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Testimony

Before the Subcommittee on Federal Financial Management, Government Information, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

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# RYAN WHITE CARE ACT

## AIDS Drug Assistance Programs, Perinatal HIV Transmission, and Partner Notification

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Highlights of [GAO-06-681T](#), a testimony before the Subcommittee on Federal Financial Management, Government Information, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

## Why GAO Did This Study

Despite progress in HIV/AIDS drug treatments and the reduction of AIDS mortality in the United States, challenges remain concerning the availability of these drugs for individuals with HIV/AIDS and the prevention of new cases. The CARE Act authorizes grants to the states and certain territories specifically for AIDS Drug Assistance Programs (ADAP) to purchase and provide HIV/AIDS drugs to eligible individuals. In its report issued today, *Ryan White CARE Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs* ([GAO-06-646](#)), GAO examines the program design of ADAPs in the 50 states, the District of Columbia, and Puerto Rico, their funding sources, and drug purchasing. GAO also reports on state approaches to reducing perinatal HIV transmissions and identifying and notifying partners of HIV-infected individuals.

## What GAO Recommends

In its report, GAO recommends that HRSA require ADAPs to report the final prices they paid for drugs, net of any rebates, and that HRSA routinely determine whether these prices are at or below the 340B prices. In commenting on these recommendations, HRSA stated that these steps would be labor intensive and it lacks capacity to carry out such oversight.

[www.gao.gov/cgi-bin/getrpt?GAO-06-681T](http://www.gao.gov/cgi-bin/getrpt?GAO-06-681T).

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](mailto:crossem@gao.gov).

# RYAN WHITE CARE ACT

## AIDS Drug Assistance Programs, Perinatal HIV Transmission, and Partner Notification

### What GAO Found

Variation in ADAPs' program design and funding amounts from CARE Act grants and other funding sources contribute to differences in coverage—who is eligible and what drugs are covered by an ADAP—among the 52 ADAPs GAO reviewed. In order to make maximum use of the funding they receive, ADAPs are expected to secure the best price available for the drugs on their formularies. ADAPs may, but are not required to, purchase their drugs through the 340B federal drug pricing program, under which drug manufacturers provide discounts on certain drugs to covered entities. The Health Resources and Services Administration (HRSA) has identified the 340B prices as a measure of ADAPs' economical use of grant funds, but the Department of Health and Human Services does not disclose 340B prices to the ADAPs. GAO found that some ADAPs reported prices that were higher than the 340B prices for selected HIV/AIDS drugs. However, these reported prices may not have reflected any rebates ADAPs eventually received. While HRSA is responsible for monitoring whether ADAPs obtain the best prices available for drugs, it does not routinely compare the drug prices ADAPs report to 340B prices.

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 prenatal HIV testing of pregnant women that is consistent with guidelines issued by the Centers for Disease Control and Prevention (CDC). GAO contacted 8 states to discuss the approach they use to test pregnant women for HIV, and these states use one of two approaches. Consistent with additional CDC recommendations on testing, three states routinely include HIV tests in standard prenatal testing, but a woman can refuse to be tested for HIV. In the other 5 states, a woman must consent to an HIV test, usually in writing, before the test can be performed. Six of the 8 states GAO contacted report that the number of HIV-positive newborns has declined. However, only 3 states GAO contacted collect the data needed to determine statewide perinatal HIV transmission rates.

GAO contacted 12 states regarding their approaches to identifying partners of HIV-infected individuals and notifying them of their possible exposure to the virus. These states used various approaches in conducting HIV partner notification activities as part of their partner counseling and referral services. These activities include eliciting partner information from HIV-infected individuals, but the participation of these individuals varies and not all partners can be reached to be notified. Of the 12 states contacted, 10 have statutory or regulatory provisions that require or permit certain health care entities or workers to notify partners, including spouses, without the consent of the known HIV-infected individual. In the remaining two states, public health officials or the health department may notify partners only with the consent of the HIV-infected individual.

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the AIDS Drug Assistance Programs (ADAP) that receive funds under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act)<sup>1</sup> and to provide a summary of our report that we are releasing today entitled *Ryan White CARE Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs*, which was prepared at your and others' request.<sup>2</sup> The report discusses the program design of 52 ADAPs in the 50 states, the District of Columbia, and Puerto Rico, their funding sources, and drug purchasing. I will also discuss our examination of state prenatal HIV testing and perinatal HIV transmission rates, and state approaches to identifying and notifying partners of HIV-infected individuals.

The CARE Act authorizes ADAP base grants to the states and certain territories specifically for ADAPs to purchase and provide HIV/AIDS drugs to eligible individuals. 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. As more people with HIV/AIDS live longer due to improved drug treatments, particularly highly active antiretroviral therapy, the demand for ADAP services will increase, and expenditures by ADAPs for HIV/AIDS drugs will also likely increase. It is, therefore, important that ADAPs achieve the maximum benefit they can with the funds provided to them for drug purchases. ADAPs may purchase their drugs through the 340B federal drug pricing program, under which drug manufacturers provide discounts on certain drugs to covered entities.<sup>3</sup> Generally, ADAPs can purchase drugs through either the 340B direct purchasing option, where ADAPs receive the 340B price discount upfront, or through the 340B rebate option, where ADAPs later request a

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<sup>1</sup>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.

<sup>2</sup>[GAO-06-646](#) (Washington, D.C.: Apr. 26, 2006). We previously reported to you on Ryan White CARE Act funding; see 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).

<sup>3</sup>Under Section 340B of the Public Health Service Act, a 340B price, sometimes referred to as a 340B ceiling price, is established for each covered drug that entities purchase. 42 U.S.C. § 256b (2000). Covered entities include, for example, community health centers and hemophilia treatment centers.

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340B rebate from the drug manufacturers. The Health Resources and Services Administration (HRSA) administers CARE Act grants and is responsible for monitoring the prices ADAPs pay for drugs. HRSA has identified prices under the 340B federal drug pricing program as a measure of an ADAP's economical use of its grant funds.

In carrying out this work for our report, we interviewed HRSA and other officials, analyzed and compared data ADAPs reported on program design, funding, and drug prices paid, compared 340B drug prices to prices available under other federal drug pricing programs, and interviewed officials from selected states about prenatal HIV testing and partner notification. We performed our work in accordance with generally accepted government auditing standards. The report's appendix III provides a more detailed explanation of our scope and methodology.

In summary, we report that variation in ADAPs' program design and funding amounts contributed to differences in who and what was covered by each program, that some ADAPs reported prices that were higher than the 340B prices for selected HIV/AIDS drugs, that HRSA is not routinely comparing the drug prices ADAPs pay to 340B prices, and that 340B prices were higher for some selected drugs than the prices available under other federal drug pricing programs. However, these latter prices are not available to ADAPs, except for prices under one program to the District of Columbia ADAP. We also report that the majority of states have adopted a policy of voluntary prenatal HIV testing of pregnant women that is consistent with guidelines issued by the Centers for Disease Control and Prevention (CDC) for reducing perinatal transmission of HIV, and most of the 8 states we contacted reported that the number of HIV-positive newborns has declined. Further, among efforts to reduce the transmission of HIV, the 12 states we contacted used various approaches to conduct HIV partner notification activities as part of their partner counseling and referral programs, but cooperation of infected individuals varies.

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## ADAPs' Program Design and Additional Funding

Variation in ADAPs' program design and funding amounts from the CARE Act grants and other funding sources contributes to differences in coverage—who and what is covered by an ADAP. Because of the variation in program criteria, an individual eligible for ADAP services in one state may not be eligible for or receive the same ADAP services in another. ADAP income ceilings for individuals, program enrollment caps, and drug formularies vary considerably among ADAPs. 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

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for the 2004 grant year that ranged from 125 percent of the federal poverty level in North Carolina to 556 percent in Massachusetts. Sixteen ADAPs reported that they had 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.

The additional funding that some ADAPs reported receiving from sources other than the ADAP base grant, such as transfers from other CARE Act 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, in addition to receiving funds from the ADAP base grant of about \$89.6 million, the California ADAP received about \$123.5 million from other sources.

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## ADAPs' Reported HIV/AIDS Drug Prices

ADAPs are expected to use every means at their disposal to secure the best price available for the drugs on their formularies. ADAPs are eligible, if they so choose, to participate in the federal 340B drug pricing program. Generally, ADAPs can purchase drugs through either the 340B direct purchasing option or through the 340B rebate option. Drug manufacturers that participate in the 340B drug pricing program agree to sell drugs to 340B entities, including ADAPs that participate in the program, at prices no higher than 340B prices.

HRSA has identified the 340B prices as a measure of ADAPs' economical use of grant funds, whether ADAPs use the 340B program, including the 340B prime vendor—which negotiates prices directly with drug manufacturers for ADAPs using the 340B direct purchase option—or negotiate drug prices on their own with drug manufacturers. However, the Department of Health and Human Services does not disclose to the ADAPs or the 340B prime vendor what the 340B prices are that should not be exceeded—a situation which disadvantages both the prime vendor's and the ADAPs' negotiating positions.

In our analysis using the top 10 HIV/AIDS drugs by ADAP expenditures, we found that in 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 1 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

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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.

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## HRSA's Monitoring of ADAPs' Reported Drug Prices

Although HRSA is responsible for monitoring whether ADAPs obtain the best prices available for drugs, it does not routinely compare the drug prices ADAPs report to 340B prices. Further, the ADAP drug price information that HRSA currently uses to make its comparisons is not complete. The reported prices do not reflect the rebates eventually received by ADAPs using the 340B rebate option to purchase drugs. 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.

In the report we are releasing today, we are recommending that HRSA, to ensure that ADAPs are obtaining the best prices for the drugs they provide, require ADAPs to report the final prices they paid for drug purchases, net of rebates, and that HRSA routinely determine whether these prices are 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. As we stated in our report, however, while 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.

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## 340B Prices and Other Federal Drug Pricing Programs

We found that 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 federal supply schedule (FSS) and federal ceiling price (FCP) drug pricing programs.<sup>4</sup> Using the top 10 HIV/AIDS drugs by ADAP expenditures, we compared 2003 drug prices under the 340B prime vendor, FSS, FCP, and Medicaid 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 prices,<sup>5</sup> available to state Medicaid programs, were consistently higher than the 340B program prices and 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.

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## Prenatal HIV Testing and Perinatal HIV Transmission Rates

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. 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. We contacted eight states to discuss the approach they use to test pregnant women for HIV. The eight states we contacted—California, Connecticut, Illinois, Louisiana, Michigan, New Jersey, New York, and North Carolina—use two approaches. Consistent with additional CDC recommendations on testing, 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

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<sup>4</sup>The FSS has prices available to all federal government purchasers for the drugs listed on the schedule. The FCP is the maximum price that drug manufacturers can charge four agencies—the Department of Defense, the Department of Veterans Affairs, the Public Health Service, and the Coast Guard—for the brand-name drugs listed on the FSS, even if the FSS prices are higher. The District of Columbia ADAP has access to the FCP.

<sup>5</sup>The Medicaid price is the average amount state Medicaid programs paid net of the basic rebate provided under the Medicaid Drug Rebate Program.

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HIV test, usually in writing, before a test can be performed. Of the eight states that we contacted, three—Connecticut, New Jersey, and New York—collect the data needed to determine statewide perinatal HIV transmission rates. Six of the eight states we contacted reported that the number of HIV-positive newborns declined in their state from 1997 to 2002.

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## 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.<sup>6</sup> 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. Partner counseling and referral services (PCRS) assist HIV-infected persons with notifying their partners, including spouses, of their exposure to HIV.<sup>7</sup> We contacted 12 states to determine what approaches they use to identify and notify partners of HIV-infected individuals.<sup>8</sup> These states 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<sup>9</sup>—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, including spouses,<sup>10</sup> without the consent of the index case. In the

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<sup>6</sup>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).

<sup>7</sup>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.

<sup>8</sup>The 12 states we contacted were California, Connecticut, Florida, Kentucky, Massachusetts, Minnesota, Missouri, New York, North Carolina, Pennsylvania, Texas, and Washington.

<sup>9</sup>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.

<sup>10</sup>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.

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remaining two states, public health officials or the health department may notify partners only with the consent of the HIV-infected individual. The participation of HIV index cases in PCRS program activities varies. Not all HIV-infected individuals are willing to share the names of their partners and not all partners can be reached to be notified.

Some states reported integrating their HIV partner notification activities with established programs that are focused on syphilis and other sexually transmitted diseases, or STDs.

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Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions that you or other Members of the Subcommittee may have.

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## Contact and Acknowledgments

For future contacts regarding this testimony, please contact Marcia Crosse at (202) 512-7119 or at [crossem@gao.gov](mailto:crossem@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. 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 statement.

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