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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.