPA	Office of Pharmacy Affairs
PCRS	partner counseling and referral services
STD	sexually transmitted disease
VA	Department of Veterans Affairs

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United States Government Accountability Office
Washington, DC 20548

April 26, 2006

The Honorable Michael B. Enzi
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy, and Human Resources
Committee on Government Reform
House of Representatives

The Honorable Tom Coburn, M.D.
The Honorable Judd Gregg
United States Senate

Since the first cases of acquired immunodeficiency syndrome (AIDS) were identified in the United States nearly 25 years ago, advancements in prescription drug treatments have significantly reduced AIDS mortality and slowed the progression from a human immunodeficiency virus (HIV) -positive diagnosis to AIDS.[1] The introduction of combination drug treatments—highly active antiretroviral therapy (HAART)—in 1996 was followed by a decline in the number of AIDS deaths and new AIDS cases in the United States for the first time since the beginning of the epidemic.[2] While drug treatments have extended the lifespan of those living with HIV/AIDS, the number of new HIV infections has not decreased. The Department of Health and Human Services's (HHS) Centers for Disease Control and Prevention (CDC) estimates approximately 40,000 people are newly infected annually. CDC also estimates that between 1,039,000 and 1,185,000 people in the United States were living with HIV/AIDS at the end of 2003. The number of people with HIV/AIDS is likely to have risen since

[1]HIV is the virus that causes AIDS. Throughout this report, we use the common term HIV/AIDS to refer to HIV disease, inclusive of cases that have progressed to AIDS. When we use these terms alone, HIV refers to the disease without the presence of AIDS, and AIDS refers exclusively to HIV disease that has progressed to AIDS.

[2]HAART drug regimens usually combine three or more drugs and are used to suppress the progression of the disease HIV/AIDS by reducing the amount of the HIV virus in a person's blood. HAART therapy can cost about $12,000 or more per person annually.

then, and CDC estimates that, as of December 2004, it included 415,193 individuals with AIDS.

The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act),[3] administered by HHS's Health Resources and Services Administration (HRSA), was enacted to address the needs of jurisdictions, health care providers, and people with HIV/AIDS and their family members.[4] Title II of the CARE Act[5] authorizes AIDS Drug Assistance Program (ADAP) grants to states, including the District of Columbia, and certain territories[6] specifically to operate ADAPs. ADAPs purchase and provide HIV/AIDS drugs to infected individuals who meet eligibility requirements. Each state and territory is given broad authority under the CARE Act to design its own program. The scope of an ADAP's coverage—who and what is covered—is determined by each ADAP's program design, which includes criteria for who is eligible to receive drugs, and other criteria such as the number and types of drugs it will provide. There are no uniform program design criteria across ADAPs.

ADAPs are a critical source of prescription drugs for low-income people with HIV/AIDS who have no or limited prescription drug coverage and are the programs of last resort for these individuals.[7] In fiscal year 2005, CARE Act funding for ADAP grants was $787.5 million. As the number of people who know their HIV-positive status grows, the number of people with HIV/AIDS needing to rely on ADAPs will likely increase. Some ADAPs have struggled to meet the demand for their services. Limited resources

[3]Pub. L. No. 101-381, 104 Stat. 576 (codified as amended at 42 U.S.C. §§ 300ff—300ff–111 (2000)). Unless otherwise indicated, references to the CARE Act are to current law.

[4]See also GAO, *HIV/AIDS: Changes Needed to Improve the Distribution of Ryan White CARE Act and Housing Funds*, GAO-06-332 (Washington, D.C.: Feb. 28, 2006).

[5]The 1990 CARE Act added a new title XXVI to the Public Health Service Act. In general, because Part A of that new title, which authorizes grants to metropolitan areas, was established by Title I of the CARE Act, it is commonly referred to as Title I, and because Part B, which authorizes grants to states and territories, was established by Title II of the CARE Act, it is commonly referred to as Title II.

[6]In addition to the 50 states, ADAP grants are authorized for the District of Columbia, the Commonwealth of Puerto Rico, Guam, and the Virgin Islands.

[7]ADAPs and other programs funded through CARE Act grants serve as the payers of last resort for eligible individuals who have no other private or public source available for the services they need. HRSA policy provides that ADAPs are to identify and evaluate other potential sources of payment for drugs to ensure that the ADAPs are the payers of last resort.

have contributed to ADAPs establishing waiting lists for eligible individuals and taking other measures that restrict access.

Grants under Title II of the CARE Act are subject to conditions set out by HRSA in the notice of grant award, including conditions related to ADAP drug prices.[8] One of these conditions identifies 340B drug prices as the measure of ADAPs' economical use of grant funds. Under Section 340B of the Public Health Service Act, drug manufacturers provide discounts on certain outpatient drugs to covered entities;[9] a 340B price, sometimes referred to as a 340B ceiling price, is established for each covered drug that entities purchase. ADAPs are allowed to purchase drugs through the Section 340B program and are required to submit quarterly HIV/AIDS drug pricing reports to HRSA that indicate what they paid for drugs. Other federal drug pricing programs are used by federal agencies to purchase HIV/AIDS drugs, including the federal supply schedule (FSS) and federal ceiling price (FCP) programs. State Medicaid programs receive rebates from drug manufacturers for purchases of certain outpatient drugs including HIV/AIDS drugs through the federal Medicaid drug rebate program. ADAPs are not authorized by statute to purchase drugs under these other drug pricing programs.

As Congress prepares for the reauthorization of CARE Act programs, you asked us to examine certain aspects of ADAPs. Specifically, we are reporting on (1) how each ADAP's program design and funding sources contribute to differences in coverage among ADAPs, including those ADAPs with waiting lists, (2) how the prices that ADAPs report to HRSA they paid for HIV/AIDS drugs compare to the 340B prices, (3) how HRSA monitors the drug prices ADAPs pay, and (4) how the 340B prices for HIV/AIDS drugs compare to prices under selected federal drug pricing programs. You also asked us to provide information on state prenatal HIV testing and perinatal HIV transmission rates, and state approaches to identifying and notifying partners of HIV-infected individuals; this information is provided in appendixes I and II, respectively.

[8]Under the CARE Act, states and territories determine which drugs approved by the Food and Drug Administration to include on their ADAP drug formularies. Drug formularies are a preferred list of drug products that typically limit the number of drugs available within a therapeutic class for purposes of drug purchasing, dispensing, and reimbursement.

[9]42 U.S.C. § 256b (2000). Other entities eligible to purchase drugs through the 340B program include, for example, community health centers, hemophilia treatment centers, and HIV early intervention projects.

To report on these issues, we reviewed the 1990 CARE Act, and subsequent amendments, HRSA policy manuals, HHS's Office of Inspector General (OIG) reports on the CARE Act and ADAPs, Institute of Medicine (IOM) reports on the CARE Act, and other related reports, and documents. We interviewed HRSA and HHS OIG officials, as well as officials from the National Alliance of State and Territorial AIDS Directors (NASTAD) and the Association of State and Territorial Health Officials.

We reviewed 52 ADAPs to determine what program design elements contribute to the coverage differences among ADAPs.[10] We analyzed and compared data ADAPs reported to HRSA for grant year 2004 on program design elements such as eligibility income levels for individuals, enrollment caps, the number of drugs covered, and funding from various sources during fiscal year 2004.[11] We also analyzed and compared these data among ADAPs with waiting lists of eligible individuals.

To compare the prices that ADAPs reported paying for HIV/AIDS drugs to 340B prices for such drugs, we first determined which HIV/AIDS drugs were the top ten by ADAP expenditure using 2002 data, the most recently available expenditure data at the time of our analysis. These drugs accounted for 73 percent of ADAP drug spending. We then compared the prices ADAPs reported paying for the top ten HIV/AIDS drugs to the 340B program prices for those same drugs. For this comparison, we used the 2003 340B program prices and the purchase prices that 52 ADAPs provided in their quarterly reports submitted to HRSA for 2003. At the time of our analysis, 2003 was the most recent full year of ADAP drug price data.

To determine how HRSA monitors the prices ADAPs pay for HIV/AIDS drugs, we interviewed HRSA officials. To determine how the 340B prices compare with prices under selected federal drug pricing programs, we used the 2003 prices for the 340B drug pricing program from HRSA and compared them to FSS and FCP program prices from the Department of Veterans Affairs (VA), which administers these pricing programs. To determine how the 340B prices compare with the Medicaid prices, we calculated prices state Medicaid agencies paid including rebates states

[10]Our analyses of ADAPs throughout this report include the 50 states, the District of Columbia, and Puerto Rico.

[11]For our analyses, the ADAP grant year 2004 covered the period April 1, 2004, through March 31, 2005, and the fiscal year 2004 covered the period October 1, 2003, through September 30, 2004.

received under HHS's Centers for Medicare & Medicaid Services' (CMS) Medicaid drug rebate program. We found the data from these sources to be sufficient and reliable for our analyses.

Appendix III provides a more detailed explanation of the scope and methodology for this report. We performed our work from July 2004 through April 2006, in accordance with generally accepted government auditing standards.

Background

In 1990, Congress passed the CARE Act to address the needs of jurisdictions, health care providers, and people with HIV/AIDS and their family members. The CARE Act authorizes grants to eligible metropolitan areas (EMA) under Title I, and to states and territories under Title II.[12] Title II of the CARE Act authorizes the grants by which states and certain territories receive funds specifically to operate ADAPs. ADAPs purchase HIV/AIDS drugs for enrolled low-income people who are uninsured or underinsured. Each state and territory is responsible for and has significant flexibility in determining its ADAP eligibility criteria for who receives services, the services it provides, and which drugs to include in its formularies.

States and certain territories receive ADAP base grants distributed by a formula based on each grantee's proportion of total estimated living AIDS cases (ELC).[13] The ADAP grant program, administered by HRSA's HIV/AIDS Bureau, distributed $787.5 million or 38 percent of the about $2.1 billion in CARE Act funding for fiscal year 2005. ADAPs may receive funds from various other Title II grants awarded to states and territories, including Title II base grants and Severe Need grants. (See table 1.) Severe Need grants are made to states and certain territories with a need for funding to increase access to drugs.

[12]EMAs are metropolitan areas with a population of at least 500,000 and more than 2,000 reported AIDS cases in the last 5 calendar years.

[13]HRSA calculates a jurisdiction's ELCs by using data from the CDC on the reported AIDS case counts for the last 10 years and weights those numbers to account for the likelihood of deaths. See also GAO-06-332 for a discussion of ELCs.

Table 1: Key CARE Act Title II Grants through which ADAPs May Receive Funds

Grant	Purpose	Eligible grantees	Distribution
Base Grant	Support primary and home-based health care, insurance coverage, medications, support services, and early intervention services, such as HIV counseling, testing, and referral.	States and territories[a]	Distributed based 80 percent on each grantee's proportion of all ELCs and 20 percent on each grantee's proportion of all ELCs located outside EMAs.[b] Minimum grants of $200,000 are provided for states with less than 90 ELCs; $500,000 for states with 90 or more ELCs; and $50,000 for territories.
ADAP Base Grant	Provide medications, drug treatment adherence and support efforts,[c] and health insurance coverage with prescription drug benefits.	States and certain territories[d]	Distributed based on each grantee's proportion of all ELCs.
Severe Need Grant	Provide increased access to HIV/AIDS drugs.	States and certain territories[d] with a severe need for a grant to increase access to medications.	Distributed based on each grantee's proportion of all ELCs; grantees must agree to match 25 percent of their severe need grant and not to impose ADAP eligibility requirements stricter than those in place on January 1, 2000.[e]

Source: HRSA.

[a]In addition to the 50 states, base grants are authorized for the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.

[b]Under Title I of the CARE Act, EMAs are metropolitan areas with a population of at least 500,000 and more than 2,000 reported AIDS cases in the last 5 calendar years.

[c]Drug treatment adherence and support efforts are intended to increase individuals' ability to comply with the treatment regimen, for example, by providing care for depression.

[d]In addition to the 50 states, these grants are authorized for the District of Columbia, the Commonwealth of Puerto Rico, Guam, and the Virgin Islands.

[e]To be eligible for a Severe Need grant, a jurisdiction must have met one of four eligibility criteria as of January 1, 2000. It must have limited (1) the eligibility of ADAP enrollees to those with incomes at or below 200 percent of the federal poverty level, (2) the number of ADAP enrollees by using medical eligibility restrictions, (3) the number of antiretroviral drugs covered in its drug formulary, or (4) the number of opportunistic infection medications to less than 10 in its drug formulary. (Opportunistic infections are illnesses such as parasitic, viral, and fungal infections, and some types of cancer, some of which usually do not cause disease in people with normal immune systems.) In addition, a jurisdiction must also have agreed to provide a 25 percent match and not impose eligibility requirements more restrictive than those in place on January 1, 2000. According to HRSA, grantees can provide funds or in-kind services to meet the matching requirements.

ADAPs serve as the HIV/AIDS drug assistance program of last resort for individuals who, for example, cannot afford to pay for drugs, do not have insurance coverage for drugs, or do not qualify for other federal programs such as Medicaid that provide HIV/AIDS services to eligible individuals. Medicaid is the largest source of federal funding for HIV/AIDS health care services. In fiscal year 2005, Medicaid provided an estimated $5.7 billion in HIV/AIDS health care assistance.[14] Because Medicaid funds HIV/AIDS health care services, including drugs, to eligible individuals, state eligibility determinations for Medicaid are important in determining eligibility for ADAPs that provide HIV/AIDS services as a last resort.[15] Individuals who have received HIV/AIDS drugs through their state Medicaid programs and who are dual eligibles—eligible for both Medicaid and Medicare—will be affected by the Medicare Part D prescription drug benefit implemented in January 2006. Rather than receiving their drug coverage under Medicaid, dual eligibles will be covered by private insurance plans provided through Part D. Since Medicaid drug benefits vary from state to state, and Medicare Part D plans vary, which dual eligibles, if any, will be able to receive ADAP drug coverage as a last resort will also vary.

Unlike Medicaid, under which states receive more federal funds when their expenditures increase, due, for example, to greater enrollment, ADAPs do not receive additional federal funds when they have more eligible individuals than funds to provide services. When an ADAP cannot cover everyone it determines is eligible for its services, it may, but is not required to, establish a waiting list. ADAPs may establish waiting lists anytime that they determine it is necessary and the number of ADAPs with waiting lists is not constant. Since ADAPs may also cap the number of individuals they are willing to enroll for services, the ADAPs with waiting lists may not represent all eligible individuals who are not being served.

[14]Medicaid is a jointly funded federal-state health care program that covers certain low-income families, and certain individuals who are aged or disabled. By statutory formula, the federal government matches from 50 to 83 percent of each state's reported Medicaid expenditures for medical assistance.

[15]Eligibility criteria for Medicaid programs vary among the states. States have latitude within federal guidelines to design their individual Medicaid programs with respect to eligibility, services, payment, and whether to include prescription drug coverage. Although all state Medicaid programs have drug coverage, the HIV/AIDS drug coverage provided varies among states.

During fiscal year 2004, there were 14 ADAPs that reported having waiting lists for at least part of the year.[16]

When eligible individuals are on ADAP waiting lists, there are limited drug assistance options available to help those who qualify until they can be served by the ADAP. If they do not qualify for these options, the result can be an interruption of needed drug treatment. According to HHS's HIV treatment guidelines, if an individual's HAART regimen is interrupted, the individual can develop drug resistance upon resuming treatment.[17] Individuals who develop drug resistance can transmit drug-resistant strains of the HIV virus. Among the drug assistance options are pharmaceutical manufacturers' patient assistance programs that provide free or cost-reduced drugs, non-ADAP pharmacy assistance programs using Title I funds,[18] and state-sponsored pharmacy assistance programs. An ADAP-eligible individual's ability to use these options may be limited by factors such as availability in a particular state, financial and medical eligibility criteria for the individual, and coverage duration.

ADAPs and the 340B Drug Pricing Program

Section 340B of the Public Health Service Act requires drug manufacturers, as a condition of their payment under Medicaid, to sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services. Drug manufacturers agree to charge covered entities, including ADAPs, that participate in the 340B drug pricing program prices for certain outpatient drugs that do not exceed an amount determined by statutory formula—the 340B price.[19] HRSA's Office of Pharmacy Affairs (OPA), within the Healthcare Systems Bureau, administers the 340B

[16]Reliable data were not available to determine the number of unduplicated individuals on waiting lists during a year or the length of time an individual was on a waiting list before being served by the ADAP.

[17]HHS's Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents generally recommend the HAART drug treatment, which includes combination regimens of three drugs, and does not recommend one-drug regimens. The guidelines are updated regularly.

[18]Under Title I of the CARE Act, HRSA provides grants to EMAs; some EMAs use Title I grants to provide HIV/AIDS pharmaceutical assistance.

[19]If a drug manufacturer fails to sell drugs at or below the 340B prices, it can be dropped as a participating drug provider in the 340B and Medicaid programs.

program and calculates the 340B prices on a quarterly basis,[20] which are below the average manufacturer price (AMP).[21] ADAPs are eligible to participate in the 340B drug pricing program and receive 340B drug prices for the HIV/AIDS drugs they cover.[22] Like the other covered entities, an ADAP's participation in the 340B program is voluntary—they may choose, for example, to negotiate drug prices themselves with drug companies. For an ADAP to purchase drugs through the 340B program, it must inform both OPA and the HIV/AIDS Bureau's Division of Service Systems to activate its status as a 340B covered entity.

ADAPs participating in the 340B program have options for how they purchase drugs. Generally, ADAPs can purchase drugs through either the 340B direct purchasing option (sometimes referred to as point-of-purchase) or through the 340B rebate option. ADAPs choose one of these options when they activate their status as a 340B entity. Under the direct purchase option, ADAPs purchase drugs from drug manufacturers or through a third-party such as a drug purchasing agent. Using the 340B direct purchase option, ADAPs receive the 340B price discount up front. Under the rebate option, ADAPs typically contract with entities such as a pharmacy network or pharmacy benefits management company for the purchase of covered drugs. ADAPs later request a 340B rebate from the drug manufacturers. ADAPs that have activated their 340B status and are using the 340B direct purchase option can also use the 340B prime vendor to negotiate for them.[23] The prime vendor assists covered entities by negotiating drug prices at or below the 340B drug prices. Participation in this program is voluntary, but ADAPs that utilize the 340B rebate option or those that negotiate prices themselves and do not participate in the 340B drug pricing program are not eligible to participate in the prime vendor program.

[20]Prior to October 1, 2005, CMS calculated the 340B prices quarterly.

[21]42 U.S.C. § 256b(a)(1) (2000). AMP is the average price paid to the manufacturer for a drug by wholesalers for drugs distributed to the retail pharmacy class of trade. 42 U.S.C. § 1396r-8(k)(1) (2000). AMP is used to calculate the 340B price and by CMS to calculate the Medicaid rebate—the amount state Medicaid programs receive from drug manufacturers for covered drugs through the federal Medicaid rebate program.

[22]42 U.S.C. § 256b(a)(4)(E) (2000).

[23]Section 340B of the Public Health Service Act requires the Secretary of Health and Human Services to establish a prime vendor program for 340B covered entities. 42 U.S.C. § 256b(a)(8) (2000).

Grants under Title II of the CARE Act are subject to conditions set out in the notice of grant award, including conditions related to ADAP drug prices. One of these conditions identifies 340B prices as the measure of ADAPs' economical use of grant funds. Specifically, the notice states that "HHS and Congress expect that states will use every means at their disposal to secure the best price available for all products on their ADAP formularies in order to achieve maximum results with these funds." Further, the notice requires grantees to "adopt at least one defined cost-saving practice for their ADAP program that is equal to or more economical than the 340B Drug Pricing Program and its Prime Vendor Program."[24] For example, ADAPs may negotiate prices with drug manufacturers that are at or below the 340B prices for the same drugs. However, HHS does not disclose to ADAPs or the prime vendor what the 340B prices are for the drugs they purchase because of statutory provisions relating to the confidentiality of certain drug pricing information.[25] All ADAPs submit quarterly HIV/AIDS drug pricing reports to the HIV/AIDS Bureau that indicate what they paid. The Bureau can request that OPA compare the ADAP price reports to the 340B prices, but OPA does not share its price comparisons with the Bureau due to the confidentiality of the 340B prices. If a state or territory does not comply with the grant conditions, HRSA can either restrict the use of its current grant funds or deny the state or territory future grant funds.

Other Federal Drug Pricing Programs

Federal agencies and state Medicaid programs purchase drugs subject to other statutory provisions regarding prices. The FSS has prices available to all federal government purchasers for the drugs listed on the schedule. Another program, FCP, is the maximum price that drug manufacturers can charge four agencies—the Department of Defense, the VA, the Public Health Service, and the Coast Guard—for brand-name drugs listed on the

[24]Citing HHS policy that grantees must expend funds used for drug purchases in the most economical manner feasible, HRSA requested comments on a proposed requirement that all covered entities receiving grants participate in, or demonstrate good cause for not participating in, the 340B program. 63 Fed. Reg. 56,656, 56,657 (Oct. 22, 1998). HRSA later announced instead that, to increase participation in the 340B program, it would add a statement in its notice of grant award on the need for grantees to determine if their drug purchasing practices meet federal requirements for reasonable and cost effective purchasing. 65 Fed. Reg. 6,383 (Feb. 9, 2000).

[25]42 U.S.C. § 1396r-8(b)(3)(D) (2000).

FSS, even if the FSS prices are higher.[26] State Medicaid programs receive rebates on their covered drugs, including HIV/AIDS drugs, through the federal Medicaid drug rebate program. The minimum Medicaid rebate amount is 15.1 percent of AMP. ADAPs are not authorized to purchase drugs under these drug pricing programs, except for the District of Columbia ADAP, which purchases drugs using the FCP.

Results in Brief

Variation in ADAPs' program design and funding amounts from the CARE Act and other sources contributes to differences in coverage among the 52 ADAPs we reviewed. ADAP program eligibility and other design criteria, including income ceilings, program enrollment caps, and drug formularies, that states and territories establish vary considerably. For example, each ADAP determines a maximum income level, or income ceiling, as a criterion for an individual's eligibility for enrollment. ADAPs reported income ceilings for the 2004 grant year that ranged from 125 percent of the federal poverty level in North Carolina to 556 percent in Massachusetts. Also, of the 52 ADAPs, 16 reported that they have limits on the assets that individuals enrolled in the program are allowed to have. Twelve ADAPs reported having caps on program enrollment or on amounts expended per individual for HIV/AIDS drugs. The total number of drugs ADAPs included on their formularies ranged from 20 in Colorado to 1,000 in Massachusetts, New Hampshire, and New Jersey. Because of the variation in program criteria, an individual eligible for ADAP services in one state may not be eligible for services in another. The funding that some ADAPs reported receiving from sources other than the ADAP base grant, such as transfers from Title II base grants, and states' or other governmental entities' funds, also varied among ADAPs for fiscal year 2004. Funding from these various sources significantly increased funds available to cover individuals for some ADAPs. For example, the California ADAP, which had an ADAP base grant of about $89.6 million, received about $123.5 million in total additional funding. Eligibility and other program design criteria also varied among ADAPs that had waiting lists of eligible individuals in fiscal year 2004, as did the amount and sources of additional funding for those ADAPs.

[26]Drug manufacturers that do not make drugs available through the FSS and FCP programs may not receive payments for drugs from Medicaid, certain federal agencies, or any covered entity receiving funds under the Public Health Service Act. 38 U.S.C. § 8126(a)(4) (2000).

Some ADAPS reported prices to HRSA for some of the top 10 HIV/AIDS drugs that were higher than the 340B program prices. Drug manufacturers that agree to participate in the 340B drug pricing program agree to sell HIV/AIDS drugs to 340B entities, including ADAPs that participate in the program, at prices no higher than 340B prices. ADAPs are expected to secure the best price available for drugs on their formularies whether they use the 340B program, including the 340B prime vendor, or negotiate drug prices on their own with drug manufacturers. In our analysis using the top 10 HIV/AIDS drugs by ADAP expenditures, we found that in calendar year 2003 all of the 25 ADAPs that used the 340B direct purchase option reported prices to HRSA that were higher than the 340B price for at least one of the top 10 drugs. For example, 7 of the 25 ADAPs reported purchasing the drug Viramune at prices higher than the 340B price. Of the 27 ADAPs that used the 340B rebate option to purchase drugs in 2003, all except 3 ADAPs reported paying drug prices that were higher than the 340B prices for many of the top 10 drugs. However, the prices that ADAPs using the rebate option report to HRSA for each drug they purchase may not reflect the rebates that they eventually receive and therefore may not be the final prices these ADAPs pay for the drugs.

Although HRSA is responsible for monitoring whether ADAPs are complying with grant conditions, it does not routinely compare the drug prices ADAPs pay to 340B prices. A HRSA HIV/AIDS Bureau official said that the Bureau has occasionally asked OPA to compare the prices ADAPs report they paid for drugs to the 340B prices and provide the results. Bureau and OPA officials also said that they are discussing plans for OPA to begin making routine comparisons of drug prices. However, the ADAP drug price information that OPA currently uses to make its comparisons is not complete. The prices ADAPs report paying do not include all rebates they receive under the 340B rebate option. Also, OPA does not systematically check whether the prices obtained by the 340B prime vendor program are at or below the 340B prices. Without the final ADAP rebate amount on a drug purchase, HRSA cannot determine whether the final drug prices paid were at or below the 340B price.

The 340B program prices were higher for some of the top 10 drugs than the 340B prime vendor prices and the prices federal agencies paid for the same drugs under the FSS and FCP drug pricing programs. Using the top 10 HIV/AIDS drugs by ADAP expenditures, we compared 2003 drug prices under the 340B prime vendor, FSS, FCP, and Medicaid rebate drug pricing programs to the 340B prices. We found that the FCP and 340B prime vendor prices were lower than the 340B prices for 6 of the 7 drugs that had prices available under all five programs. The 6 HIV/AIDS drugs were

Combivir, Epivir, Sustiva, Trizivir, Zerit, and Ziagen. The Medicaid rebate program prices, available to state Medicaid programs, were the highest of all the drug pricing programs for 3 of the 7 drugs for which we had prices from all programs. The 3 drugs were Norvir, Sustiva, and Trizivir.

We are making recommendations to the Administrator of the Health Resources and Services Administration to require that all ADAPs report final prices they paid for drugs that reflect any discounts or rebates received, and to routinely determine whether the prices ADAPs paid for the drugs they purchased were at or below the 340B prices. In commenting on these recommendations, HRSA stated that it would like to verify final drug prices but this would be labor intensive because reports ADAPs currently provide do not contain the needed information. HRSA further stated that it lacks the resources to conduct a comprehensive price comparison, but is making efforts to develop systems to allow ADAPs to check drug prices. We believe that, while monitoring the prices paid for all the drugs on each ADAP's formulary might be challenging, HRSA could use a cost-effective, automated process to compare ADAP reported prices to 340B prices for selected drugs and could modify its schedule of ADAP reports to allow for rebate reconciliation.

Variation in Program Design and Funding Contributes to Coverage Differences among ADAPs

The program eligibility and other criteria that ADAPs establish and additional funding that some ADAPs receive vary and contribute to coverage differences among the 52 ADAPs we reviewed. As a result, an individual eligible for ADAP services in one state may not be eligible in another state. Also, some of the ADAPs received funding from sources other than ADAP base grants, such as Severe Need grants, transfers from Title I grants or Title II base grants, and contributions from their state or territory. The additional funding that some ADAPs received in fiscal year 2004 significantly increased funds available to support ADAP enrollees and services. Eligibility and other program design criteria varied among ADAPs that had waiting lists of eligible individuals in fiscal year 2004, as did the amount and sources of additional funding for those ADAPs. This variation among ADAPs with waiting lists contributes to coverage differences, just as it does among all ADAPs.

Variation in ADAPs' Eligibility and Other Program Criteria Contributes to Coverage Differences among ADAPs

ADAP program eligibility and other criteria, including income ceilings, copayments, and drug formularies, that states and territories establish vary considerably and contribute to coverage differences among ADAPs. According to the National ADAP Monitoring Project,[27] some ADAPs use these criteria and others that can limit access to their services to contain program costs. Because these criteria vary among ADAPs, a person determined eligible and who receives certain ADAP services in one jurisdiction may not be eligible or receive the same ADAP services in another.

Income level is one program eligibility criterion that varies among ADAPs. Each ADAP has an income ceiling, which is the maximum income an individual can have and be eligible for the program. Among the 52 ADAPs included in our review, income ceilings reported to HRSA for the 2004 grant year ranged from the most restrictive at 125 percent of the federal poverty level,[28] or $11,638, in North Carolina to the most generous at 556 percent, or $51,764, in Massachusetts. (See table 2.) Eleven ADAPs had income ceilings that were 200 percent or less of the federal poverty level. Sixteen ADAPs reported income ceilings that were 400 percent or greater than the federal poverty level.

[27]The National ADAP Monitoring Project, an initiative of the Henry J. Kaiser Family Foundation and NASTAD, issues a report on its annual survey of all jurisdictions receiving ADAP base grants. The survey provides data on the status of ADAP programs and assesses key trends.

[28]The HHS 2004 federal poverty level for a single person was $9,310; the poverty levels were higher for Alaska ($11,630) and Hawaii ($10,700). The poverty level was not defined for Puerto Rico.

Table 2: ADAP Program Eligibility by Income Ceiling, Reported for ADAP Grant Year 2004

	Eligibility income ceiling and its percent of the federal poverty level[a]	
ADAP	**Dollars**	**Percent**
Alabama	$23,275	250
Alaska[b]	34,890	300
Arizona	27,930	300
Arkansas	27,930	300
California	37,240	400
Colorado	27,930	300
Connecticut	37,240	400
Delaware	46,550	500
District of Columbia	37,240	400
Florida	32,585	350
Georgia	27,930	300
Hawaii[c]	42,800	400
Idaho	18,620	200
Illinois	37,240	400
Indiana	27,930	300
Iowa	18,620	200
Kansas	27,930	300
Kentucky	27,930	300
Louisiana	18,620	200
Maine	27,930	300
Maryland	37,240	400
Massachusetts	51,764	556
Michigan	41,895	450
Minnesota	27,930	300
Mississippi	37,240	400
Missouri	27,930	300
Montana	30,723	330
Nebraska	18,620	200
Nevada	37,240	400
New Hampshire	27,930	300
New Jersey	46,550	500
New Mexico	27,930	300
New York	45,340	487

ADAP	Eligibility income ceiling and its percent of the federal poverty level[a]	
	Dollars	Percent
North Carolina	11,638	125
North Dakota	37,240	400
Ohio	46,550	500
Oklahoma	18,620	200
Oregon	18,620	200
Pennsylvania	35,378	380
Puerto Rico[d]	18,620	200
Rhode Island	27,930	300
South Carolina	27,930	300
South Dakota	27,930	300
Tennessee	27,930	300
Texas	18,620	200
Utah	37,240	400
Vermont	18,620	200
Virginia	27,930	300
Washington	27,930	300
West Virginia	23,275	250
Wisconsin	27,930	300
Wyoming	18,620	200

Source: GAO analysis of ADAP data.

Note: The ADAP 2004 grant year covered April 1, 2004, through March 31, 2005.

[a]The HHS 2004 federal poverty level for a single person was $9,310 except as noted.

[b]The HHS 2004 federal poverty level for Alaska was $11,630.

[c]The HHS 2004 federal poverty level for Hawaii was $10,700.

[d]The HHS 2004 federal poverty level was not defined for Puerto Rico; we calculated the eligibility income ceiling for Puerto Rico by multiplying Puerto Rico's 200 percent income ceiling by the federal poverty level of $9,310.

Of the 52 ADAPs we reviewed, 29 reported to HRSA that their programs had one or more program design limitations, which also contributed to coverage differences among ADAPs for grant year 2004. These included a limit on an individual's assets, copayment requirements, caps on program enrollment, or caps on expenditures per individual enrollee. (See table 3.) Sixteen ADAPs reported that they have a limit on assets that enrollees are allowed to have, 9 reported having a copayment for drugs provided, 7 reported having a cap on the number of individuals enrolled, and 5

reported having a cap on amounts expended per enrollee for HIV/AIDS drugs. Eight ADAPs reported using more than one of these criteria.

Table 3: Program Eligibility and Other Criteria, Reported for ADAP Grant Year 2004

ADAP	Enrollee asset limitation[a]	Copayments[b]	Caps on number of enrollees[c]	Caps on expenditures per enrollee[d]
Alabama				
Alaska				
Arizona				
Arkansas			X	
California		X		
Colorado	X		X	
Connecticut				
Delaware	X	X		
District of Columbia	X			
Florida	X			
Georgia	X			
Hawaii	X			
Idaho			X	X
Illinois				X
Indiana				
Iowa				
Kansas		X		
Kentucky	X			
Louisiana	X			
Maine				
Maryland		X		
Massachusetts				
Michigan				
Minnesota	X			
Mississippi				
Missouri				X
Montana			X	
Nebraska				
Nevada	X			
New Hampshire				
New Jersey				

ADAP	Enrollee asset limitation[a]	Copayments[b]	Caps on number of enrollees[c]	Caps on expenditures per enrollee[d]
New Mexico	X			
New York	X			
North Carolina			X	
North Dakota				
Ohio				
Oklahoma			X	X
Oregon	X	X		
Pennsylvania				
Puerto Rico				
Rhode Island				
South Carolina		X		
South Dakota			X	X
Tennessee	X			
Texas		X		
Utah	X	X		
Vermont				
Virginia				
Washington	X	X		
West Virginia				
Wisconsin				
Wyoming				
Total ADAPs	**16**	**9**	**7**	**5**

Sources: GAO analysis of HRSA and ADAP data.

Note: The ADAP 2004 grant year covered April 1, 2004, through March 31, 2005.

[a]An enrollee asset limitation is a maximum amount of assets, as defined by each ADAP, that an individual may have and be eligible to receive drug assistance from the respective ADAP. The asset limitations were reported as either the ADAP had a limitation or it did not, or by the dollar amount of the ADAP's limit. For those ADAPs reporting a dollar amount, the range was from $2,500 in Colorado to $25,000 in Florida, Minnesota, and New York.

[b]A copayment is money that an individual must pay to receive the ADAP's drug assistance. The copayments were reported as either the ADAP had a fixed or sliding scale copayment or it did not.

[c]The cap on the number of enrollees is a maximum number of eligible individuals who will be able to receive the ADAP's drug assistance. The caps were reported as either the ADAP had a cap or it did not, or by the number of ADAP enrollees allowed. For the 5 ADAPs that reported an enrollee cap number, the range was from 75 in South Dakota to 3,600 in North Carolina.

[d]A cap on expenditures per enrollee is the maximum dollar amount for drug assistance that an ADAP will provide an eligible individual. The caps were reported as either the ADAP had a cap or it did not, or by the dollar amount of the ADAP's cap. For the five ADAPs that reported an expenditure cap, the range was from $1,200 per month in Idaho to $24,000 per year in Illinois.

The number and type of drugs covered under ADAPs' drug formularies vary and can also contribute to coverage differences among ADAPs. ADAPs are not required to cover particular drugs or a minimum number of drugs. The Food and Drug Administration (FDA) has approved 27 HIV/AIDS drugs in four drug classes.[29] According to NASTAD, the majority of ADAPs cover several drugs in three of the classes.[30] In the ADAP 2004 grant year, 26 ADAPs reported that they covered Fuzeon, which is the only FDA-approved drug in the fourth class of drugs—fusion inhibitors.[31] (See table 4.) The more drugs an ADAP covers under its formulary, the more likely it is that eligible individuals will receive the prescribed drugs they need, and that individuals who develop resistance to a particular HIV/AIDS drug regimen will have other drug treatment options available. In grant year 2004, the number of drugs included in ADAPs' formularies ranged from 20 drugs in Colorado to 1,000 drugs in Massachusetts, New Hampshire, and New Jersey.[32] Thirty-nine ADAPs reported they had 100 or fewer drugs, including 15 with fewer than 50 drugs on their formularies.

[29]The HIV/AIDS drug classes are protease inhibitors, nucleoside/nucleotide reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, and fusion inhibitors.

[30]National ADAP Monitoring Project's Annual Report (Washington, D.C., April 2005).

[31]Fuzeon is for individuals who have used other anti-HIV drugs but still have ongoing HIV viral replication; it was approved by the FDA in 2003. Fuzeon is to be used with a combination of medications for individuals with limited treatment options.

[32]ADAPs may include in their formularies drugs to prevent or treat opportunistic infections and other HIV-related conditions.

Table 4: Number of Drugs Included in ADAP Formularies and ADAPs that Cover Fuzeon, Reported for ADAP Grant Year 2004

ADAPs	Drugs in formulary	Fuzeon included
Alabama	32	
Alaska	63	
Arizona	46	Yes
Arkansas	46	Yes
California	152	
Colorado	20	
Connecticut	176	Yes
Delaware	241	
District of Columbia	67	
Florida	57	Yes
Georgia	51	
Hawaii	89	
Idaho	39	
Illinois	74	Yes
Indiana	77	Yes
Iowa	37	Yes
Kansas	52	Yes
Kentucky	45	
Louisiana	21	Yes
Maine	36	Yes
Maryland	99	Yes
Massachusetts	1,000	
Michigan	178	Yes
Minnesota	131	
Mississippi	45	Yes
Missouri	272	Yes
Montana	105	
Nebraska	100	
Nevada	59	
New Hampshire	1,000	
New Jersey	1,000	Yes
New Mexico	65	
New York	495	Yes
North Carolina	55	Yes

ADAPs	Drugs in formulary	Fuzeon included
North Dakota	85	
Ohio	74	
Oklahoma	48	
Oregon	62	Yes
Pennsylvania	600	Yes
Puerto Rico	63	
Rhode Island	65	Yes
South Carolina	52	Yes
South Dakota	41	
Tennessee	80	Yes
Texas	31	
Utah	39	Yes
Vermont	80	
Virginia	62	Yes
Washington	125	Yes
West Virginia	30	
Wisconsin	67	Yes
Wyoming	73	
Total ADAPs	**52**	**26**

Sources: GAO analysis of HRSA and ADAP data.

Notes: Fuzeon is a fusion inhibitor medication for individuals who have used other anti-HIV drugs but still have ongoing HIV viral replication; it was approved by the FDA in 2003. Fuzeon is to be used with a combination of medications for individuals with limited treatment options.

Variation in Funding Amounts from Sources Other than the ADAP Base Grant Can Contribute to Coverage Differences among ADAPs

Most ADAPs received funding from various sources, in addition to ADAP base grants. The amounts of funding and sources varied among ADAPs. The additional funding that ADAPs received can contribute to differences in the number of individuals served and the level of services provided. In fiscal year 2004, 46 of 52 ADAPs we reviewed reported receiving additional funds from sources that included Severe Need grants, transfers from Title II base grants, transfers from Title I grants, contributions from the state or territory, and other sources. Nineteen ADAPs received funds from three or more of the additional funding sources. (See table 5.)

Table 5: Additional ADAP Funding Sources and Amounts by ADAP, Fiscal Year 2004

ADAP	Title II Severe Need grant[a]		Title II base grant transfer[b]	Title I grant transfer from EMA[c]	Contributions from jurisdiction funds[d]	Other funding sources[e]	Total additional ADAP funding
	Severe Need grant	State matching funds for Severe Need grant					
Alabama	$824,913	$206,228	$0	0[f]	$2,500,000	$0	$3,531,141
Alaska	0	0	0	0[f]	50,000	0	50,000
Arizona	0	0	0	0	1,000,000	78,546	1,078,546
Arkansas	0[g]	0[g]	0	0[f]	330,810	393,000	723,810
California	0[g]	0[g]	12,168,628	0	63,934,245	47,370,750	123,473,623
Colorado	660,427	165,107	136,000	560,254	934,134	3,212,522	5,668,444
Connecticut	0[g]	0[g]	0	0	606,678	0	606,678
Delaware	0[g]	0[g]	0	0[f]	0	832,382	832,382
District of Columbia	0[g]	0[g]	0	0	400,000	0	400,000
Florida	0[g]	0[g]	1,916,336	0	9,000,000	0	10,916,336
Georgia	2,789,298	697,324	0	1,540,022	11,305,339	0	16,331,983
Hawaii	0[g]	0[g]	0	0[f]	440,535	0	440,535
Idaho	54,663	13,666	261,150	0[f]	163,461	300,000	792,940
Illinois	0[g]	0[g]	0	0	7,000,000	5,619,843	12,619,843
Indiana	0[g]	0[g]	2,720,419	0[f]	0	102,331	2,822,750
Iowa	0	0	0	0[f]	0	0	0
Kansas	0[g]	0[g]	0	0[f,h]	400,000	550,000	950,000
Kentucky	481,282	120,320	100,000	0[f]	90,000	199,462	991,064
Louisiana	1,628,705	407,176	0	0	0	422,638	2,458,519
Maine	0	0	0	0[f]	57,638	125,327	182,965
Maryland	0[g]	0[g]	65,250	105,925	0	2,100,000	2,271,175
Massachusetts	0[g]	0[g]	0	104,819	747,990	1,900,000	2,788,809
Michigan	0[g]	0[g]	0	0	0	5,500,000	5,500,000
Minnesota	0[g]	0[g]	0	0	1,100,000	2,743,522	3,843,522
Mississippi	0[g]	0[g]	1,093,008	0[f]	750,000	0	1,843,008
Missouri	0[g]	0[g]	771,167	1,549,422	669,000	1,913,547	4,921,136
Montana	36,525	9,131	178,548	0[f]	0	7,120	231,324
Nebraska	130,445	32,611	74,000	0[f]	115,938	160,000	512,994
Nevada	0[g]	0[g]	0	65,250	1,350,947	0	1,416,197
New Hampshire	0[g]	0[g]	0	0[f,h]	0	0	0
New Jersey	0[g]	0[g]	0	0	0	13,050,000	13,050,000

ADAP	Title II Severe Need grant[a]		Title II base grant transfer[b]	Title I grant transfer from EMA[c]	Contributions from jurisdiction funds[d]	Other funding sources[e]	Total additional ADAP funding
	Severe Need grant	State matching funds for Severe Need grant					
New Mexico	0[g]	0[g]	0	0[f]	0	0	0
New York	0[g]	0[g]	2,524,145	5,870,000	33,000,000	64,500,000	105,894,145
North Carolina	1,511,429	377,857	0	0[f]	8,355,195	3,338,000	13,582,481
North Dakota	0	0	85,400	0[f]	0	32,000	117,400
Ohio	0[g]	0[g]	0	300,000	7,843	20,000	327,843
Oklahoma	419,165	104,791	486,486	0[f]	786,000	361,000	2,157,442
Oregon	0[g]	0[g]	0	0	300,000	5,650,000	5,950,000
Pennsylvania	0[g]	0[g]	0	0	10,452,000	6,044,000	16,496,000
Puerto Rico	2,661,337	0[i]	3,455,671	0	2,093,000	0	8,210,008
Rhode Island	0[g]	0[g]	0	0[f]	0	700,000	700,000
South Carolina	1,382,225	345,556	0	0[f]	500,000	0	2,227,781
South Dakota	0	0	330,744	0[f]	0	0	330,744
Tennessee	0	0	0	0[f]	0	0	0
Texas	5,943,843	1,485,961	500,000	0	28,538,504	0	36,468,308
Utah	0	0	0	0[f]	0	0	0
Vermont	0	0	0	0[f]	175,000	130,000	305,000
Virginia	1,707,470	426,867	0	0	2,612,200	0	4,746,537
Washington	0[g]	0[g]	0	800,487	4,842,484	925,000	6,567,971
West Virginia	153,553	38,388	75,000	0[f,h]	0	180,000	446,941
Wisconsin	374,441	93,610	0	0[f,h]	186,658	855,317	1,510,026
Wyoming	0[g]	0[g]	0	0[f]	0	0	0
Total	**$20,759,721**	**$4,524,593**	**$26,941,952**	**$10,932,179**	**$194,795,599**	**$169,334,307**	**$427,288,351**

Sources: GAO analysis of HRSA and ADAP data.

[a]To be eligible for a Severe Need grant, a jurisdiction must have met one of four eligibility criteria as of January 1, 2000. It must have limited (1) the eligibility of ADAP enrollees to those with incomes at or below 200 percent of the federal poverty level, (2) the number of ADAP enrollees by using medical eligibility restrictions, (3) the number of antiretroviral drugs covered in its drug formulary, or (4) the number of opportunistic infection medications to less than 10 in its drug formulary. (Opportunistic infections are illnesses such as parasitic, viral, and fungal infections, and some types of cancer, some of which usually do not cause disease in people with normal immune systems.) In addition, a jurisdiction must also have agreed to provide a 25 percent match and not impose eligibility requirements more restrictive than those in place on January 1, 2000. According to HRSA, grantees can provide funds or in-kind services to meet the matching requirements.

[b]The Title II base grant transfers are CARE Act funds that were awarded to the state or territory where the ADAP is located, and that the respective state or territory decides to provide or transfer to the ADAP program.

[c]Title I grant transfers from EMAs are CARE Act funds that were awarded to EMAs in the state or territory where the ADAP is located, and that the EMA decides to provide or transfer to the ADAP program.

[d]Contributions from jurisdiction funds are additional funds provided by the state or territory where the ADAP is located to the ADAP program.

[e]Other funding sources may include drug rebates ADAPs receive from manufacturers against prices paid for drug purchases. These rebates do not actually constitute additional funding. However, we were unable to identify the amounts attributable to drug rebates in these ADAPs' reports.

[f]State did not have an EMA.

[g]State was not eligible for a grant.

[h]The state did not have its own EMA but a portion of the state was included in an EMA in another state.

[i]HRSA officials told us that the agency did not require Puerto Rico to provide matching funds.

The number of ADAPs that reported receiving funding from sources other than ADAP base grants and the amounts they received for fiscal year 2004 varied:

- **Severe Need grants**: Fifteen states and Puerto Rico received Severe Need grant funds for their ADAPs ranging from about $37,000 in Montana to about $6 million in Texas.[33] The total amount of funds from Severe Need grants these ADAPs received was about $20.8 million.
- **Title II base grant transfers**: Eighteen ADAPs reported receiving transfers from their respective jurisdiction's Title II base grants. These transfers ranged from $65,250 in Maryland to about $12.2 million in California. The total amount of these transfers was about $26.9 million.
- **Title I grant transfers from EMAs**: Nine ADAPs reported receiving Title I fund transfers from the EMAs in their states ranging from $65,250 in Nevada to about $6 million for New York. The total amount of Title I grantee transfers was about $10.9 million.
- **Contributions from state and Puerto Rico funds**: Thirty-five ADAPs reported receiving contributions from their respective jurisdiction's non-CARE Act funds ranging from about $8,000 in Ohio to about $64 million in California. For example, states can appropriate funds to be used by their respective ADAPs. The total amount of these contributions was about $194.8 million—the largest total amount received from the various sources.

[33]There were 25 grantees eligible to receive ADAP Severe Need grants in fiscal year 2004. To receive these grants, eligible grantees must agree to match 25 percent of the funds. Of the 25 eligible grantees in fiscal year 2004, 16 received the grants, and 15 agreed to make the match. HRSA awarded a grant to Puerto Rico but did not require it to provide matching funds.

Other sources: Thirty-two ADAPs reported receiving funding from other sources[34] ranging from about $7,000 in Montana to $64.5 million in New York. The total amount of funds received from these sources was about $169.3 million.

Among the ADAPs that reported receiving funding from sources other than ADAP base grants, the total dollar amounts received ranged from $50,000 in Alaska to about $123.5 million in California. Six ADAPs—Iowa, New Hampshire, New Mexico, Tennessee, Utah, and Wyoming—did not report receiving any additional funding.

The amount of additional funding some ADAPs received significantly increased their funds available to support ADAP enrollees and services. The increases in funding per ELC and as a percent of the ADAP base grant varied among the ADAPs. (See table 6.) For example, the highest amount of additional funding received per ELC was $3,604, or 171 percent of the ADAP base grant, in Idaho. The lowest amount of additional funding received—excluding the 6 ADAPs with no additional funds—per ELC was $61, or 3 percent of the ADAP base grant, in the District of Columbia. Of the 46 ADAPs that received additional funding, 8 ADAPs—California, Colorado, Idaho, Minnesota, North Carolina, North Dakota, Oregon, and South Dakota—received total additional funding that was more than 100 percent of the ADAP base grants to their states. Ten ADAPs—Alaska, Arizona, Connecticut, District of Columbia, Florida, Louisiana, Maryland, Massachusetts, Ohio, and South Carolina—received total additional funding that was less than 20 percent of the ADAP base grants to their states.

[34]Other funding sources may include drug rebates ADAPs receive from manufacturers against prices paid for drug purchases. These rebates do not actually constitute additional funding. However, we were unable to identify the amounts attributable to drug rebates in these ADAPs' reports.

Table 6: Total Additional ADAP Funding as a Percentage of the CARE Act ADAP Base Grants and Total Additional Funding Per ELC by ADAP, Fiscal Year 2004

ADAP	Total additional ADAP funding	ADAP base grant	Total additional ADAP funding as percentage of the ADAP base grant	Total additional ADAP funding per ELC with rank among 46 ADAPs	
				Dollars	Rank
Alabama	$3,531,141	$7,004,635	50	$1,064	18
Alaska	50,000	472,602	11	223	42
Arizona	1,078,546	8,392,903	13	271	41
Arkansas	723,810	3,116,716	23	494	34
California	123,473,623	89,623,465	138	2,907	4
Colorado	5,668,444	5,607,928	101	2,133	8
Connecticut	606,678	11,315,018	5	113	44
Delaware	832,382	3,202,722	26	548	32
District of Columbia	400,000	13,842,594	3	61	46
Florida	10,916,336	80,386,630	14	287	40
Georgia	16,331,983	23,684,951	69	1,455	14
Hawaii	440,535	2,084,512	21	446	36
Idaho	792,940	464,163	171	3,604	1
Illinois	12,619,843	25,746,254	49	1,034	20
Indiana	2,822,750	6,529,924	43	912	24
Iowa	0	1,305,985	0	0	--
Kansas	950,000	2,045,495	46	991	22
Kentucky	991,064	4,086,741	24	512	33
Louisiana	2,458,519	13,829,935	18	375	39
Maine	182,965	833,383	22	463	35
Maryland	2,271,175	25,746,254	9	186	43
Massachusetts	2,788,809	14,684,416	19	401	37
Michigan	5,500,000	11,002,763	50	1,055	19
Minnesota	3,843,522	3,010,727	128	2,693	6
Mississippi	1,843,008	5,795,703	32	671	30
Missouri	4,921,136	7,409,723	66	1,401	15
Montana	231,324	310,145	75	1,574	12
Nebraska	512,994	1,107,661	46	977	23
Nevada	1,416,197	4,738,678	30	631	31
New Hampshire	0	755,319	0	0	--
New Jersey	13,050,000	34,877,598	37	789	25
New Mexico	0	2,127,024	0	0	--

ADAP	Total additional ADAP funding	ADAP base grant	Total additional ADAP funding as percentage of the ADAP base grant	Total additional ADAP funding per ELC with rank among 46 ADAPs	
				Dollars	Rank
New York	105,894,145	124,956,784	85	1,788	9
North Carolina	13,582,481	12,834,095	106	2,233	7
North Dakota	117,400	92,543	127	2,730	5
Ohio	327,843	10,909,930	3	63	45
Oklahoma	2,157,442	3,655,707	59	1,279	17
Oregon	5,950,000	4,225,989	141	2,971	3
Pennsylvania	16,496,000	27,090,216	61	1,285	16
Puerto Rico	8,210,008	22,598,388	36	767	27
Rhode Island	700,000	1,911,506	37	773	26
South Carolina	2,227,781	11,736,984	19	400	38
South Dakota	330,744	204,654	162	3,410	2
Tennessee	0	12,018,438	0	0	--
Texas	36,468,308	50,471,351	72	1,524	13
Utah	0	1,980,565	0	0	--
Vermont	305,000	382,007	80	1,685	11
Virginia	4,746,537	14,498,751	33	691	29
Washington	6,567,971	7,966,718	82	1,739	10
West Virginia	446,941	1,303,875	34	723	28
Wisconsin	1,510,026	3,179,514	47	1,002	21
Wyoming	0	160,347	0	0	--
Total	**$427,288,351**	**$ 727,320,929**	**59%**		

Sources: HRSA and GAO analysis.

Note: A dash indicates an ADAP that did not receive additional funding and could not be ranked.

ADAPs with Waiting Lists Also Varied in Program Design and Additional Funding Sources and Amounts

The eligibility and other program design criteria and additional funding ADAPs received varied among ADAPs with waiting lists and can contribute to coverage differences. When an ADAP cannot cover everyone it determines is eligible for its services, it may, but is not required to, establish a waiting list. HRSA's HIV/AIDS Bureau does not have guidance on what conditions should trigger an ADAP to establish a waiting list. In fiscal year 2004, 14 ADAPs had waiting lists of individuals they determined were ADAP eligible but the programs were unable to serve.[35] (See table 7.) Due to the lack of reliable data on both the number of unduplicated individuals on a list and the length of time individuals spend on waiting lists, we could not determine, for example, the exact number of individuals during a specific period who were on waiting lists. Based on data ADAPs with waiting lists reported to HRSA for fiscal year 2004, the average number of individuals on waiting lists for a particular ADAP and among ADAPs varied.[36] For example, Montana's monthly average ranged from 5 to 14 individuals during fiscal year 2004, while North Carolina's monthly average ranged from 38 to 861. We do not know whether any ADAP turned away individuals who would have been eligible without establishing a waiting list.

[35]In 2005, HRSA reported that all ADAPs that maintained waiting lists determined individuals' eligibility before placing them on the lists. *Maximizing Access to Medications through Efficient Use of CARE Act Resources* (Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau, May 2005).

[36]The average number of individuals on a monthly waiting list could represent the total number of individuals on the list during the entire month, or the total number of individuals on the list at any time during the entire month.

Table 7: ADAPs with Waiting Lists and Number of Months Each Had Waiting Lists, Fiscal Year 2004

ADAPs	Number of Months
Alabama	12
Alaska	10
Arkansas	4
Colorado	10
Idaho	9
Indiana	2
Iowa	5
Kentucky	12
Montana	11
Nebraska	3
North Carolina	12
Oregon	2
South Dakota	12
West Virginia	12

Sources: HRSA and GAO analysis.

Eligibility and other program design criteria reported for ADAP grant year 2004 varied among ADAPs with waiting lists. For example, for

- **Income ceilings**: Among the 14 ADAPs with waiting lists, income ceilings ranged from the most restrictive at 125 percent of the poverty level, or $11,638 in North Carolina to the most generous at 330 percent of the poverty level, or $30,723 in Montana.
- **Enrollment and service caps**: Among the 14 ADAPs with waiting lists, 6 ADAPs capped the number of enrollees, and two capped the amount they expend per individual for all HIV/AIDS drugs.
- **Drug formularies**: Among the 14 ADAPs with waiting lists, the total number of drugs on their formularies ranged from 20 drugs in Colorado to 105 drugs in Montana.

In fiscal year 2004, the majority of ADAPs received funding from other sources in addition to ADAP base grants. The majority of ADAPs with waiting lists—13 of 14—also received additional funding. For example, for

- **Severe Need grants**: Among the 14 ADAPs with waiting lists, 8 received funds from Severe Need grants.[37]
- **Title II base grant transfers**: Among the 14 ADAPs with waiting lists, 8 received transfers of Title II base grant funds.
- **Title I grant transfers from EMAs**: Among the 14 ADAPs with waiting lists, only one ADAP—Colorado—received a Title I transfer.
- **Contributions from state and Puerto Rico funds**: Among the 14 ADAPs with waiting lists, 9 received these contributions.
- **Other sources**: Among the 14 ADAPs with waiting lists, 10 ADAPs reported receiving funding from other sources.[38,39] Among those 10 ADAPs, the amount of funds from other sources ranged from about $7,000 in Montana to about $5.6 million in Oregon.

Of the 13 ADAPs with waiting lists that received additional funding in fiscal year 2004, 5—Colorado, Idaho, North Carolina, Oregon, and South Dakota—were among the 10 ADAPs that received the most additional funding per ELC. (See table 8.) Idaho at $3,604 per ELC, South Dakota at $3,410 per ELC, and Oregon at $2,971 per ELC respectively ranked the highest among the 46 ADAPs that received additional funding. The rank order of the remaining 10 ADAPs with waiting lists among all ADAPs that received additional funding ranged from seventh—North Carolina at $2,233 per AIDS case—to forty-second—Alaska at $223 per ELC.

[37]Three states whose ADAPs had waiting lists were eligible to receive Severe Need grants in fiscal year 2004, but did not apply.

[38]Other funding sources may include drug rebates ADAPs receive from manufacturers against prices paid for drug purchases. These rebates do not actually constitute additional funding. However, we were unable to identify the amounts attributable to drug rebates in these ADAPs' reports.

[39]In June 2004, the President announced that $20 million would be used to provide HIV/AIDS drug assistance to over 1,700 individuals then on ADAP waiting lists in 10 states. The 10 ADAPs were in Alabama, Alaska, Colorado, Idaho, Iowa, Kentucky, Montana, North Carolina, South Dakota, and West Virginia. However, these funds were not distributed to the ADAPs. HRSA contracted with Chronimed StatScript Pharmacy, a pharmaceutical distributor, to provide the HIV/AIDS drugs directly to these individuals. Chronimed began providing drugs in October 2004, the first month of fiscal year 2005. The contract with Chronimed, now known as BioScript, was extended by HRSA through March 2006 to allow the approximately $1 million of remaining funds to be used.

Table 8: Ranking of 13 ADAPs with Waiting Lists among the 46 ADAPs that Received Additional Funding Per ELC; Fiscal Year 2004

ADAPs with waiting lists that received additional funding	Rank among 46 ADAPs by additional funding per ELC	Additional funding per ELC
Idaho	1	$3,604
South Dakota	2	3,410
Oregon	3	2,971
North Carolina	7	2,233
Colorado	8	2,133
Montana	12	1,574
Alabama	18	1,064
Nebraska	23	977
Indiana	24	912
West Virginia	28	723
Kentucky	33	512
Arkansas	34	494
Alaska	42	223

Sources: GAO analysis of HRSA and ADAP data.

Some ADAPs Reported HIV/AIDS Drug Prices that Were Higher than the 340B Prices

Some ADAPs reported prices to HRSA that they paid for some of the top 10 HIV/AIDS drugs purchased during 2003 that were higher than the 340B program prices.[40] However, the reported prices may not be the final prices paid by ADAPs that receive rebates on the purchase price of their drugs. States and territories are expected to use every means at their disposal to secure the best price possible for HIV/AIDS drugs and are also required to adopt at least one cost-saving practice that is equal to or more economical

[40]The drugs were the top 10 drugs by expenditure that ADAPs purchased in 2002, the most current expenditure data available at the time of our analysis. The expenditures for these 10 drugs represented 73 percent of the total ADAP drug expenditures in 2002. The 10 drugs were Combivir, Viracept, Sustiva, Norvir, Zerit, Trizivir, Epivir, Ziagen, Viramune, and Viread. See appendix III for a more detailed description of our methodology.

than the 340B and prime vendor programs.[41] While HRSA has identified 340B prices as the measure of cost effectiveness, HHS does not provide ADAPs with the 340B prices to use as a guide when purchasing HIV/AIDS drugs due to statutory provisions regarding the confidentiality of information used to determine them. Drug manufacturers that participate in the 340B program are aware of the 340B prices, and as a condition of their participation in the Medicaid program, have agreed to sell HIV/AIDS drugs to those ADAPs that use the 340B direct purchase or rebate options at prices no greater than the 340B prices.[42] We found that among both the 25 ADAPs that used the direct purchase option and the 27 that used the rebate option to purchase their drugs in 2003, nearly all of the ADAPs reported drug prices that were higher than the 340B prices for at least one of the top 10 drugs.

All of the 25 ADAPs that used the 340B direct purchase option to buy HIV/AIDS drugs in 2003 reported prices that were higher than the 340B prices for at least one of the top 10 HIV/AIDS drugs.[43] (See table 9.) For example, 7 ADAPs reported prices that were above the 340B price for Viramune. Three ADAPs reported prices that were more than the 340B price for at least 8 of the 10 drugs—Delaware (10), Oklahoma (9), and Kentucky (8). All 25 ADAPs reported prices that were more than the 340B price for the drug Norvir. Since ADAPs are not provided the 340B prices,

[41]A HRSA official told us in 2005 that four ADAPs—District of Columbia, Kentucky, Michigan, and Pennsylvania—had special pricing arrangements other than under the 340B program; these pricing arrangements were to be at least equivalent to the 340B prices. The District of Columbia had access to the FCP; Kentucky used a direct purchase option with a fixed price contract; Michigan had a voluntary rebate agreement with drug manufacturers; and Pennsylvania had a mandated drug manufacturer rebate. As of February 2006, all ADAPs except the District of Columbia, which has FCP access, were either 340B direct purchase or rebate ADAPs.

[42]If a drug manufacturer does not comply with the 340B program pricing requirements, it can be dropped as a participating drug provider in the 340B and Medicaid programs.

[43]We received the 340B prices from HRSA for our analysis. The 340B drug prices are not publicly available, so we do not report any pricing-related information that would allow a specific drug's 340B price to be determined. See appendix III for an explanation of our price comparison methodology.

they may be unknowingly paying more than the 340B price for a drug.[44] Because the 340B, the 340B prime vendor, the FCP, and Medicaid drug prices are not public, we indicate only whether a reported price is above the 340B price.

Table 9: 25 340B Direct Purchase ADAPs that Reported Prices for the Top 10 HIV/AIDS Drugs that Were Above 340B Prices; 2003

ADAP	Combivir	Epivir	Norvir[a]	Sustiva	Trizivir	Viracept	Viramune	Viread	Zerit	Ziagen
Alabama			X							
Arizona			X							
Arkansas			X	X				X		
Colorado			X	X						
Delaware	X	X	X	X	X	X	X	X	X	X
District of Columbia			X				N/A			
Florida			X							
Georgia			X							
Hawaii			X					X		
Iowa			X							
Illinois			X				X			
Kentucky	X	X	X		X	X	N/A	X	X	X
Louisiana			X							
Mississippi			X	X				N/A		
Montana			X					X		
Nebraska			X							
New Mexico	X	X	X				X		X	X
Nevada			X		X					
Ohio			X							
Oklahoma	X	X	X		X	X	X	X	X	X

[44]In a general review of the 340B program, the HHS OIG testified that in some cases drug manufacturers may not bill 340B covered entities the correct 340B prices. The Department of Health and Human Services Office of Inspector General, Testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections, on 340B Drug Pricing Program Oversight and Administration, before the Subcommittee on Oversight and Investigations of the U.S. House Committee on Energy and Commerce (Washington, D.C.: Department of Health and Human Services, 2005.)

ADAP	Combivir	Epivir	Norvir[a]	Sustiva	Trizivir	Viracept	Viramune	Viread	Zerit	Ziagen
Puerto Rico			X				X	X	X	
South Carolina			X							
Tennessee			X				X			
Texas			X	N/A			N/A			
Virginia			X				X			
Total	**4**	**4**	**25**	**4**	**4**	**3**	**7**	**7**	**5**	**4**

Sources: HRSA and GAO analysis.

N/A = ADAP did not purchase the drug.

Notes: An empty table cell indicates that the ADAP purchased the drug and paid at or below the 340B price for that drug. To compare the prices that ADAPs reported paying for HIV/AIDS drugs to 340B prices for such drugs, we first determined which HIV/AIDS drugs were the top 10 by ADAP expenditure using 2002 data, the most recently available expenditure data. We then compared the prices ADAPs reported they paid for the top 10 HIV/AIDS drugs to the 340B program prices for those same drugs. For this comparison, we used the 2003 340B program prices and the purchase prices that 52 ADAPs provided in their quarterly reports submitted to HRSA for 2003. At the time of our analysis, 2003 was the most recent full calendar year of ADAP drug price data.

[a]In December 2003, Abbott Laboratories, the manufacturer of Norvir, an HIV/AIDS protease inhibitor, substantially increased the wholesale price per patient. In February 2004, Abbott Laboratories announced a permanent Norvir price freeze for ADAPs at the price in place prior to the December 2003 re-pricing.

Among the 27 ADAPs that reported they used the 340B rebate option in 2003, most reported prices for the top 10 HIV/AIDS drugs that were above the 340B prices. The 3 ADAPs that reported HIV/AIDS drug prices at or below the 340B prices, and the number of drugs they purchased at these prices were Kansas (3), Washington (3), and Pennsylvania (1). ADAPs using the 340B rebate option report the prices they paid for drugs to HRSA, but these reports may not reflect the drug rebates ADAPs may eventually receive that would determine the final amount paid for the drug. The ADAPs that use the 340B rebate option almost always reported HIV/AIDS drug prices higher than the 340B prices. An OPA official told us that there is no reporting that reconciles the rebate savings an ADAP may receive against the price it pays for a drug.

ADAPs that negotiate their own HIV/AIDS drug discounts with drug manufacturers, or use the 340B prime vendor to negotiate drug discounts for them, are expected to negotiate prices equal to or less than the 340B prices.[45] However, HHS does not disclose to the ADAPs or the 340B prime vendor what the 340B prices are that they should not exceed. A HRSA official told us that the ADAPs' and the 340B prime vendor's negotiating position is disadvantaged because they rely on the drug manufacturers they negotiate with to tell them whether the negotiated prices are equal to or better than the 340B prices.

In 2003, 10 ADAPs joined together to negotiate HIV/AIDS drug prices directly with drug manufacturers. These ADAPs formed a task force under the auspices of NASTAD to directly negotiate drug prices with eight drug manufacturers for HIV/AIDS antiretroviral drug discounts on behalf of all ADAPs.[46] According to the ADAP task force representatives we interviewed, the negotiated drug discounts they agreed to were the total of the 340B discount plus whatever additional discounts they could negotiate. The representatives said that the discounts they agreed to were lower than prices available under the 340B program, but we did not verify the representatives' claim. The quarterly reports that ADAPs provide the Bureau do not indicate whether a drug price is the result of negotiations conducted by an ADAP or other options such as the 340B direct purchase or rebate. All of these 10 ADAPs reported prices on their 2003 quarterly reports that were more than the 340B price for at least 1 of the top 10 drugs.

[45]The 340B prime vendor assists 340B covered entities, including ADAPs that use the 340B direct purchase option, by negotiating drug prices at or below the 340B drug prices.

[46]The 10 ADAPs represented were: California, Florida, Hawaii, Illinois, Maryland, Massachusetts, New Jersey, New York, North Carolina, and Texas. All of the ADAPs except Hawaii and North Carolina were among the top ten ADAPs based on total cumulative AIDS cases reported from the beginning of the epidemic through December 2003. The eight drug manufacturers involved in the negotiations were: Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb Company, Gilead Sciences, GlaxoSmithKline, Hoffman-La Roche, Inc., Merck & Company, and Pfizer, Inc. The ADAP representatives in these negotiations said that they negotiated on behalf of all ADAPs, not just the 10 task force members, and each ADAP decided if it wanted to take advantage of the negotiated prices.

HRSA Does Not Routinely Determine Whether Drug Prices ADAPs Report Paying Are Higher than the 340B Prices

HRSA's HIV/AIDS Bureau is responsible for monitoring grantees' compliance with the conditions of their grants, including those related to HIV/AIDS drug prices. HRSA does not routinely compare the HIV/AIDS drug prices ADAPs report they pay to 340B program prices. When comparisons are made, they may not be complete, because the prices ADAPs report paying may not include all rebates they may receive under the 340B rebate option. If an ADAP is found to be out of compliance, HRSA can restrict the ADAP's use of its current funds or deny it future grant funds.

To monitor ADAP drug prices, a Bureau official told us that the Bureau had only occasionally requested that ADAP drug prices be compared to the 340B prices. For example, the Bureau has requested some spot checks rather than conducting quarterly price comparisons using the ADAPs' quarterly drug price reports. No Bureau official has access to the 340B price information. HRSA's OPA administers the 340B drug pricing program, including the 340B prime vendor program, and has access to the 340B prices and the prime vendor's negotiated prices.[47] Therefore, to determine how ADAP reported prices compare to 340B prices, the Bureau has to request that OPA make these price comparisons. When OPA makes the price comparisons at the Bureau's request, the comparison results that OPA provides indicate whether an ADAP reported price is below, above, or close to the 340B price, or may show, for example, that a drug's price is within a percentage range above or below the 340B price for that drug. According to the Bureau and OPA officials, requests for these comparisons are not routinely made by the Bureau.

The results of OPA price comparisons do not necessarily show whether final prices paid by ADAPs using the rebate option are higher than the 340B prices. According to HRSA officials, the drug prices reported paid by ADAPs that use the rebate option are not reflective of the final prices

[47]An OPA official told us that OPA does not routinely monitor whether the prices negotiated by the 340B prime vendor are at or below the 340B prices, but plans to develop a monitoring system.

because they have not been reconciled by factoring in rebate savings.[48] A Bureau official and an OPA official stated that without the reconciled ADAP rebate savings information on a particular drug purchased, it cannot be determined whether the final drug prices paid are at or below the 340B prices or whether ADAPs that use the rebate purchase option are paying more than the 340B price for any drugs.

Based on its finding that HRSA did not conduct systematic monitoring of 340B prices, in December 2005, the HHS OIG recommended that HRSA develop monitoring mechanisms to compare the 340B prices to the prices paid by 340B entities, which include ADAPs.[49] During the course of our review, Bureau and OPA officials told us that they were discussing plans for OPA to begin making routine comparisons of the prices reported by the ADAPs to the 340B prices. As of April 2006, final decisions have not been made about when the comparisons will begin, how often they will be made during a year, or whether the results will be shared with the ADAPs. If the price comparisons do not include the rebates ADAPs receive and 340B prime vendor prices, the comparisons cannot indicate whether the prices all ADAPs paid for their drugs were at or below the 340B prices.

[48]ADAPs' financial data submitted to HRSA contain information on the total expected rebate savings but not the rebate expected on the purchase of a specific drug, which is the information needed to make drug price comparisons to the 340B prices. ADAPs report the total amount of projected drug rebates they expect to receive on their ADAP profile reports. The rebates they report can include (1) the section 340B drug discount program rebates, (2) negotiated rebates, and (3) the NASTAD task force negotiated rebates. ADAPs can also report their sources of funding, such as rebates, on another report—the ADAP quarterly data report. Neither report asks ADAPs to list the amount of rebates they receive by drug or to provide their rebate agreements.

[49]The Department of Health and Human Services Office of Inspector General, Testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections, on 340B Drug Pricing Program Oversight and Administration, before the Subcommittee on Oversight and Investigations of the U.S. House Committee on Energy and Commerce (Washington, D.C.: Department of Health and Human Services, 2005.)

HIV/AIDS Drug Prices Are Sometimes Higher Under the 340B Program than Some Federal Programs

ADAPs that purchase HIV/AIDS drugs at the 340B prices paid more for some of the top 10 drugs by expenditure than prices for these same drugs paid under the 340B prime vendor program and prices federal agencies pay under the FSS and FCP drug pricing programs. ADAPs paid less for their top 10 drugs than drugs purchased under the Medicaid program.[50] ADAPs do not have access to the federal drug pricing programs. In our comparison of drug prices in 2000 to drug prices in 2003, all but one of the top 10 drug prices that we included in our analysis increased under the 340B, FSS, and FCP. During the same period, all top 10 drug prices for which we had data available decreased under the Medicaid program.

340B Prices for Several Top 10 HIV/AIDS Drugs Were Higher than Prices Under Other Federal Drug Pricing Programs

The results of our analysis show that the 340B prices paid in 2003 for most of the top 10 HIV/AIDS drugs were higher than prices under the FCP and 340B prime vendor programs, but lower than Medicaid prices.[51] We compared 2003 drug prices under four drug pricing programs—340B prime vendor,[52] FCP, FSS, and Medicaid rebate—to the 340B prices. Seven of the top 10 HIV/AIDS drugs—Combivir, Epivir, Norvir, Sustiva, Trizivir, Zerit, and Ziagen—had 2003 prices available for comparison under all five drug pricing programs. The price comparisons are indicated by rank, rather than by the drug prices, because the prices for the 340B, the 340B prime vendor, the FCP, and Medicaid are not public. (See table 10.)

[50]For purposes of this report, the Medicaid price is the average amount state Medicaid programs paid net of the basic rebate provided under the Medicaid Drug Rebate Program.

[51]The drugs were the top 10 drugs by expenditure that ADAPs purchased in 2002, the most current expenditure data available at the time of our analysis. The expenditures for these 10 drugs represented 73 percent of the total ADAP drug expenditures in 2002. The 10 drugs were Combivir, Viracept, Sustiva, Norvir, Zerit, Trizivir, Epivir, Ziagen, Viramune, and Viread. See appendix III for an explanation of our price comparison methodology.

[52]For purposes of this comparison, we have treated the 340B prime vendor as a separate drug pricing program since it may have different prices than the 340B prices for the same brand name drugs.

Table 10: Ranking of Top 10 HIV/AIDS Drugs from Lowest (1) to Highest (5) Unit Price Across Drug Programs; 2003

Top 10 HIV/AIDS drugs ranked by ADAP expenditure[a]	340B price	340B prime vendor price	Federal ceiling price	Federal supply schedule price	Medicaid price[b]
Combivir	3	2	1	5	4
Viracept	2	NPA	NPA	1	3
Sustiva	4	3	1	2	5
Norvir	1	4	2 (tied)	2 (tied)	5
Zerit	3	1	2	5	4
Trizivir	3	2	1	4	5
Epivir	3	2	1	5	4
Ziagen	3	2	1	5	4
Viramune	1	NPA	NPA	NPA	NPA
Viread	3	NPA	1	2	4

Sources: GAO analysis of HRSA, VA, and CMS data.

NPA = no price was available for the drug.

Notes: The unit price for a drug is the price for a unit of the dosage form and strength involved indicated by the National Drug Code (NDC). Each FDA-approved drug has at least one NDC which is a universal product identifier number for human drugs maintained by FDA. An NDC indicates a drug's manufacturer or distributor, a drug's strength, dosage form and formulation, and its package size. For the 10 drugs we used, we determined the NDC for each drug that was most commonly purchased by 52 ADAPs, and used the price for that NDC for our comparisons. For example, since Sustiva has more than one NDC, we chose the Sustiva NDC that was most commonly purchased by ADAPs to identify which of Sustiva's drug prices to use for our comparison. For a drug marked NPA, there was no price available using the NDC we identified under the drug pricing program. The available 2003 prices were for brand name drug prices. The comparisons are indicated by rank, rather than price, because only the FSS prices are publicly available.

[a]The drugs were the top 10 by ADAP drug expenditures for 2002, the most recent expenditure data available at the time of the analysis.

[b]The Medicaid price is the average amount state Medicaid programs paid net of the basic rebate provided under the Medicaid Drug Rebate Program.

We found that for six of the seven drugs that had prices available under all five programs—Combivir, Epivir, Sustiva, Trizivir, Zerit, and Ziagen—FCP and the 340B prime vendor prices were lower than 340B prices. The FSS price for one of the seven drugs—Sustiva—was lower than the 340B price. Although some drug prices under FCP and FSS were lower than the 340B prices, ADAPs do not have access by statute to these two federal drug

pricing programs.[53] The 340B price was the lowest for one of the seven drugs—Norvir. Medicaid prices were the highest of all the pricing programs for three of the seven drugs—Norvir, Sustiva, and Trizivir. (See table 10.)

Fuzeon is the only fusion inhibitor approved for individuals who have used other anti-HIV drugs, but still have ongoing HIV-viral replication. It was approved in 2003 by FDA, and was therefore not among the top 10 HIV/AIDS drugs by ADAP expenditures for 2002 that we included in our analysis. However, we compared the 2003 340B price for Fuzeon to prices under the other pricing programs included in our analysis. In comparing the 2003 Fuzeon prices under the five drug pricing programs, we found that Fuzeon's 340B price was higher than both the FCP and FSS prices, but lower than either the 340B prime vendor price or Medicaid price.

Changes in Drug Prices Varied Widely Among HIV/AIDS Drugs and Among Drug Pricing Programs

We found wide variability in the percentage change in unit price among the top 10 HIV/AIDS drugs and among the 340B, FCP, FSS, and Medicaid rebate pricing programs.[54] Because ADAPs provide drug coverage for eligible individuals over longer periods due to improved drug treatments, and increased life expectancy, the cost of HIV/AIDS drugs over time is an important concern for ADAPs. We analyzed the changes in the prices of the top 10 HIV/AIDS drugs under these programs by comparing the prices in 2000 to the prices in 2003. (See table 11.) From 2000 to 2003, all available prices for the top 10 HIV/AIDS drugs increased under the 340B, FCP, and FSS, except for Norvir which had a decrease in its 340B price.[55]

[53]The Institute of Medicine (IOM) and the HHS OIG have previously recommended allowing ADAPs to purchase HIV/AIDS drugs at FCP drug discount prices because those prices would be lower than the 340B prices. However, both the IOM and OIG also raised concerns about whether drug companies might be less willing to invest in HIV/AIDS drug research if they might experience revenue losses from providing lower drug prices to additional entities such as ADAPs. Institute of Medicine of the National Academies, *Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White* (Washington, D.C.: The National Academies Press, 2005, and the Department of Health and Human Services Office of Inspector General, *AIDS Drug Assistance Program Cost Containment Strategies* (Washington, D.C.: Department of Health and Human Services, 2000).

[54]The 340B prime vendor program was not included in this comparison because drug prices for 2000 were not available.

[55]In December 2003, Abbott Laboratories, the manufacturer of Norvir, a HIV/AIDS protease inhibitor, substantially increased the wholesale price per patient. In February 2004, Abbott Laboratories announced a permanent Norvir price freeze for ADAPs at the price in place prior to the December 2003 re-pricing.

During the same period, all available drug prices decreased under the Medicaid program.

Table 11: Percentage of Unit Price Increases or Decreases from 2000 to 2003 for Top 10 HIV/AIDS Drugs

Top 10 HIV/AIDS drugs ranked by expenditure[a]	340B price	Federal ceiling price	Federal supply schedule	Medicaid price[b]
Combivir	7.95	18.42	7.52	-5.94
Viracept	116.91	NPA	NPA	-1.56
Sustiva	16.60	1.93	1.78	-1.92
Norvir	-41.68	3.63	3.63	-13.77
Zerit	6.94	29.15	87.95	-11.66
Trizivir	NPA	NPA	NPA	-2.46
Epivir	7.90	24.84	7.53	-6.18
Ziagen	8.08	8.49	7.53	-5.48
Viramune	113.59	NPA	NPA	NPA
Viread	NPA	NPA	NPA	NPA

Sources: GAO analysis of HRSA, VA, and CMS data.

NPA = no price was available for the drug.

Notes: The unit price for a drug is the price for a unit of the dosage form and strength involved indicated by the National Drug Code (NDC). Each FDA-approved drug has at least one NDC which is a universal product identifier number for human drugs maintained by FDA. An NDC indicates a drug's manufacturer or distributor, a drug's strength, dosage form and formulation, and its package size. For the 10 drugs we used, we determined the NDC for each drug that was most commonly purchased by 52 ADAPs in 2003, and used the price for that NDC for our comparisons. For example, since Sustiva has more than one NDC, we chose the Sustiva NDC that was most commonly purchased by ADAPs to identify which of Sustiva's drug prices to use for our comparison. For a drug marked NPA, there was no price available using the NDC we identified under the drug pricing program for either 2000 or 2003 or both, so no calculations could be made. The available 2000 and 2003 prices were for brand name drug prices. No 2000 prices were available for the 340B prime vendor.

[a]The drugs were the top 10 by ADAP expenditures for 2002, the most recent expenditure data available at the time of the analysis.

[b]The Medicaid price is the average amount state Medicaid programs paid net of the basic rebate provided under the Medicaid Drug Rebate Program.

All four drug pricing programs had prices that we could compare for 6 of the 10 HIV/AIDS drugs—Combivir, Epivir, Norvir, Sustiva, Zerit, and Ziagen. Among the four programs, the price changes varied widely. Under both FCP and FSS, prices for the 6 drugs increased between 2000 and 2003. The FCP price increases ranged from 1.93 percent for Sustiva to 29.15 percent for Zerit. The FSS price increases ranged from 1.78 percent for Sustiva to 87.95 percent for Zerit. The FSS had the lowest percentage increase in price from 2000 to 2003 for four of the six drugs—Combivir,

Epivir, Sustiva, and Ziagen. Medicaid prices for all six drugs decreased with changes ranging from -13.77 percent for Zerit to -1.92 for Sustiva. The 340B prices increased for 5 of the 6 drugs—from 6.94 percent for Zerit to 16.60 percent for Sustiva, and decreased for 1 of the 6—Norvir—by -41.68 percent.

Among the same 6 HIV/AIDS drugs, the price increases and decreases varied widely among the drugs and by drug pricing program. For example, Combivir prices ranged from its highest price increase—FCP's 18.42 percent—to its only price decrease—Medicaid's -5.94 percent. Sustiva prices ranged from its highest price increase—340B's 16.60 percent—to its only price decrease—Medicaid's -1.92 percent. Norvir prices ranged from its only highest price increase—FCP's and FSS's 3.63 percent—to its lowest price decrease—340B's -41.68 percent. Zerit prices ranged from its highest price increase—FCP's 87.95 percent—to its only price decrease—Medicaid's -11.66 percent.

Conclusions

As the number of people with HIV/AIDS live longer due to improved drug treatments, the demand for ADAP services will increase, and expenditures by ADAPs for HIV/AIDS drugs will also likely increase. Therefore, it is important that ADAPs achieve the maximum benefit with the funds provided to them for drug purchases, and to do this, they have been given access to the 340B program. However, HRSA does not systematically and routinely determine whether ADAPs, particularly those using the 340B rebate option or those that have negotiated drug prices, are acquiring drugs at prices at or below the 340B prices. The HHS OIG has previously identified shortcomings in HRSA's oversight of the 340B program and recommended that HRSA verify manufacturers' calculations of 340B prices and monitor their compliance with program requirements; HRSA acknowledged the need to increase its oversight. HRSA also needs to determine whether ADAPs are purchasing drugs at prices at or below the 340B prices. While monitoring the prices paid for all the drugs on each ADAP's formulary might be challenging, as some formularies have as many as 1,000 drugs, HRSA could routinely compare ADAP reported prices to 340B prices for selected drugs. For instance, all antiretrovirals could be compared, which would include the top 10 drugs we used in our drug pricing analysis and which represented 73 percent of the total ADAP drug expenditures in 2002. Ensuring that the prices are reported on a schedule to allow for the rebate reconciliation could also help HRSA to better monitor the final prices paid for the drugs and to gauge whether ADAPs are achieving maximum results with their grant funds.

Recommendations for Executive Action

To ensure that ADAPs are obtaining the best prices for drugs they provide, we recommend that the Administrator of the Health Resources and Services Administration take the following two actions:

- require that all ADAPs report final prices they paid for drugs, and that those final prices reflect any discounts or rebates received.
- routinely determine whether the prices ADAPs paid for the drugs they purchased were at or below the 340B prices.

Agency Comments and Our Evaluation

HRSA provided written comments on a draft of this report. HRSA commented that the report highlights a key issue facing ADAPs and HRSA in administering the program, but the agency raised concerns about its ability to implement our recommendations. The comments are reprinted in appendix IV.

HRSA stated that it would like to verify final drug prices but this would be labor intensive because reports ADAPs currently provide do not contain the needed information. Specifically, HRSA noted that ADAPs may receive rebate checks many months after the drugs were purchased, which complicates the task of comparing prices. HRSA further stated that it is taking steps to develop the information it will require to determine whether the prices ADAPs paid for the drugs they purchased are at or below the 340B prices, but that it lacks the resources to conduct manual cost comparisons on a large scale. HRSA noted that it is making efforts to develop systems to allow ADAPs to check drug prices and that the agency has requested that drug manufacturers who participate in the 340B program voluntarily submit quarterly 340B prices on covered drugs to HRSA for comparison with the government computed 340B ceiling prices.

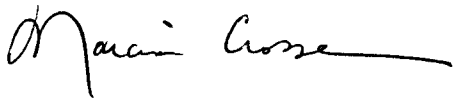
As we stated in the draft report, ADAPs' financial data submitted to HRSA contain information on the total expected rebate savings but not the rebate expected on the purchase of a specific drug, which is the information needed to make drug price comparisons to the 340B prices. While we recognize that monitoring the prices paid for all the drugs on each ADAP's formulary might be challenging, HRSA could compare ADAP reported prices to 340B prices for selected drugs and could modify its schedule of ADAP reports to allow for rebate reconciliation. For example, HRSA could compare ADAP reported prices to 340B prices for all antiretrovirals, which would include the top 10 drugs we used in our drug pricing analysis and which represented over 70 percent of the total ADAP drug expenditures in a year. HRSA indicated that a manual comparison would be required, but in conducting our analysis we created a computer

program that automatically compared information from the ADAP reports with the 340B prices, and HRSA could construct a similar cost-effective, automated process. Further, HRSA's plans to develop systems that allow ADAPs to check drug prices would be a useful tool in assisting the ADAPs to obtain the best prices, but would still not fulfill HRSA's responsibilities to oversee the programs to ensure compliance with the conditions of the grants. Given that we found ADAPs reported prices that were above the 340B prices, we believe that HRSA needs to take additional steps to monitor the program.

HRSA also provided technical comments, which we have incorporated where appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, the Administrator of Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and to interested congressional committees. We will also make copies available to others upon request. In addition, the report will be available on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7119 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.



Marcia Crosse
Director, Health Care

Appendix I: Prenatal HIV Testing and Perinatal HIV Transmission Rates within States

In 2000, approximately 6,000 to 7,000 women infected with the human immunodeficiency virus (HIV), gave birth in the United States and an estimated 280 to 370 HIV-infected infants were born, according to the Centers for Disease Control and Prevention (CDC). When pregnant women are infected with HIV, they can transmit the virus to their infants during pregnancy, during labor and delivery, or after delivery through breast feeding. Antiretroviral therapy can reduce the risk of HIV transmission from mother to child. According to CDC, the prevention of perinatal HIV transmission depends on routine testing of pregnant women for HIV and the use of antiretroviral drug treatment and obstetrical interventions. This appendix provides information on prenatal HIV testing and perinatal HIV transmission rates in certain states with and without mandatory HIV testing of newborns.

Background

In 1994, a pediatric acquired immunodeficiency syndrome (AIDS) clinical trials study group demonstrated that the risk of HIV transmission from mother to child could be reduced by nearly 70 percent if the antiretroviral drug, zidovudine, is administered to the mother during pregnancy, during labor and delivery, and to the baby after birth.[1] In 1995, as a result of these findings, CDC issued guidelines calling for universal counseling of pregnant women about the risk of AIDS and the benefits of HIV testing. The guidelines recommended voluntary testing of all pregnant women and providing information about antiretroviral treatment for those women testing positive.[2] In 1999, the Institute of Medicine (IOM) issued a report on preventing perinatal transmission of HIV.[3] The report described factors that lead to perinatal transmission including the lack of prenatal HIV testing and antiretroviral therapy for HIV-infected women and HIV-exposed infants. IOM recommended that the U.S. adopt a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care. Subsequent to this recommendation, in its 2001 revised guidelines, CDC endorsed universal HIV testing as a routine part of

[1]E.M. Connor et al. "Reduction of Maternal-Infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment," *The New England Journal of Medicine*, 331, 1173-80 (1994).

[2]Department of Health and Human Services, Centers for Disease Control and Prevention, "U.S. Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women," *Morbidity and Mortality Weekly Report*, vol. 44 (1995).

[3]Institute of Medicine, "Reducing the Odds: Preventing Perinatal Transmissions of HIV in the United States," (National Academy Press, Washington, D.C.: 1999).

prenatal care. Under CDC's prenatal HIV testing guidelines women would have the right to refuse HIV testing, and CDC makes it clear that existing state laws must be followed. In 2005, the U.S. Preventive Services Task Force recommended that clinicians screen all pregnant women for HIV.[4]

Prenatal HIV Testing Encouraged to Reduce HIV Perinatal Transmission

All 50 states, the District of Columbia, and Puerto Rico have policies or have enacted laws regarding HIV testing of pregnant women to help reduce perinatal HIV transmission. The majority of states have adopted a policy of voluntary testing of pregnant women that is consistent with CDC's guidelines. The eight states we contacted—California, Connecticut, Illinois, Louisiana, Michigan, New Jersey, New York, and North Carolina—use two approaches to testing pregnant women. Three states routinely include HIV tests in a standard battery of prenatal testing but a woman can refuse to be tested for HIV. In the other five states, a woman is counseled during prenatal care and must consent to an HIV test, usually in writing. Few states collect the data needed to determine statewide perinatal HIV transmission rates. Six of the eight states we contacted, however, reported that the number of HIV-positive newborns declined in their state from 1997 to 2002.

States Encourage Prenatal Testing of Pregnant Women to Help Reduce Perinatal HIV Transmission

All 50 states, the District of Columbia, and Puerto Rico have policies or have enacted laws regarding HIV testing of pregnant women to help reduce perinatal HIV transmission, and most are consistent with CDC's guidelines. CDC guidelines recommend HIV counseling and voluntary testing for all pregnant women and support a woman's right to refuse testing. According to a 2004 report on state approaches to HIV testing for mothers and newborns, most states, the District of Columbia, and Puerto Rico rely on voluntary HIV testing that follows CDC guidelines.[5] All eight states in our review require providers to give, or at least offer, pregnant women HIV counseling or information related to testing. Seven of the eight states have specific requirements that providers offer or perform HIV tests

[4]The United States Preventive Services Task Force is a source of recommendations and guidelines for screening tests, counseling, immunizations, and use of medications for disease prevention. It is composed of medical experts and sponsored by the Department of Health and Human Services' Agency for Healthcare Research and Quality.

[5]The Henry J. Kaiser Family Foundation State Health Facts Online, "50 State Comparisons: HIV Testing for Mothers and Newborns, 2004." http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=HIV%2fAIDS&subcategory=HIV+Testing&topic=HIV+Testing+for+Mothers+and+Newborns> (downloaded Jan. 19, 2006).

on pregnant women, but performing the test is contingent on obtaining informed consent.[6]

Allowing pregnant women to opt-out of HIV testing is the approach to HIV testing that CDC recommends. Under this approach, pregnant women are notified that an HIV test is routinely included in the standard battery of prenatal tests for all pregnant women, but they can decline HIV testing. Officials from three of the eight states we contacted—California, North Carolina, and Michigan—said that their states use an opt-out approach. Officials from the remaining five states—Connecticut, Illinois, Louisiana, New Jersey, and New York—said their states use the opt-in approach. Under this approach, pregnant women typically receive HIV counseling during prenatal care but must specifically consent to an HIV antibody test, usually in writing. Connecticut and New York supplement the opt-in approach with mandatory newborn HIV testing requirements. CDC has stated that the opt-in approach is associated with lower testing rates than either the opt-out or the mandatory newborn HIV testing approach.[7]

Connecticut and New York have enacted laws that require HIV testing of newborns. Under Connecticut's newborn testing law enacted in 1999, HIV testing must be offered to pregnant women and newborn testing is mandatory if the pregnant woman refuses to be tested.[8] Under New York's newborn testing law enacted in 1997, newborns are required to be tested for HIV, regardless of whether the mother's HIV status is known. The testing is done with or without the mother's consent. Officials from Connecticut and New York told us that their mandatory newborn testing laws resulted in an increase in the number of pregnant women who were tested for HIV. A Connecticut official stated that the rate of HIV testing of pregnant women before the state's mandatory testing law passed was about 25 percent and since the law was enacted, the state's testing rate has increased to 90 percent or more. Similarly, New York officials told us that prenatal HIV testing has increased. Data on New York prenatal testing

[6]Officials in the remaining state, Louisiana, said that in all of their perinatal prevention efforts with providers they emphasize routine offering of HIV tests as the standard of care supported by federal guidelines.

[7]Centers for Disease Control and Prevention, "HIV Testing Among Pregnant Women—United States and Canada, 1998-2001", *Morbidity and Mortality Weekly Report*, vol. 51, no. 45 (2002).

[8]This mandatory testing requirement does not apply when parents object based on conflicts with their religious tenets and practice.

show that the prenatal HIV testing rate had increased from 64 percent in 1997 to 95 percent in 2003.

Few States We Contacted Collect the Data Needed to Determine Statewide Perinatal HIV Transmission Rates

Less than half of the states we contacted collected data sufficient to calculate a statewide perinatal HIV transmission rate in 2002.[9] Of the eight states we contacted, three—Connecticut, New Jersey, and New York—reported data sufficient to calculate their statewide perinatal HIV transmission rate for 2002. The 2002 perinatal HIV transmission rates for these states were 0.0 percent, 3.0 percent, and 3.1 percent, respectively. One state, New Jersey, reported sufficient data that showed its perinatal HIV transmission rate declined from 13.3 percent in 1997 to 3.0 percent in 2002. The perinatal transmission rates calculated for different states may not be directly comparable because of variations in the specific procedures used to collect or categorize the data. For example, while New York includes newborns who have had a single positive test for HIV in its count of HIV-positive newborns along with those newborns whose HIV-positive status has been confirmed by a second test, other states may use different approaches to collecting data.

Although data collected by most of the states we contacted were not sufficient to calculate statewide perinatal HIV transmission rates, some states collected information on the number of HIV-positive newborns for the 2 years we inquired about. Six of the eight states we contacted—California, Connecticut, Michigan, North Carolina, New Jersey, and New York—reported that the number of HIV-positive newborns declined in their state in 2002 compared to 1997. Louisiana reported an increase in the number of HIV-positive newborns in 2002 compared to 1997. Louisiana officials said that the number of newborns with HIV in 1997 was unusually low. The change in the number of HIV-positive newborns from 1997 to 2002 was not reported by the remaining state—Illinois—because the data on HIV-positive newborns were not available for 1997.

[9]Perinatal transmission rate is defined as the frequency with which newborns contract HIV through exposure by pregnant women immediately preceding, during, or immediately following birth. We calculated statewide perinatal HIV transmission rates by dividing the number of newborns that tested positive for HIV by the number of live births to pregnant women that tested HIV-positive.

Appendix II: State Approaches to Identifying and Notifying Partners of HIV-Infected Individuals of Possible HIV Exposure

Research suggests that most new HIV infections originate from HIV-infected persons not yet aware of their infection.[1] This emphasizes the need to identify HIV-infected persons and link them with appropriate services as soon as possible. The Ryan White CARE Act Amendments of 1996 provided for states to take action to require a good faith effort be made to notify spouses who may have been exposed to HIV.[2] Partner counseling and referral services (PCRS) assist HIV-infected persons with notifying their partners, including spouses, of their exposure to HIV.[3] This appendix provides information on state approaches to identifying and notifying partners of HIV-infected individuals of possible HIV exposure.

Background

In 1996, legislation amending the CARE Act also prohibited CARE Act grants to any state that did not take administrative or legislative action to require that a good faith effort be made to notify the spouse of an HIV-infected individual that he or she may have been exposed to HIV and should seek testing. CDC, in coordination with the Health Resources and Services Administration (HRSA), took the lead in determining state compliance with the requirement. In December 1996, CDC asked the states to certify compliance with the spousal notification requirement and to submit a summary of additional actions taken or planned for assuring that a good faith effort is made to notify spouses of a known HIV-infected person. Because states had been administering partner notification programs that included spouses for years, particularly programs for syphilis and other sexually transmitted diseases (STD), the actions states certified were both ongoing efforts and additions to their PCRS programs that were designed to specifically address the spousal notification

[1]G. Marks, N. Crepaz, J. W. Senterfitt, and R. S. Janssen, "United States: Meta-Analysis of High-Risk Sexual Behavior in Persons Aware and Unaware They Are Infected with HIV in the United States," *Journal of Acquired Immune Deficiency Syndromes*, vol. 39, no. 4 (2005).

[2]Pub. L. No. 104-146, § 8, 110 Stat. 1346, 1372 (codified at 42 U.S.C. § 300ff-27a (2000)). The statute defines a spouse as "any individual who is the married partner of an HIV-infected patient, or who has been the married partner of that patient at any time within the 10-year period prior to the diagnosis of HIV infection."

[3]CDC's PCRS guidance for HIV defines PCRS as a prevention activity with the goals of (1) providing services to HIV-infected persons and their sex and needle-sharing partners so they can avoid infection or prevent transmission to others, and (2) helping partners gain earlier access to individualized counseling, HIV testing, medical evaluation, treatment, and other prevention services.

requirements. In 1997, CDC approved the certifications of compliance submitted by all states, the District of Columbia, and five territories.[4]

In August 1999, the Department of Health and Human Services' (HHS) Office of Inspector General issued a report on state implementation of their CDC-approved plans for the spousal notification requirement.[5] The HHS Inspector General reported that all 11 sampled states had followed up on the actions reported to and approved by CDC for compliance with the spousal notification requirement. For example, states were revising training materials, revising counseling guidelines, and retraining counselors based on the spousal notification requirement. Also, several states were undertaking promising notification efforts, according to the report. The HHS Inspector General recommended that states make additional efforts to ensure maximum notification while ensuring confidentiality.

States Use Various Approaches to Elicit Information and Notify Partners of Possible HIV Exposure

We contacted 12 states to determine what approaches they use to identify and notify partners of HIV-infected individuals.[6] These 12 states said they use various approaches in conducting HIV partner notification activities as part of their PCRS programs. These activities include eliciting partner information from known HIV-infected individuals—referred to as index cases[7]—and notifying the partners of their possible exposure to the virus. The states use a variety of entities and individuals trained to conduct these activities. Of the 12 states we contacted, 10 have statutory or regulatory provisions that require or permit certain health care entities or workers to notify partners without the consent of the index case. Some states reported integrating their HIV activities with established programs that are focused on syphilis and other STDs.

[4]The five territories included Guam, the Northern Mariana Islands, the Republic of Palau, the Commonwealth of Puerto Rico, and the Virgin Islands.

[5]Department of Health and Human Services Office of Inspector General, *The Ryan White CARE Act: Implementation of the Spousal Notification Requirement* (Washington, D.C.: Department of Health and Human Services, 1999).

[6]The 12 states we contacted were California, Connecticut, Florida, Kentucky, Massachusetts, Minnesota, Missouri, New York, North Carolina, Pennsylvania, Texas, and Washington.

[7]Index case is a generic term for a person who has tested positive for HIV and is asked to name spouses and partners at the start of the notification process.

States Conduct HIV Partner Notification Activities Using a Variety of Trained Workers

Officials from all 12 states we contacted reported having PCRS programs that include eliciting information about the partners of individuals known to be infected with HIV, notifying the partners of their possible exposure to the virus, and providing the partners with counseling and testing services. Officials in all 12 states said that they use public health care workers known as disease intervention specialists for conducting partner notification activities.[8] Four states also use physicians; three states use community-based organizations; one state uses staff at counseling and testing sites; and one state uses staff working in jails to help conduct partner notification activities.

Officials from all 12 states told us that the state provides training for the individuals who conduct partner notification activities for their PCRS programs. These individuals are trained to use various techniques for eliciting information from index cases, their partners, and their social associates, and for notifying partners of their possible exposure to HIV or other communicable diseases. Officials from all 12 states said they provide CDC-developed training and other training for disease intervention specialists.[9] In addition, some state officials said they provide training to other groups that are involved in PCRS. For example, New York officials said that the state department of health conducts PCRS training with a variety of groups, including community-based organizations and staff working in jails, to improve their skills in eliciting information about partners. Massachusetts officials told us that they were training community-based organization staff in how to elicit partner information and notify exposed partners in an effort to integrate them into prevention services, and California officials said that they were training staff working at community-based organizations and disease counseling and testing sites.

[8]Disease intervention specialists interview patients, at-risk individuals, and those infected with STDs (including HIV), and ensure appropriate examination, treatment, and follow-up to persons exposed or infected with an STD. Pennsylvania uses its field staff to perform duties similar to those of disease intervention specialists in other states. In this report, we refer to these Pennsylvania field staff as disease intervention specialists.

[9]CDC training includes courses such as Introduction to STD Intervention, Fundamentals of STD Intervention, and HIV Partner Counseling and Referral Services.

States Primarily Use Interviews to Identify Partners and Various Methods to Notify Them of Their Possible Exposure to HIV

Generally, all 12 states use similar methods to obtain identifying information about partners of persons known to be infected with HIV and notifying the partners of their possible exposure to the virus. The states elicit information about HIV-exposed partners primarily through interviewing the index cases about their direct sex and needle-sharing partners. Some states also use interviews and a technique called clustering to identify social associates of the index case that may be at risk of exposure to HIV. In clustering, states may try to obtain information about things such as buildings where drug use occurs or other venues frequented by HIV-infected individuals. Because participation in PCRS is voluntary, some index cases may opt not to participate and may not provide information about their partners and other contacts. For example, New York officials we contacted said that the proportion of HIV index cases that do not provide partner identifying information is quite high. They do not know what percent of index cases refuse to divulge the information versus the health care provider's failure to ask or record the information. In 2003, New York City health care providers submitted 5,213 reports to the city's HIV Epidemiology Program that were completed on patients with a new diagnosis of HIV. Seventy-five percent of the reports did not list a partner of the newly diagnosed HIV-positive patients.

Once partners are identified, states primarily use three CDC-suggested methods to notify them of their possible exposure to HIV.[10] These methods are (1) client self-referral, in which index cases notify partners, (2) contract referral, in which a time frame is negotiated and agreed to with index cases for them to notify partners, and (3) provider referral, in which the health care provider or health department conducts the follow-up with partners.

In all 12 states we contacted, index cases retain the option of notifying their partners that they have exposed them to HIV. Although they have this option, index cases may prefer to receive assistance from individuals trained in partner notification. For example, North Carolina officials said that most index cases prefer to have trained disease intervention specialists do the notification on their behalf because of concerns with confronting their partners about their HIV infection and having exposed them to the virus. When index cases opt to notify their partners, it is

[10]Centers for Disease Control and Prevention, *Program Operations Guidelines for STD Prevention: Partner Services* (Atlanta, Ga.: Centers for Disease Control and Prevention, 2001).

difficult for the health department to track whether partners indeed have been notified. Eight of the 12 states negotiate agreements with index cases that include, for example, that index cases will notify their partners by a certain date or the state may notify the partners. In Connecticut, such agreements are in writing and outline how partners will be informed, how it will be confirmed that partners were notified, and what follow-up is required when partner counseling and referral services are not provided.

In all 12 states, health care providers or workers may notify partners. With this CDC-suggested method, index cases request provider assistance with partner notification and may give the provider identifying information such as addresses and phone numbers to follow-up with their partners. Research suggests that the use of health care providers or workers is more effective than the index cases notifying partners of their possible exposure to HIV.[11]

Of the 12 states we contacted that conduct partner notifications, 10 have statutory or regulatory provisions that require or permit certain health care workers or entities, such as physicians and health departments, to notify partners, including spouses, of their possible exposure to HIV without the consent of the index case.[12] In New York, North Carolina, and Texas, statutory or regulatory provisions require that public health officials or health departments notify partners, including spouses,[13] of their possible exposure to HIV. In California, Connecticut, Florida, Kentucky, Missouri, New York, Pennsylvania, and Washington the provisions permit health care providers, public health officials, or health departments to notify partners, including spouses, of their possible exposure to HIV.[14] In California where physicians are permitted to notify partners, a California

[11]Suzanne E. Landis et al., "Results of a Randomized Trial of Partner Notification in Cases of HIV Infection in North Carolina," *The New England Journal of Medicine*, vol. 326, no. 2, 101-106 (1992). Beth A. Macke and Julie E. Maher, "Partner Notification in the United States: An Evidence-Based Review," *American Journal of Preventive Medicine*, vol. 17, no. 3, 230-242, (1999).

[12]In some of these states, physicians or health departments may notify partners only when certain conditions are met, such as when the index case has been advised to notify partners but refuses. Some states have provisions also permitting parties other than health care providers or health departments to notify partners.

[13]The North Carolina provision applies only to notification of spouses; state officials told us that they generally notify partners with the consent of the index case.

[14]One New York provision requires public health officials to notify partners; another permits physicians to notify partners.

official told us that the health department is trying to get physicians more involved in partner notification but said that generally physicians do not have the time or staff to conduct the notifications. In the remaining 2 states—Massachusetts and Minnesota—public health officials or health departments may notify partners, including spouses, only with the consent of the index case. Moreover, Massachusetts has an HIV-specific confidentiality provision that explicitly prohibits health care providers and facilities from disclosing an individual's name or HIV test results without the individual's written informed consent. Massachusetts officials said that they believe the number of partners notified is lower in states with strict confidentiality laws compared to states without strict laws.

Some states use the Internet as a tool for contacting and notifying partners of known HIV-infected individuals. A California official told us that the Internet provides a new opportunity to facilitate partner notification. Officials from Minnesota, Missouri, Pennsylvania, and Texas said they obtain information, such as Web site addresses and associated chat rooms that partners use, partners' screen names, and e-mail addresses, from index cases and use the Internet to initiate contact and send messages to partners. Officials from three states expressed concern about using the Internet and visiting certain Web sites to contact partners because of confidentiality concerns or provisions that prohibit employees from visiting sexually-oriented sites. The extent to which states use the Internet for HIV partner notification varies. For example, Kentucky, New York, and Washington State officials said that their use of the Internet is limited to certain geographic areas within the state.

After partners are contacted and notified about their possible exposure to HIV, they are usually counseled about HIV and offered testing. CDC guidelines state that counseling should consist of providing a description of the ways in which HIV is transmitted, the importance of obtaining test results, the meaning of HIV test results, and ways to prevent future exposure to HIV. Officials from all 12 states we contacted said that disease intervention specialists that notify partners of their possible exposure to a communicable disease encourage them to get tested. Officials from these states said that when partners have been exposed to more than one communicable disease, such as syphilis and HIV, they will encourage partners to get tested for both diseases. Officials in California and Connecticut told us that when index cases are co-infected and want health department assistance with informing their partners about possible exposure to syphilis but not HIV, the partners will not be told about their exposure to HIV. Instead, the partners may be told that the risk behavior

that exposed them to syphilis may have also exposed them to HIV and that getting tested for both is recommended.

The participation of HIV index cases and partners in PCRS program activities varies among the states. As previously mentioned, participation in state PCRS is voluntary. New York officials told us that the number of index cases that do not provide partner identifying information is quite high, but they do not know what percentage of index cases refuse to divulge this information. Pennsylvania Department of Health officials told us that in 2004, there were over 300 HIV-positive cases in the state, and that 89, or less than one-third, used PCRS. A California state official told us that because the state does not use name-based reporting of individuals diagnosed with HIV, the state is not able to track those who received partner services and how many actually got tested. PCRS data collected by CDC show wide variability in elicitation and notification activities among states. Among 10 of the 12 states in our review,[15] CDC data for 2002 show that the percentage of index cases interviewed for PCRS ranged from about 46 percent to 100 percent. Similarly, the percentage of partners elicited who were located and notified ranged from about 42 percent to 83 percent. Among partners who were located and notified, about 89 percent received counseling, and approximately 90 percent of partners who were counseled were then tested for HIV.

Seven States Have Integrated HIV and STD Partner Notification Activities and Training

Health officials from 7 of the 12 states we contacted said they have combined certain activities in their HIV and STD programs to facilitate partner notification. In these 7 states, staff that conduct partner notification are trained in notifying partners of their exposure to HIV and other STDs. For example, Texas state public health officials said that their PCRS program integrates HIV and STD activities. They said a large percentage of their HIV cases are also infected with syphilis, and disease intervention specialists that are trained in all STDs can notify partners of their exposure regardless of the disease. In Texas, local health departments that have separate HIV and STD units have been encouraged to consolidate their efforts. Florida officials said that information from a syphilis outbreak among men who have sex with men shows that in 2004, 28 percent of these men were infected with HIV at the time they were

[15]CDC's 2002 PCRS data did not include data from Massachusetts and Missouri. CDC told us that Massachusetts did not use its CDC HIV prevention funds for PCRS so it was not required to report PCRS data. Missouri's data did not pass CDC's reliability tests.

diagnosed with syphilis. These officials said that from a resource standpoint, it does not make sense to have one person notify partners about their exposure to HIV and another person notify them about syphilis. Florida maximizes its resources by using the same staff to conduct all STD notifications. North Carolina health officials told us that their HIV and STD programs are totally integrated because it is hard to separate HIV and STD prevention efforts. North Carolina disease intervention specialists are trained in all STDs and can notify partners of their exposure to HIV and other STDs. Washington officials said that some, but not all, of their STD and HIV programs are integrated. In some jurisdictions the programs are divided while in others the staff is shared. They said that small health departments are more integrated because they cannot afford to have separate staff doing partner notification for the different diseases.

Appendix III: Scope and Methodology

The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act) authorized grants to states, territories, and metropolitan areas to provide health care, medications, and support services to individuals and families affected by AIDS. The CARE Act Amendments of 1996 authorized AIDS Drug Assistance Program (ADAP) grants for states, including the District of Columbia, and certain territories specifically to operate their own ADAPs to purchase and provide HIV/AIDS medications to eligible individuals. We examined how program design and funding sources contributed to differences in coverage—who and what is covered—among ADAPs, how the prices ADAPs reported paying for HIV/AIDS drugs compare to prices under the 340B program, how HRSA monitors the drug prices ADAPs pay, and how the 340B prices compare to selected other federal drug pricing programs. We also developed information on state prenatal HIV testing and perinatal HIV transmission rates and state approaches to identifying and notifying partners of HIV-infected individuals of possible exposure to HIV.

ADAP Coverage Differences Analysis

To determine how program design and funding sources contributed to the coverage differences among 52 ADAPs in the states—including the District of Columbia—and Puerto Rico, we reviewed and summarized program eligibility criteria, including enrollment limitations, and funding sources available to ADAPs, including and in addition to the CARE Act ADAP base grants. We obtained data from ADAP profile reports submitted to HRSA by 52 ADAPs and analyzed the ADAP grant year 2004 data covering the period April 1, 2004, through March 31, 2005. We did not verify the data reported by ADAPs. In our analysis of funding sources available to ADAPs, we determined the total amount of additional funding each ADAP reported for fiscal year 2004, and calculated the percentage that this total represented of each ADAP's fiscal year 2004 base grant. The percentages were then compared among the ADAPs to show which programs had more or less additional funding than their ADAP base grants. We also determined for each ADAP how much the total additional ADAP funding represented on a per estimated living AIDS case (ELC) basis.[1]

[1]HRSA calculates a jurisdiction's ELCs using data from CDC on the reported AIDS case counts for the last 10 years and weights those numbers to account for the likelihood of deaths. See also GAO, *HIV/AIDS: Changes Needed to Improve the Distribution of Ryan White CARE Act and Housing Funds*, GAO-06-332 (Washington, D.C.: Feb. 28, 2006) for a discussion of ELCs.

To examine coverage for ADAPs with waiting lists, we used HRSA ADAP waiting list data for fiscal year 2004. When an ADAP has more eligible individuals than it has funds to provide services and cannot cover everyone it determines is eligible for its services, it may establish a waiting list. We determined that the available data were not reliable to establish the number of unduplicated individuals on waiting lists during a year or the length of time an individual was on a waiting list before being served by the ADAP, but this data were sufficiently reliable to indicate whether or not a waiting list existed and what were the average number of individuals on lists.

ADAP HIV/AIDS Drug Pricing Analysis

For our ADAP drug pricing analysis, we used the top 10 HIV/AIDS drugs by expenditure among those purchased by ADAPs in 2002, the most current expenditure data available at the time of our review. The expenditures for these 10 drugs represented 73 percent of total ADAP drug expenditures in 2002. The 10 drugs were Combivir, Epivir, Norvir, Viracept, Sustiva, Trizivir, Viramune, Viread, Zerit, and Ziagen; these drugs are all brand name drugs.

We used the purchase prices for these 10 drugs that 52 ADAPs provided on their quarterly drug pricing reports submitted to HRSA for 2003—the most recent full calendar year of ADAP drug price data available at the time of our analysis. ADAPs report the following data to HRSA for the drugs they purchase: (a) the drug by national drug code (NDC);[2] (b) the quantity for a 30-day supply by units; (c) the unit price; (d) the total cost of the drug (the quantity by units multiplied by the unit price); (e) the dispensing fee; and (f) the gross price (the total cost of the drug plus the dispensing fee).

To determine how the prices an ADAP reported it paid compared to the 340B price for any of the top 10 drugs it purchased in 2003, we compared each ADAP's 2003 average price over the four quarters to the 2003 340B price for the same drug. For each of the 10 drugs they purchased, each ADAP also reported that drug's NDC identifier. Because all ADAPs did not purchase the same version of the same drug, we used the NDCs each ADAP reported to determine which drug's price to compare to the 340B price. We then categorized the ADAPs by those using the 340B direct

[2]Each drug approved by the Food and Drug Administration has at least one national drug code (NDC) which is a universal product identifier number for a human drug. An NDC indicates a drug's manufacturer or distributor, a drug's strength, dosage form and formulation, and its package size and types.

option, and those using the 340B rebate option, and determined how many drugs they reported at prices above the 340B prices. ADAPs that use the 340B rebate option reported to HRSA the drug prices that they paid which may not reflect the drug rebate amount they may later have received from a drug manufacturer.

To determine how the 340B prices for some HIV/AIDS drugs compared to prices available through selected federal drug pricing programs, we compared prices for the top 10 drugs across five federal drug pricing programs. We used the 2003 prices[3] from the following federal drug pricing programs to make price comparisons: (a) the 340B prices provided by HRSA's Office of Pharmacy Affairs; (b) the 340B prime vendor negotiated prices provided by HRSA's Office of Pharmacy Affairs;[4] (c) federal supply schedule (FSS) prices provided by the Department of Veterans Affairs (VA) Pharmacy Benefits Management; (d) the federal ceiling prices (FCP) provided by the VA Pharmacy Benefits Management; and (e) Medicaid prices[5] that we calculated using publicly available pricing data and rebate data provided by the Centers for Medicare & Medicaid Services (CMS). Because a drug may have more than one NDC, ADAPs did not always report the same NDC for the same drug they purchased. For each of the 10 drugs, we determined the NDC that was most commonly purchased by 52 ADAPs during 2003.[6] We used the 10 most commonly purchased NDCs in 2003 for the price comparisons we did among the five federal drug pricing programs. However, the 340B prime vendor, the FSS, the FCP, and Medicaid did not have prices for all 10 drugs. In addition some federal drug pricing programs did not have a price for a particular common NDC

[3]The 2003 price data were the most recent data available at the time of our review.

[4]We treated the 340B prime vendor as a separate drug pricing program for price comparison purposes. Section 340B of the Public Health Service Act required the Secretary of Health and Human Services to establish a prime vendor program for 340B covered entities. 42 U.S.C. § 256(a)(8) (2000). Because the prime vendor negotiates its own prices, it can have different prices than the 340B prices for the same drugs.

[5]For purposes of this report, the Medicaid price is the average amount state Medicaid programs paid net of the basic rebate provided under the Medicaid Drug Rebate Program.

[6]For the 10 drugs we used, we determined which NDC for each drug that was most commonly purchased by 52 ADAPs, and used the price for that NDC for our comparisons. For example, since Sustiva has more than one NDC, we chose the Sustiva NDC that was most commonly purchased by ADAPs to identify which of Sustiva's drug prices to use for our comparison.

that could be used to compare prices across federal pricing programs.[7] Although we had the drug prices from all the federal drug pricing programs, only the FSS prices are publicly available. To prevent the possible calculation of a non-public drug price, we used rankings to indicate which drug pricing program had the lower prices for the drugs. We ranked a drug "1" under a particular drug pricing program when that program had the drug's lowest price for the drug across the drug pricing programs. We ranked a drug "5" when that program had the drug's highest price for the drug across the drug pricing programs.

To determine whether the five federal drug pricing programs had price increases or decreases over time for the 10 drugs, we compared the prices in 2000 to the prices in 2003 for the ADAPs' most commonly purchased NDC for each drug in 2003 across the federal drug pricing programs. When a federal drug pricing program was missing a price for either 2000 or 2003 or both, no price comparison could be made. No price comparisons could be made for the 340 prime vendor prices because no 2000 drug price data were available. Some of the drug prices are not publicly available, so we reported only the drugs' percent of price increase or decrease so that a specific drug's price could not be determined.

To assess the reliability of the drug pricing data from HRSA, VA, and CMS, we (1) reviewed existing documentation related to the data sources, and (2) electronically tested the data to identify any obvious problems with completeness or accuracy. We determined that the HIV/AIDS drug pricing data were sufficiently reliable for the purposes of this report.

Prenatal HIV Testing and Perinatal HIV Transmission

To develop information on state prenatal HIV testing and perinatal HIV transmission within states, we reviewed data on approaches that states use to test pregnant women and newborns for HIV and studies and reports by CDC, the Institute of Medicine, and various states related to prenatal testing for and perinatal transmission of HIV. We also requested prenatal HIV testing and perinatal HIV transmission data for 1997 and 2002,[8] from eight states—California, Connecticut, Illinois, Louisiana, Michigan, New Jersey, New York, and North Carolina, to determine their statewide

[7]Even if a drug discount program had no price available for the most commonly purchased NDC we used, it may have had prices for the same drug under a different NDC than we used.

[8]Data for 2002 were the latest available at the time of our initial data request.

perinatal transmission rates. These states were selected based on (1) their high cumulative numbers of HIV infections among children as of 2002; (2) variations in the type of approaches they followed for HIV testing of pregnant women; and (3) geographic location. In addition, we interviewed officials from each of the eight states' departments of health to discuss prenatal testing for HIV and perinatal HIV transmission within the states. We used a definition of perinatal transmission rate that describes the frequency with which newborns contract HIV through exposure by pregnant women immediately preceding, during, or immediately following birth. We calculated statewide perinatal HIV transmission rates by dividing the number of newborns that tested positive for HIV by the number of live births to pregnant women that tested HIV positive. The majority of the eight states did not have complete data on prenatal HIV testing and perinatal HIV transmissions for the 2 years we requested.

To assess the reliability of data the eight states collected and provided to us, we reviewed the data for accuracy and completeness and discussed the information with state officials. We determined that data limitations, such as incomplete information on live births to pregnant women who tested HIV-positive, precluded us from accurately calculating statewide perinatal transmission rates for five of the eight states. We therefore report such data only for Connecticut, New Jersey, and New York.

Partner Notification of HIV Exposure

To determine what approaches states are using to identify and notify partners of HIV-infected individuals, we reviewed reports related to partner notification programs; reviewed and analyzed data from CDC's 2002 PCRS database and states' Web sites; and contacted 12 states in 2004 and 2005.[9] Of the 12 states we contacted, seven—California, Florida, Massachusetts, Minnesota, New York, North Carolina, and Texas—were recommended by CDC and the National Alliance of State and Territorial AIDS Directors (NASTAD) because of their innovation in partner notification efforts. The other five states—Connecticut, Kentucky, Missouri, Pennsylvania, and Washington—were randomly selected. We interviewed officials from CDC, NASTAD, HRSA, and the 12 states.

[9]The 12 states that we contacted were California, Connecticut, Florida, Kentucky, Massachusetts, Minnesota, Missouri, New York, North Carolina, Pennsylvania, Texas, and Washington.

To assess the reliability of these data, we held discussions with CDC officials about the completeness and accuracy of the data in their databases and any limitations associated with the information. We also followed up with states about the accuracy of the data they provided. Based on our review of the data and discussions with CDC and state officials, we determined that CDC's 2002 PCRS data and the data states provided were sufficiently reliable for the purposes of this report.

We performed our work from June 2004 through April 2006, in accordance with generally accepted government auditing standards.

Appendix IV: Comments from the Health Resources and Services Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES Health Resources and Services Administration

Rockville, Maryland 20857

APR 20 2006

TO: Marcia Crosse
Director, Health Care
Government Accountability Office

FROM: Administrator

SUBJECT: Comments on Draft Report: "RYAN WHITE CARE ACT: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs" (Code # GAO-06-646)

Thank you for the opportunity to provide comments on the above subject draft report. Attached please find our comments.

Questions may be referred to Gail Lipton in HRSA's Office of Federal Assistance Management (OFAM) at (301) 443-6509.

Betty James Duke

Attachment

Department of Health and Human Service's Comments on the Government Accountability Office's Draft Report: "RYAN WHITE CARE ACT: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs" (Code # GAO-06-646)

The Department has reviewed the draft Government Accountability Office (GAO) report, titled: "RYAN WHITE CARE ACT: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs." The Department believes that the report has highlighted one of the key issues facing ADAPs and the administration of these programs both at the State level and within the Health Resources and Services Administration (HRSA).

GAO Recommendation:

To ensure that ADAPs are obtaining the best prices for drugs they provide, we recommend that the Administrator of HRSA take the following actions:

- Require that all ADAPs report final prices they paid for drugs, and that those final prices reflect any discounts or rebates received.

HRSA Response:

While HRSA would like to have the capacity to verify final prices after discounting rebates, a current obstacle as the GAO noted in its report on page 32: "...there is no reporting that reconciles the rebate savings an ADAP may receive against the price it pays." Further, acquiring this data and reconciling it would be a labor intensive task both on the part of ADAPs and HRSA staff.

HRSA staff have verified, through recent discussions with ADAPs, that rebates paid by the manufacturer after the drugs are purchased are not routinely itemized thus, making it difficult to conduct a comparison analysis. In addition, receipt of rebate checks can come many months after the drugs were purchased, further complicating a comparison of the price initially paid to determine the final price.

GAO Recommendation:

- Routinely determine whether the prices ADAPs paid for the drugs they purchased were at or below the 340B prices.

HRSA Response:

HRSA has taken several actions to develop both the information it will require and the internal resource capacity needed to properly analyze and report this data to ADAPs. In fiscal year (FY) 2005, HRSA instituted a new ADAP Quarterly Reporting (AQR) System (OMB approval # 0915-0294). As a requirement of the new system, ADAPs are required to report the prices they have paid for all medications on their formulary during the

quarter. In addition, the AQR also collects information on the type of additional funds including rebates that the ADAPs receive each quarter. The AQR was implemented with the FY 2005 grant year. This reporting system was designed to produce several reports that would be reviewed by HRSA to determine if ADAPs are purchasing medications at or below the 340B ceiling price. As the GAO Report notes, considerable resources within HRSA will be needed to conduct a comprehensive price comparison. HRSA does not have the resource capability to perform manual cost comparisons on a large scale.

The GAO Report also identifies problems associated with the current lack of 340B price transparency. The Office of the Inspector General (OIG) has advocated for increased 340B price transparency in a previous report (Deficiencies in the Oversight of the 340B Drug Pricing Program, OEI-05-02-00072). One suggestion proposed by OIG was to institute a password-protected web-based query function to allow entities to check the prices they paid against 340B ceiling prices, while still protecting the confidentiality of the manufacturers' data. Due to legally required confidentiality, HRSA cannot provide manufacturer's price data.

There are efforts within HRSA to develop systems that will allow entities to submit the prices paid for a market basket of products to assess the appropriateness of the aggregate drug prices paid. This is part of the President's FY 2007 budget. In the interim, HRSA requested in a letter dated December 30, 2005, that all pharmaceutical manufacturers who have signed 340B Pharmaceutical Pricing Agreements voluntarily submit quarterly 340B price files on covered outpatient drugs to HRSA. HRSA compares these manufacturer price files with Government-computed 340B ceiling prices. Computed prices are also compared with the major wholesale distributor price files. To the extent permitted by the manufacturers, these verified prices will be made available on the password-protected PV Web site.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7119 or crossem@gao.gov

Acknowledgements

In addition to the contact above, James McClyde, Assistant Director; Robert Copeland; Helen Desaulniers; Cathy Hamann; Martha Kelly; Daniel Ries; Opal Winebrenner; Craig Winslow; and Suzanne Worth made key contributions to this report.

Related GAO Products

HIV/AIDS: Changes Needed to Improve the Distribution of Ryan White CARE Act and Housing Funds. GAO-06-332. Washington, D.C.: February 28, 2006.

Ryan White CARE Act: Factors that Impact HIV and AIDS Funding and Client Coverage. GAO-05-841T. Washington, D.C.: June 23, 2005.

HIV/AIDS: Use of Ryan White CARE Act and Other Assistance Grant Funds. GAO/HEHS-00-54. Washington, D.C.: March 1, 2000.

HIV/AIDS Drugs: Funding Implications of New Combination Therapies for Federal and State Programs. GAO/HEHS-99-2. Washington, D.C.: October 14, 1998.

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