

**Memorandum**

Date JAN - 2 1998
From June Gibbs Brown
Inspector General *June G Brown*
Subject Audit of State AIDS Drug Assistance Programs' Use of Drug Price Discounts
(A-01-97-01501)
To Claude E. Fox, M.D., M.P.H.
Acting Administrator
Health Resources and Services Administration

Attached are two copies of the U.S. Department of Health and Human Services, Office of Inspector General's report entitled *Audit of State AIDS Drug Assistance Programs' Use of Drug Price Discounts*. The objective of this performance audit was to determine whether the Health Resources and Services Administration ensured that AIDS Drug Assistance Programs effectively utilized available discount drug pricing programs.

Officials in your office concurred with three of the five recommendations set forth on page 11 of the attached report and agreed to take action to implement those recommendations. Of the remaining two recommendations, we revised one in consideration of comments from your office. We believe the remaining recommendation is warranted, as described on pages 12 and 13 of the attached report, and request that your office take action. Officials in your office also provided us with technical comments which we incorporated into the report. We appreciate the cooperation given to us during this audit.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please contact me or have your staff contact Joseph J. Green, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582.

To facilitate identification, please refer to Common Identification Number A-01-97-01501 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF STATE AIDS DRUG
ASSISTANCE PROGRAMS' USE OF
DRUG PRICE DISCOUNTS**



JUNE GIBBS BROWN
Inspector General

JANUARY 1998
A-01-97-01501

EXECUTIVE SUMMARY

BACKGROUND

Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 authorized States to use funds to provide treatments that have been determined to prolong life or prevent serious deterioration of health for low-income people with AIDS who do not have adequate health insurance or other resources. The 1996 Amendments to the CARE Act require States to utilize a portion of CARE Act funds for AIDS Drug Assistance Programs (ADAPs).

Congress introduced drug pricing controls in 1990 with the passage of the Omnibus Budget Reconciliation Act (OBRA 1990). The OBRA 1990 established the Medicaid Drug Rebate Program requiring drug manufacturers to provide State Medicaid agencies statutory rebates for covered outpatient drugs. The OBRA 1990 provided a foundation for the Veterans Health Care Act of 1992 which enacted Section 340B of the Public Health Service (PHS) Act. Section 340B extended the OBRA 1990 price limitations by providing discount drug prices (establishing ceiling prices) to eligible entities (including ADAPs). A manufacturer's decision to participate in the 340B program is voluntary. However, the manufacturer's continued participation in the Medicaid program is contingent upon participation in the 340B program.

Entity participation in the 340B Drug Pricing Program is voluntary, subject to the Health Resources and Services Administration's (HRSA) Office of Drug Pricing's (ODP) guidelines. For those ADAPs not participating in the 340B Drug Pricing Program, ODP has under consideration a draft Federal Register notice to establish a manufacturer rebate option (340B rebate) as a means of accessing the 340B Drug Pricing Program.

OBJECTIVE

The objective of this performance audit was to determine whether HRSA ensured that ADAPs effectively utilized available discount drug pricing programs.

SUMMARY OF FINDINGS

While ADAPs utilized various cost savings strategies, 34 of 53 ADAPs did not participate in the 340B Drug Pricing Program (nonparticipating ADAPs) in Fiscal Year (FY) 1996. We analyzed calendar year 1996 drug expenditures for five of the ten highest dollar volume nonparticipating ADAPs. We found those five ADAPs could have purchased an additional eight percent or \$4.4 million of drug therapies, subject to some additional distribution costs, had they participated in the 340B Drug Pricing Program¹. Eight of the ten highest dollar volume nonparticipating ADAPs informed us they did not participate because the 340B implementing guidelines limiting an entity to one contract pharmacy service provider are too restrictive. As a result, those ADAPs are not purchasing drugs at the best possible prices. *Accordingly, there is*

¹ One ADAP became a participating 340B ADAP as of April 1997, after our initial inquiries.

potential for nonparticipating ADAPs to provide additional drug therapies that could improve the quality and length of life for individuals with the Human Immunodeficiency Virus (HIV).

Congress expects States receiving ADAP funding to employ cost savings strategies that maximize assistance to HIV patients. Further, Congress expects HRSA to assure States obtain the best possible prices for ADAP drugs. Such strategies include the 340B Drug Pricing Program, voluntary manufacturer rebates, pharmacy discounts, and other strategies.

Officials from eight of ten nonparticipating ADAPs we contacted informed us they did not participate in the 340B Drug Pricing Program because they believed ODP's implementing guidelines are too restrictive and would severely limit client/patient (patient) access. In this respect, a participating ADAP must purchase drugs directly from a manufacturer or wholesaler and either have its own pharmacy dispense drugs or utilize a single contract pharmacy service provider. In effect, the use of a single pharmacy could restrict access to many patients.

Of the remaining nonparticipating ADAPs contacted, one converted to a participating ADAP in 1997 and the other did not know whether it was cost effective to participate as ODP does not release prices for comparison because of the confidentiality of manufacturers' pricing data. However, the Health Care Financing Administration (HCFA) does provide unit rebate information to State Medicaid agencies without disclosing average manufacturer prices (AMP). We determined that HHS can share ceiling prices (AMPs less unit rebates) or unit rebates with ADAPs without violating confidentiality as long as AMPs are not disclosed.

In an attempt to facilitate and encourage participation by entities, such as ADAPs, which do not have on-site pharmacies, the ODP issued guidelines in the Federal Register providing for participation through a single contract pharmacy service provider. Comments received on the initial proposal of the contract pharmacy service provider guidelines sensitized ODP to the issues involving potential drug diversion (pharmacies reselling discounted drugs to individuals who are not patients of the eligible entity). In effect, ODP believes the use of a single contract pharmacy service provider should minimize potential diversion and ODP will consider any submitted proposals for multiple contract pharmacy service providers.

RECOMMENDATIONS

We recommend that HRSA:

- (1) require ADAPs to develop drug purchasing and distribution mechanisms that enable participation in the 340B Drug Pricing Program unless the ADAPs demonstrate that participation is not cost efficient or not possible under ODP's current guidelines;
- (2) develop new guidelines to allow ADAPs to participate in the 340B Drug Pricing Program with multiple pharmacy service providers (contract or otherwise) and work with ADAPs to implement the new guidelines;
- (3) explore alternatives for funding reviews to deter and detect drug diversion;

(4) work with HCFA to devise a mechanism to share 340B ceiling prices or rebates (without disclosing AMPs) with eligible entities which express a need for the information (e.g., perform cost effectiveness analysis and verify the receipt of appropriate rebates or 340B ceiling prices) while maintaining confidentiality; and

(5) continue its efforts to finalize guidelines establishing a rebate option for ADAPs.

In its written response to our draft report (See APPENDIX), HRSA agreed with recommendation numbers one, four and five as presented above and indicated that action has been or will be taken. The HRSA did not agree with recommendation number two. We revised draft recommendation number three in response to HRSA's comments.

Regarding recommendation number two, HRSA does not believe that adequate safeguards to prevent drug diversion can be incorporated into pharmacy delivery systems that entail the use of multiple pharmacy service providers. However, HRSA offers no evidence supporting its position that existing safeguards would not be effective in deterring and detecting drug diversion. We believe the potential to provide additional drug therapies which could improve the quality and length of life for many individuals outweighs the risk that existing safeguards could be circumvented.

The HRSA also indicated they are implementing a rebate option for ADAPs so that maximum savings can be realized. Although this option provides access to the 340B Drug Pricing Program, it does not maximize savings. As indicated in EXHIBIT I and EXHIBIT III, ADAPs could achieve a greater savings (\$4.4 million for the five ADAPs reviewed) by purchasing drugs directly from manufacturers rather than purchasing drugs from pharmacies and subsequently obtaining rebates from manufacturers.

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INTRODUCTION

BACKGROUND

Requirement to Establish AIDS Drug Assistance Programs

The Ryan White CARE Act of 1990 was created to help States, communities, and families cope with the growing impact of the AIDS epidemic. In particular, the CARE Act is intended to support systems of care for people with AIDS who do not have adequate health insurance or other resources. Title II of the CARE Act authorized States to use funds to provide treatments that have been determined to prolong life or prevent serious deterioration of health. This enabled States to continue and often expand State ADAPs, which were established in 1987 with Federal funding administered by HRSA.

The 1996 Amendments to the CARE Act now require States to utilize CARE Act funds for ADAPs. All 50 States, the District of Columbia, Puerto Rico and the Virgin Islands currently have ADAPs. The ADAPs generally are supported with Title II CARE Act funds (approximately 60% of ADAP funding in FY 1996). Title I-funded cities contributed 13 percent while States contributed 27 percent to ADAPs in FY 1996.

ADAP Funding

Federal support for ADAPs has grown significantly over the last three years. Title II expenditures have grown from \$39 million in Calendar Year (CY) 1994 to \$119.8 million in FY 1996, including \$62 million earmarked by Congress. For FY 1997, total Title II funding for ADAPs will be approximately \$220 million. While FY 1996 Title II expenditures for ADAPs were reported to be \$119.8 million, an estimated

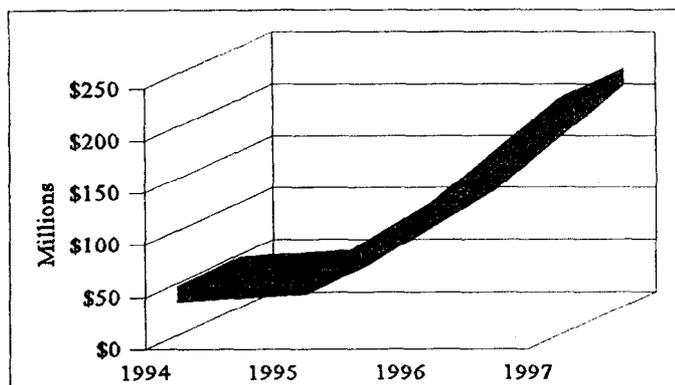


Figure 1- ADAP Title II Funding

\$215.1 million was available for ADAP programs: \$119.8 million Title II; \$25.8 million contributed by Title I grantees; \$53 million from State general revenue; and \$16.5 million from cost recovery strategies, such as rebates from manufacturers. Funding increases are in response to recognition of the increasing costs of drug purchases.

Drug Pricing Controls

In 1997 appropriations language, Congress expects "...that all States receiving AIDS drug assistance funding will employ cost-saving strategies to maximize assistance to HIV patients." The Congress first introduced drug pricing controls in 1990 with the passage of OBRA 1990. The OBRA 1990 established the Medicaid Drug Rebate Program and required manufacturers to sign rebate agreements with the Department of Health and Human Services (HHS) to provide

State Medicaid agencies with statutory rebates for covered outpatient drugs. While OBRA 1990 applied to the Medicaid program, it provided a foundation for legislation establishing the PHS 340B Drug Pricing Program.

On November 4, 1992 Congress passed the Veterans Health Care Act of 1992 (Public Law 102-585) which enacted Section 340B of the PHS Act. Similar to OBRA 1990, Section 340B requires drug manufacturers to sign pharmaceutical pricing agreements with HHS. Section 340B extended the OBRA 1990 price limitations by providing discount drug prices (establishing ceiling prices) to eligible entities for

purchases of covered drugs. A manufacturer's decision to participate in the 340B program is voluntary.

However, the manufacturer's continued participation in the Medicaid program is

The Section 340B price cannot exceed AMP less the Medicaid Rebate.

contingent upon participation in the 340B program. In effect, Section 340B ceiling prices are equivalent to average manufacturers' prices (AMPs - the average drug price paid by wholesalers) less statutory Medicaid rebates for covered drugs. (See EXHIBIT I for an explanation of the pricing structure of pharmaceuticals.) While the 340B Drug Pricing Program established ceiling prices, HRSA's ODP implemented the program without providing a means for entities (ADAPs included) not purchasing directly from manufacturers to receive any price reductions. In this regard, entities eligible for the 340B Program which do not purchase drugs directly from manufacturers do not receive at least the Medicaid rebates used in calculating the 340B ceiling prices. The ODP issued a Federal Register notice seeking comments on the establishment of a rebate option for ADAPs. This rebate option would result in ADAPs receiving the full statutory Medicaid rebates and would also reduce the burden on each nonparticipating ADAP to separately negotiate with individual manufacturers for voluntary rebates.

Some 13,000 entities, including 53 ADAPs, are eligible to participate in the 340B Drug Pricing Program. Entity participation in the 340B Drug Pricing Program is voluntary subject to the ODP's implementing guidelines.

Potential to Improve the Quality and Length of Life for People With HIV

Promising new drug therapies offer hope for improving the quality and length of life for individuals with HIV. These drug therapies, when used in combination with other antiretrovirals, have significantly reduced the progression of HIV and even decreased the amount of HIV in the blood for some infected individuals. Three of these drugs--Ritonavir, Indinavir, and Saquinavir--currently are estimated to cost \$6,500, \$6,000, and \$7,200 per year, per individual, respectively. Recent studies have shown that these new drug therapies can help people live longer and get fewer opportunistic infections.

The ADAPs are intended to provide medications and treatment to low income individuals with HIV, who do not have adequate, or any, prescription benefits through private insurance or Medicaid. As such, ADAPs make it possible for individuals with HIV to have access to therapies they could not otherwise afford. However, ADAPs are facing continuing fiscal challenges from: (1) rapidly increasing numbers of low income people living with HIV; and (2) increased costs of drug treatments due to a changing standard of care which includes new costly drugs and combination therapies. As such, it is imperative that ADAPs receive the best possible prices for all drugs. Doing so will allow States to provide more drug therapies to potentially serve more individuals with HIV, thereby improving and extending their quality of life.

OBJECTIVE, SCOPE AND METHODOLOGY

The objective of this performance audit was to determine whether HRSA ensured that ADAPs effectively utilized available discount drug pricing programs. To accomplish our objective, we:

- ◆ Reviewed applicable laws, regulations, and implementing guidelines and sought legal counsel for assurance that there is no statutory bar to the implementation of our recommendations.
- ◆ Met with and maintained on-going discussions with HRSA officials--ODP and the Division of HIV Services. We also reviewed FY 1996 Ryan White Title II applications for supplemental ADAP funds for the 15 largest ADAPs, and HRSA studies, reports, and reviews relating to ADAPs.
- ◆ Reviewed Ryan White Title I and Title II annual administrative reports for CYs 1994 and 1995. We also reviewed HRSA's FY 1996 and FY 1997 Ryan White Title II Application Guidance for States.
- ◆ For the largest 15 ADAPs - California, Connecticut, Florida, Georgia, Illinois, Maryland, Massachusetts, Missouri, New Jersey, New York, Ohio, Pennsylvania, Puerto Rico, Texas, and Virginia - we contacted the appropriate officials and: (1) obtained information on ADAP policies, procedures, and record keeping systems; and (2) requested computer extract files for CY 1996 drug purchase data, as well as data pertaining to manufacturer rebates billed and expected. Only five of these ADAPs participated in the 340B program at the time of our request.
- ◆ Held discussions with HCFA officials concerning the Medicaid Drug Rebate Initiative (MDRI) file and obtained a computer extract of quarterly Medicaid drug pricing data for CY 1996.
- ◆ Performed computer analysis of CY 1996 ADAP drug purchase data provided by six of the 15 selected ADAPs, 5 of which were 340B nonparticipating ADAPs (Connecticut,

Illinois, Maryland, New Jersey, and New York). Specifically, we compared the ADAPs CY 1996 drug expenditures to the MDRI information used to calculate the 340B ceiling prices (Average Manufacturers' Prices less Medicaid statutory rebates). For the Texas ADAP (a 340B participating ADAP), we limited our analysis to drug purchases pertaining to the first quarter of CY 1996. We determined whether the Texas ADAP received the correct 340B drug prices for purchases made in the first quarter of CY 1996.

We conducted our audit in accordance with generally accepted government auditing standards. Our audit was conducted at HRSA in Rockville, Maryland and our regional office in Boston, Massachusetts, during the period December 1996 through June 1997.

We issued a draft report to HRSA on August 4, 1997. The HRSA's written comments to the draft report are appended (See APPENDIX) and summarized on page 11. Based on HRSA's technical comments, we have made appropriate changes to the report and we have deleted these technical comments since they are no longer relevant.

FINDINGS AND RECOMMENDATIONS

While ADAPs were utilizing various cost savings strategies, 34 of 53 ADAPs did not participate in the 340B Drug Pricing Program (nonparticipating ADAPs) in FY 1996. According to HRSA, the number of nonparticipating ADAPs was reduced to 30 in FY 1997. We analyzed CY 1996 drug expenditures for five of the ten highest dollar volume nonparticipating ADAPs and found that they could have purchased an additional eight percent or \$4.4 million (95 percent Federal share) of drug therapies, subject to some additional distribution costs, had they participated in the 340B Drug Pricing Program². Eight of the ten highest dollar volume nonparticipating 340B ADAPs informed us that they do not participate because the 340B implementing guidelines limiting an entity to one contract pharmacy service provider are too restrictive. As a result, those ADAPs are not purchasing drugs at the best possible prices. *Accordingly, there is significant potential for nonparticipating ADAPs to provide additional drug therapies that could improve the quality and length of life for many individuals with HIV.*

Congress stated in its FY 1997 appropriations language (H.R.104-863 to accompany H.R. 3610, dated September 28, 1996) that it expects States receiving ADAP funding to employ cost saving strategies that maximize assistance to HIV patients. Further, Congress expects HRSA to assure States obtain the best possible prices for ADAP drugs. Such strategies include one or more of the following: the Veterans' Health Care Act Office of Drug Pricing Program, manufacturers' voluntary rebates and discounts to States, and pharmacy discounts.

To participate in the 340B Drug Pricing Program, an eligible entity (ADAPs included) must purchase drugs directly from manufacturers, wholesalers, or a purchasing agent and dispense drugs through either their own pharmacy or a single contract pharmacy service provider. In all cases, the participating entity must take ownership of the drugs. (Federal Registers dated May 13, 1994 and August 23, 1996)

ADAPs Not Participating in the 340B Drug Pricing Program

Below, we discuss: (1) nonparticipating ADAP drug purchasing and distribution systems; (2) the potential for nonparticipating ADAPs to provide additional drug therapies through 340B participation; and (3) the nature of ODP's implementing guidelines for the 340B Drug Pricing Program.

² One ADAP, Illinois, became a participating 340B ADAP as of April 1997, after our initial inquiries.

Nonparticipating ADAP Drug Purchasing/Distribution Systems--See EXHIBIT II, pages one through three, for an overview of the drug purchasing and distribution systems for the 10 nonparticipating ADAPs we contacted. In general, the ADAPs ascertain client/patient (patient) eligibility based on guidelines established by each ADAP. Once the patient is enrolled and receives a drug prescription, the patient goes to the pharmacy of choice or an assigned pharmacy to fill the prescription.

Nonparticipating 340B ADAPs primarily rely on retail pharmacies to dispense drugs. The ADAPs then *reimburse* the pharmacies.

The ADAPs range from a small network of approved pharmacies to over 2,800 pharmacies (usually pharmacies participating in the Medicaid program) dispensing drugs to eligible patients. The pharmacies query ADAPs for authorization, fill prescriptions, and bill ADAPs for the cost of drugs and dispensing fees (often at the same prices the States' Medicaid agencies reimburse the pharmacies). The ADAPs *reimburse* the pharmacies and, in some instances, bill certain manufacturers on a quarterly basis for negotiated manufacturers' voluntary rebates (according to HRSA, 27 ADAPs in 1996). Two of the ten nonparticipating ADAPs primarily utilized a mail order pharmacy program. Under mail order, the patients or the physicians mail the prescriptions to the mail order pharmacies and the pharmacies mail out the filled prescriptions. The ADAPs then reimburse the mail order pharmacies.

Potential for Nonparticipating 340B ADAPs to Provide Additional Drug Therapies Through 340B Participation--We determined that the five nonparticipating ADAPs we analyzed could have utilized their CY 1996 funding to purchase an additional eight percent or \$4.4 million (95 percent Federal share) in drug therapies if: (1) they were able to purchase and distribute drugs in accordance with ODP guidelines; or (2) the ODP guidelines were revised to accommodate the nonparticipating ADAPs. In this respect, we found that the 340B ceiling prices are lower than current purchasing prices for nonparticipating ADAPs. Our analysis considers that nonparticipating ADAPs reimburse pharmacies the discounted Medicaid rate and assumes those ADAPs would receive the full statutory Medicaid rebates.

In calculating the potential to provide additional drug therapies for nonparticipating 340B ADAPs, we compared the cost of each drug purchase to the 340B statutory ceiling price (AMP less Medicaid rebate) in effect for the applicable quarter. We also compared the savings achieved through voluntary rebates received or anticipated to the full statutory Medicaid rebates used in determining the 340B ceiling prices. We reduced the potential additional funding (difference between the 340B ceiling prices and actual amounts paid) by the full Medicaid rebate amount because HRSA has already taken action

PHS 340B ceiling prices are less than ADAPs reimburse pharmacies (Medicaid prices) even after statutory Medicaid rebates.

by issuing a Federal Register notice seeking comments on the establishment of a rebate option for ADAPs. The chart in EXHIBIT III shows the potential for additional funds for the five ADAPs analyzed based on CY 1996 drug purchases. Below we discuss why ADAPs do not participate in the 340B drug pricing program.

ODP's Implementing Guidelines for the 340B Drug Pricing Program--Officials from eight of the ten nonparticipating ADAPs we contacted informed us they did not participate in the 340B Drug Pricing Program because they believed the ODP's guidelines are too restrictive and would severely limit patient access. In this respect, a participating ADAP must either have its own pharmacy to dispense drugs or utilize a single contract pharmacy service provider.

A single contract pharmacy service provider restricts patient access.

Officials from these ADAPs informed us that their programs serve patients throughout the State and to dispense drugs from a single source would require patients to travel prohibitive distances. In effect, a single dispensing pharmacy could restrict access to a large proportion of patients. Of the remaining two ADAPs, one, Illinois, converted to a participating 340B ADAP as of April 1997 and the other informed us that they did not know whether it was cost effective to participate because they did not know the 340B ceiling prices. The ODP does not release these ceiling prices to eligible entities due to the confidentiality of manufacturer pricing data.

Confidentiality - Under OBRA 1990, drug manufacturers report to HCFA confidential information regarding AMP and Unit Rebates. The HCFA provides HRSA's ODP with the 340B ceiling prices (AMP less unit rebate). In addition, HCFA provides the unit rebate data to State Medicaid agencies without disclosing AMPs. This data is confidential per section 1927(b)(3)(D) of the Social Security Act which states information disclosed by manufacturers is confidential and shall not be disclosed by the Secretary or a State agency. While ADAPs have expressed a need for this data, the ODP does not share the data with ADAPs due to confidentiality. We determined that necessary pricing data could be released which would not reveal AMPs. This could be done by sharing ceiling prices (AMPs less unit rebates).

The ODP issued guidelines in the Federal Register providing for a single contract pharmacy service provider in an attempt to facilitate and encourage participation by entities, such as ADAPs, which do not have onsite pharmacies. Comments received on the initial proposal of the contracted pharmacy service provider guidelines sensitized ODP to the issues involving potential drug diversion (pharmacies reselling discounted drugs to individuals who are not patients of the eligible entity). Section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity. In effect, ODP believes that use of a single contract pharmacy service provider should minimize

potential drug diversion³. However, the ODP indicated they will consider any submitted proposals for multiple contract pharmacy service providers. Below, we discuss ADAPs which do participate in the 340B Drug Pricing Program.

ADAPs Participating in the 340B Drug Pricing Program

Five of the 15 ADAPs we contacted participate in the 340B Drug Pricing Program. Below we provide: (1) a brief overview of participating 340B ADAPs' drug purchasing and distribution systems; and (2) a more in depth discussion of the Texas ADAP. We believe the Texas ADAP is a potential model requiring the least amount of change for nonparticipating ADAPs to emulate in transitioning to a participating 340B ADAP.

Overview of Participating 340B ADAP Drug Purchasing/Distribution Systems

Four of the five participating ADAPs we contacted purchase drugs directly from manufacturers/wholesalers through a single State or county pharmacy. (See EXHIBIT II, page four, for an overview of the drug purchasing and

distribution systems of the five participating ADAPs.) The State or county pharmacy fills prescriptions and distributes filled prescriptions to public clinics or private physicians who provide the filled prescriptions to patients. The fifth ADAP (Texas) utilizes a prime vendor, State health clinics, and 212 private pharmacies. The Texas ADAP works within ODP implementing guidelines and accomplishes the most with minimal use of State owned facilities.

To participate, an entity must purchase directly from manufacturer/wholesaler (take ownership) and distribute through its own or a single contract pharmacy service provider.

Texas ADAP System--The Texas ADAP utilizes a prime vendor to purchase drugs at the 340B ceiling prices plus one percent to cover distribution costs. Eligible patients provide prescriptions to State health clinics or private pharmacies. The public clinics and

pharmacies then query/order from the ADAP which in turn orders the drugs from the prime vendor. The prime vendor fills and distributes the orders (drop ships) to the clinics and pharmacies. The clinics and pharmacies act as a drug pick up point and provide

Multiple private pharmacies act as a pick up point, as they do not repackage and charge the ADAP.

³ Although a 1996 lawsuit filed by the Pharmaceutical Research and Manufacturers of America (trade association) was withdrawn, there is concern within HRSA that the suit might be refiled if the single contract pharmacy provision were expanded without sufficient controls to minimize the potential for drug diversion.

filled prescriptions to patients. While the private pharmacies do not charge the ADAP dispensing fees, they may charge patients up to a \$5 fee per prescription. The publicly funded clinics, serving about 75 percent of the patients, do not charge a dispensing fee.

In order to avoid the build up of inventories at private pharmacies, the ADAP and pharmacies have worked with physicians for the physicians to write prescriptions (as much as is feasible) in whole bottle amounts, approximating 30 day supplies. This minimizes the need for storing inventories. When this is not possible, for example a 10/15 day supply of an antibiotic, the ADAP orders the bottle size which is closest to the 10/15 day supply. The prime vendor then delivers to a State pharmacy which dispenses the prescribed amount, distributes, and maintains an inventory. The private pharmacies in Texas do not contract with the ADAP and do not fall within ODP's single contract pharmacy service provider provision. A contract is not necessary because the pharmacies are not charging the ADAP a dispensing fee and also not maintaining inventories. In effect, the Texas ADAP has created a partnership between the State agency, State pharmacy and health clinics, private pharmacies and physicians all working towards the successful implementation of the 340B Drug Pricing Program within ODP's guidelines.

Providing 340B Participation to all ADAPs

Under current ODP guidelines, nonparticipating ADAPs would have to make substantial changes to the way they purchase and distribute drugs in order to qualify for participation in the 340B Drug Pricing Program. We believe the Congressional

The HRSA should lead the way to enable all ADAPs to participate in the 340B Drug Pricing Program.

language for HRSA "...to assure each State seeks the best possible price for AIDS drug purchases" coupled with the potential to improve the quality and length of life for those individuals served make it imperative for HRSA to lead the way in finding a means for all ADAPs to participate in the 340B Drug Pricing Program. The options available to HRSA are: (1) work with nonparticipating ADAPs to revise purchasing and distribution methods in order to comply with ODP implementing guidelines; and (2) revise the ODP's implementing guidelines to allow ADAPs to participate through multiple contract pharmacy service providers.

Work with Nonparticipating ADAPs to Develop Systems Changes to Comply with ODP Implementing Guidelines--To participate in the 340B Drug Pricing Program, under current ODP guidelines, the 10 nonparticipating ADAPs we contacted would have to develop new or revised methods of purchasing and distributing drugs. We believe the system utilized by the Texas ADAP offers the most potential to allow those remaining nonparticipating ADAPs to participate with the least amount of change. As demonstrated by Texas, purchasing directly from the manufacturer/wholesaler can be accomplished economically without a State owned facility. In this respect, the ADAP orders from the prime vendor which charges the 340B ceiling price plus only one percent of the purchase. However, while it appears ADAPs could utilize a prime vendor, there remain obstacles to overcoming the single contract pharmacy service provider

provision. We view these obstacles as fairly significant since the ADAPs would have to avoid the build up of inventories at private pharmacies and also eliminate charges from the private pharmacies (currently these pharmacies, similar to Medicaid, charge the ADAP a dispensing fee up to \$5 above the cost of the drug).

Texas is able to address the build up of inventories at private pharmacies by working with physicians to write prescriptions (as much as is feasible) in whole bottle amounts, approximating 30 day supplies and having a State pharmacy repackage when necessary. This may or may not be feasible for other ADAPs. However, to avoid private pharmacies charging dispensing fees to the ADAPs, the ADAPs would have to pass the dispensing fees on to some patients who choose a private pharmacy, in a manner similar to Texas. While the dispensing fee on each prescription filled is relatively small it could be a significant charge for individuals who have no other insurance and qualify for ADAP services because of low financial resources. The dispensing fees paid by the five nonparticipating ADAPs we analyzed totaled \$1.2 million for CY 1996.

Build up of pharmacy inventories and passing dispensing fees to patients are significant obstacles.

Revise the ODP Implementing Guidelines to Allow ADAPs to Participate Through Multiple Contract Pharmacy Service Providers--We believe changing ODP guidelines to allow multiple contract pharmacy service providers requires the least number of significant changes for ADAPs. This would probably be the least costly and easiest way to ensure all ADAPs participate in the 340B Drug Pricing Program. In this respect, the most significant change for ADAPs would be to purchase drugs directly from manufacturers/wholesalers. As demonstrated by the Texas ADAP, direct purchasing is possible with a State prime vendor program at only one percent above the 340B ceiling price. A prime vendor allows the ADAPs to direct purchase and the prime vendor then drop ships to pharmacies, in a manner similar to Texas. The ADAPs could minimize the build up of inventories at pharmacies by working, similar to Texas, with physicians to write prescriptions as close as feasible to whole bottle amounts. However, there will be instances when the pharmacies will have to store inventory. Increasing the number of pharmacies in a participating 340B ADAP and the build up of even small inventories may increase the risk of drug diversion. However, we believe record keeping requirements for ADAPs and pharmacies (nonparticipating ADAPs, for the most part, distribute drugs through Medicaid approved pharmacies) should be sufficient to provide an audit trail to disclose diversion.

Record keeping requirements for HHS grantees such as ADAPs (45 CFR Part 92) require that grantees maintain records which adequately identify the source and application of funds. These records must contain information pertaining to grant or subgrant awards and authorizations, obligations, unobligated balances, *assets*, liabilities, outlays or expenditures, and income. Further, grantees (ADAPs) must safeguard all assets and assure they are used solely for authorized purposes. In

Adequate record keeping and contractor reviews should minimize drug diversion.

addition, pharmacies participating in the Medicaid program are required to keep records necessary to disclose the extent of services they furnish to recipients (per Medicaid Guide). Therefore, the pharmacies should already have systems to account for drugs dispensed, by patient and funding source. Accordingly, we do not believe additional record keeping requirements are needed to prevent drug diversion.

The HRSA and the ADAPs could establish a mechanism to perform reviews as a means of deterring and detecting potential drug diversion under the 340B Drug Pricing Program, if such reviews were warranted due to specific concerns/cases of drug diversion. We believe these reviews could be accomplished with HRSA grant funds. In this respect, should HRSA become aware of the significant potential for drug diversion within a specific ADAP or pharmacy, HRSA could either use or authorize grant money to conduct a localized review. We believe that the potential to provide significant additional drug therapies (\$4.4 million for the five nonparticipating ADAPs reviewed) would more than offset the judicial and occasional use of grant money to conduct localized reviews to deter and detect drug diversion, as needed.

Recommendations

We recommend that HRSA:

- (1) require ADAPs to develop drug purchasing and distribution mechanisms that enable participation in the 340B Drug Pricing Program unless the ADAPs demonstrate that participation is not cost efficient or not possible under ODP's current guidelines;
- (2) develop new guidelines to allow ADAPs to participate in the 340B Drug Pricing Program with multiple pharmacy service providers (contract or otherwise) and work with ADAPs to implement the new guidelines;
- (3) explore alternatives for funding reviews to deter and detect drug diversion;
- (4) work with HCFA to devise a mechanism to share 340B ceiling prices or rebates (without disclosing AMPs) with eligible entities which express a need for the information (e.g., perform cost effectiveness analysis and verify the receipt of appropriate rebates or 340B ceiling prices) while maintaining confidentiality; and
- (5) continue its efforts to finalize guidelines establishing a rebate option for ADAPs.

Auditee Comments

The HRSA concurred with recommendation numbers one, four, and five of our report and has indicated they will take action to address those recommendations. In this regard, the HRSA will:

- ◆ consult with the Administrator of HCFA regarding the sharing of 340B ceiling prices or rebates; and
- ◆ finalize proposed guidelines regarding the rebate option based on entity comments.

The HRSA did not concur with recommendation number two, as HRSA does not believe that sufficient safeguards against drug diversion can be incorporated into drug delivery systems which entail the use of multiple pharmacy service providers. The HRSA indicated they are working towards the implementation of the rebate option so that maximum savings can be realized.

Regarding recommendation number three, HRSA is concerned that the localized reviews to deter and detect drug diversion will be funded with scarce grant funds. Such activity is administrative in nature, and HRSA believes grantees are already facing limits on the use of administrative funds. However, HRSA is open to discussions on the possible use of one percent evaluation funds for review purposes⁴.

Office of Audit Services' Response

We commend HRSA for its planned actions to implement recommendation numbers one, four and five. Furthermore, we are sensitive to HRSA's concerns regarding the issues of potential drug diversion and the scarcity of grant funds.

Regarding recommendation number two, we describe on pages 10 and 11 the safeguards that already exist to deter and detect drug diversion. While these and all safeguards theoretically could be circumvented by those intending to defraud the government, HRSA offers no evidence supporting its position that the safeguards would not be effective. We believe that allowing the use of multiple pharmacies would enable more ADAPs to participate in the 340B Drug Pricing Program. Therefore, additional funds would be available to provide drug therapies which may improve the quality and length of life for more individuals. While we recognize that drug diversion is a concern of the pharmaceutical industry, we believe: (1) the potential benefits of allowing greater access to the 340B Drug Pricing Program outweigh the risks associated with the potential drug diversion and (2) exploring cost-effective methods of preventing potential drug diversion would be preferable to restricting access to the program.

Regarding HRSA's implementation of a rebate option, we commend HRSA for taking this action as it will enable ADAPs to receive the full statutory Medicaid rebate and would also reduce the burden on each nonparticipating ADAP to separately negotiate with individual manufacturers for rebates. However, EXHIBIT I and EXHIBIT III demonstrate that ADAPs

⁴ Section 241 of the PHS Act provides that the Secretary may determine such portion, but not more than one per centum, of any appropriation for grants, contracts, or other payments under any provision of the PHS Act shall be available for evaluation (directly, or by grants or contracts) of any program authorized by the PHS Act.

will achieve a greater savings by purchasing drugs directly from manufacturers rather than by purchasing drugs from pharmacies and subsequently obtaining rebates from manufacturers. The rebate to be utilized under HRSA's proposed rebate option equals the rebate used in determining the 340B ceiling price. However, under the rebate option, the ADAP has already reimbursed the pharmacy AWP less 10 percent which is a higher price than the AMP utilized when purchasing directly from the manufacturer. As a result, drug prices under the rebate option would be higher than drug prices under direct purchasing from manufacturers. EXHIBIT III shows that although the five ADAPs reviewed would receive \$2.37 million in additional rebates (rebates from manufacturers not already providing voluntary rebates) under HRSA's proposed rebate option; the five ADAPs would pay \$4.4 million more under a rebate option than if they purchased the drugs directly from manufacturers.

We revised draft recommendation number three to address HRSA's concerns. We are now recommending that HRSA explore alternatives for funding reviews to deter and detect drug diversion since HRSA is open to the possible use of PHS one percent evaluation funds to conduct those reviews. However, exploration of these alternatives should not be limited to the PHS one percent evaluation funds. In light of state and local governments' vested interests in ADAPs (approximately 40 percent of ADAP funding for fiscal year 1996), HRSA could consult with state and local governments to determine the possibility that they conduct and/or contribute funds toward reviews to deter and detect drug diversion. We believe even one periodic review (e.g. every year) at an ADAP's pharmacy service provider could provide an effective deterrent to the possibility of drug diversion occurring at other multiple pharmacy service providers.

**NONPARTICIPATING ADAP REIMBURSEMENTS
TO PHARMACIES COMPARED WITH THE 340B CEILING PRICES**

Below, we compare ADAP reimbursements to pharmacies, before and after manufacturer rebates, with the 340B ceiling price for three drugs. Due to confidentiality of drug pricing information we do not disclose quantity purchased.

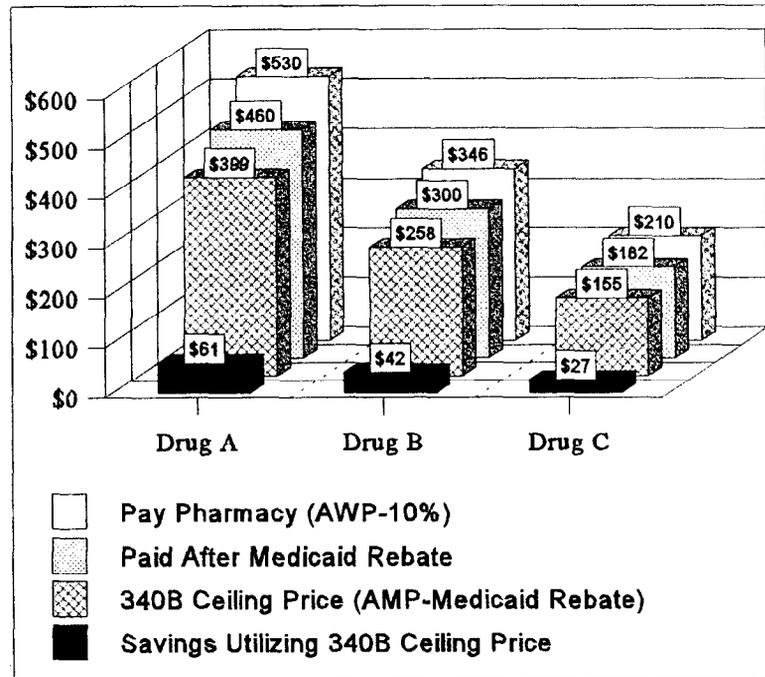
ADAPs Pay Pharmacies--Nonparticipating ADAPs primarily purchase drugs from retail pharmacies and pay a percentage of the average wholesale price (AWP), the average drug price retailers pay manufacturers. The majority of the 10 nonparticipating ADAPs we contacted indicated they reimbursed pharmacies the Medicaid prices. For example, an ADAP can establish that it pays pharmacies no more than AWP less 10 percent for drugs (generally ADAPs pay AWP less 10 percent). In addition, the ADAP will pay an additional dispensing fee (up to \$5 and frequently the same as Medicaid) to pharmacies.

Paid After Medicaid Rebates--Many ADAPs, after reimbursing the pharmacy for the cost of the drug, can bill manufacturers for negotiated voluntary rebates. While the voluntary rebates can vary among ADAPs, we found

none (five ADAPs analyzed) that exceeded the rebates used in the calculation of the 340B ceiling prices (statutory Medicaid rebates). We utilized the statutory Medicaid rebate in the chart because HRSA has proposed guidelines for an ADAP rebate option allowing ADAPs to obtain the full Medicaid rebate.

340B Ceiling Price--This is the AMP less the Medicaid rebate. The AMP is the average price paid by wholesalers to manufacturers.

Savings Utilizing 340B Ceiling Price--This is the additional savings nonparticipating ADAPs can realize by paying the 340B ceiling price rather than reimbursing pharmacies (usually at the Medicaid rate) even after considering the statutory Medicaid rebate.



Comparison of Payments to Pharmacies, Before and After Rebates with 340B Ceiling Prices - Three Drugs

DRUG PURCHASING/DISTRIBUTION SYSTEMS FOR SELECTED ADAPs

ADAPs Not Participating in the 340B Program:

Maryland--The Maryland Department of Health and Mental Hygiene centrally administers the enrollment, certification, and re-certification of ADAP patients. The ADAP has a decentralized drug purchasing and distribution system. Eligible patients take prescriptions and ADAP identification cards to pharmacies which participate in the State's Medicaid program. The pharmacies obtain authorizations from the ADAP, fill the prescriptions, and then bill the ADAP. The ADAP reimburses the pharmacies at amounts approximating the State's Medicaid rate, AWP's less 10 percent, plus dispensing fees up to \$4.65 per prescription. The ADAP also pursues voluntary manufacturer rebates.

New York--The New York Department of Health centrally administers the enrollment, certification, and re-certification of ADAP patients. The ADAP reimburses over 2,800 local pharmacies that dispense drugs. Those pharmacies include independent retailers, chain stores, mail order, and hospital and clinic outpatient pharmacies. The ADAP utilizes a State fiscal agent to centrally process ADAP claims and payments. Eligible patients take prescriptions and ADAP identification cards to pharmacies. The pharmacies use point of sale terminals to conduct on-line verification of patient eligibility. The pharmacies then fill the prescriptions and bill the State fiscal agent. The fiscal agent reimburses pharmacies at amounts equivalent to the State's Medicaid rate (AWP's less 10 percent) plus dispensing fees of \$4.50 per prescription. The fiscal agent pursues voluntary manufacturer rebates on behalf of the ADAP.

New Jersey--The New Jersey Division of Medical Assistance, which is the State Medicaid agency, centrally administers the enrollment and eligibility certification of ADAP patients. Eligible patients take prescriptions to pharmacies which participate in the State's Medicaid program. The ADAP utilizes a private contractor to process ADAP payments to pharmacies. The pharmacies dispense prescriptions to patients and bill the private contractor through an on-line computer system. The contractor subsequently bills the ADAP. The ADAP uses the State's Medicaid payment system to reimburse the contractor at amounts equivalent to the State's Medicaid rate (AWP's less 10 percent) plus dispensing fees up to \$4.07 per prescription. The ADAP also pursues voluntary manufacturer rebates.

Connecticut--The Department of Social Services (DSS), the State Medicaid agency, centrally administers the ADAP. The DSS processes ADAP applications, determines patient eligibility, issues medication cards, re-certifies patients every six months, and reviews ADAP claims. The DSS also provides support for budgeting, accounting, and payment processing. Patients present medication cards to pharmacies which fill the prescriptions and bill the DSS. The DSS reimburses pharmacies the lesser of billed or allowed amounts for drugs. Allowed amounts are equivalent to the State Medicaid rate (currently AWP's less 12 percent) plus dispensing fees of \$4.10 per prescription. The DSS also pursues voluntary manufacturer rebates.

DRUG PURCHASING/DISTRIBUTION SYSTEMS FOR SELECTED ADAPs

ADAPs Not Participating in the 340B Program:

Massachusetts--The Massachusetts Department of Health uses a private contractor to directly administer the enrollment, certification, and re-certification of ADAP patients. The contractor reimburses a network of private pharmacies which dispense drugs to ADAP patients. Eligible patients bring ADAP identification cards and prescriptions to any of 600 network pharmacies. The pharmacies verify patient eligibility, fill prescriptions, and provide billing information to a central pharmacy network site. The pharmacy network bills the private contractor who bills the ADAP for filled prescriptions. The ADAP reimburses the contractor at amounts equal to AWP less 12 percent plus dispensing fees of \$2.50 and transaction fees of \$.65 per prescription. The ADAP also submits requests for voluntary manufacturer rebates.

Pennsylvania--The State's Special Pharmaceutical Benefits Program (SPBP), which is the State Medicaid agency, directly administers enrollment, eligibility certification, and recertification of ADAP patients. The patients bring ADAP identification cards and prescriptions to pharmacies which participate in the State's Medicaid program. These pharmacies dispense prescriptions and bill the SPBP. The SPBP reimburses pharmacies at amounts equivalent to the State's Medicaid rate (AWPs less 10 percent) plus dispensing fees per prescription. The ADAP received voluntary manufacturer rebates during CY 1996. The ADAP will receive State mandated rebates of approximately 17 percent of drugs' AMPs beginning in 1997.

Missouri--The Missouri Department of Health (MDH) directly administers the overall Title II AIDS Drug Program. The MDH provides HIV drug therapies under both the overall Title II Program and the ADAP. Both programs share the same provider network and drug purchasing systems; however, they have different eligibility criteria, drug formularies, and administrative procedures. One major difference is the ADAP restricts patient eligibility to a lower income threshold. In addition, the ADAP was not established until November 1996.

Patients fill prescriptions through a mail order pharmacy or participating walk in pharmacies. The MDH contracted with three Benefits Managers (BMs) in 1996 to provide ADAP services to Missouri's six geographical regions (Missouri contracted with one BM for FY 1997). A network of Statewide service coordinators refers potential patients to the BMs. The BMs verify patient eligibility, provide identification cards, negotiate drug discounts, pay pharmacies for drug purchases, and maintain information systems to monitor regional drug expenditures. The BMs negotiate their own up front discount contracts with participating pharmacies or manufacturers. As such, each BM may pay different prices for the same drugs. The BMs send monthly invoices and supporting documentation to the MDH which reimburses the BMs. The ADAP drug prices are comparable to the State's Medicaid drug prices. The MDH is currently negotiating voluntary rebate agreements with three drug manufacturers. In May 1997, HRSA officials conducted a site visit and the State is now exploring participation.

DRUG PURCHASING/DISTRIBUTION SYSTEMS FOR SELECTED ADAPs

ADAPs Not Participating in the 340B Program:

Ohio--The Ohio Department of Health AIDS Client Resources Section (ACRS) administers the ADAP. The ADAP does not utilize a State purchasing and distribution infrastructure. The ADAP contracts with a mail order pharmacy to dispense drugs. The mail order pharmacy purchases ADAP drugs in bulk and maintains the drugs in a separate dispensing area. The ACRS provides the mail order pharmacy with information pertaining to each ADAP patient. The ADAP patients mail original prescriptions to the mail order pharmacy. The pharmacy fills prescriptions within three working days, ships drugs to the patients, and bills the ADAP monthly. The ADAP reimburses the mail order pharmacy at amounts equivalent to the AWP less 18 percent plus dispensing fees of \$2.00 per prescription. The ADAP bills several manufacturers for voluntary rebates of an average of 10 percent of the amount paid.

California--The California Department of Health Services (CDHS) administers the ADAP. The CDHS allocates ADAP funds to 46 local health jurisdictions and 3 non-profit organizations which administer their own programs. Each local health jurisdiction and non-profit organization is responsible for patient enrollment and contracting with pharmacies. There is no standard mechanism for purchasing and dispensing drugs throughout the ADAP. However, eligibility standards and drug formularies are constant. The ADAP reimburses local health jurisdictions at a rate not to exceed AWP less five percent (this is the State's Medicaid rate). However, five of the 46 local health jurisdictions do participate in the Section 340B program.

Illinois--Prior to FY 1997, the ADAP did not participate in the PHS 340B Drug Discount Program. At that time, the ADAP contracted with a mail order pharmacy to provide Statewide mail order pharmaceutical care services. Under that contract, physicians mailed or faxed prescriptions to the mail order pharmacy. The pharmacy verified patient eligibility with the ADAP, filled the prescriptions, and dispensed the drugs via the mail. The contractor charges a \$1.00 dispensing fee per prescription. (See page four of this exhibit for a description of the Illinois ADAP after April 1, 1997, when Illinois began participation in the 340B Program.)

DRUG PURCHASING/DISTRIBUTION SYSTEMS FOR SELECTED ADAPs***ADAPs Participating in the 340B Program:***

Virginia--The ADAP utilizes centralized purchasing through the Department of Health's central pharmacy. The central pharmacy purchases the drugs from a wholesaler at 1.1 percent above the 340B ceiling prices. The patients are serviced through local health departments, which determine patient eligibility and order drugs from the central pharmacy. The central pharmacy ships the filled prescriptions to the local health departments and bills the ADAP monthly. The ADAP relies on the central pharmacy to obtain the appropriate 340B ceiling prices.

Georgia--The ADAP contracted with a hospital authority to directly purchase drugs from manufacturers. All patients enter the ADAP through local health departments and clinics. The certification of patient eligibility is conducted by individual sites. The hospital authority fills prescriptions and distributes the drugs to local physicians and clinics for dispersement to the patients. The hospital authority maintains records and bills the ADAP for filled prescriptions. The ADAP relies on the hospital system to obtain drugs at or below the 340B ceiling prices.

Florida--The ADAP centrally purchases drugs through a central State pharmacy. Drugs are then distributed to 67 county health departments. Seventeen of these health departments have their own on site pharmacies that fill patient prescriptions (with drugs purchased in bulk from the central pharmacy). The remaining county health departments do not have on site pharmacies. These health departments order prescribed drugs from the central pharmacy with a five-to-seven day turn around.

Puerto Rico--The ADAP is divided into eight health regions. Each health region has a public clinic with its own pharmacy. The ADAP centrally purchases drugs (in bulk) at the 340B ceiling prices from a wholesaler and distributes to the eight regional pharmacies. The drugs are stored on the regional pharmacy shelves. Patients bring prescriptions to their regional pharmacies which fill the prescriptions free of charge. There are no dispensing fees since the pharmacies are State owned.

Illinois--The ADAP began participating in the 340B Program on April 1, 1997. The ADAP contracted with a wholesaler whereby the ADAP purchases from the wholesaler at 340B ceiling prices. The wholesaler ships the drugs to the same mail order pharmacy as Illinois utilized prior to April 1, 1997. The ADAP pays the pharmacy a fee of \$13 per transaction. However, the annual amount of payments for dispensing services shall not exceed \$650,000.

EXHIBIT III

CY 1996 AMOUNTS WHICH COULD HAVE BEEN AVAILABLE
FOR ADDITIONAL DRUG THERAPIES HAD THESE
FIVE ADAPs PARTICIPATED IN 340B DRUG PRICING PROGRAM

(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
STATE	ADAP PAID FOR DRUGS ¹	FEDERAL SHARE (%)	VOLUNTARY REBATE EXPECTED ²	FULL REBATE UNDER HRSA PROPOSAL ³	ADDITIONAL REBATES UNDER HRSA PROPOSAL ⁴	PHS 340B CEILING PRICE	ADDITIONAL FUNDS USING PHS 340B CEILING PRICE ⁵
NY	\$36,769,909	99	\$4,726,575	\$5,791,826	\$1,065,251	\$28,218,746	\$2,759,337
CT	2,503,832	73	239,389	369,677	130,288	1,910,008	224,147
NJ	5,348,990	91	471,922	807,685	335,763	3,898,559	642,746
MD	1,610,615	75	176,104	235,668	59,564	1,200,816	174,131
IL	8,575,830	90	519,552	1,298,744	779,192	6,660,198	616,888
TOTAL	\$54,809,176	95	\$6,133,542	\$8,503,600	\$2,370,058	\$41,888,327	\$4,417,249

¹ Not all CY 1996 claims were processed as of the date of our request for payment information (January 1997).

² Based on agreements with manufacturers we gave the ADAP credit for all rebates which would be expected to be collected for a full CY.

³ Because the HRSA is already moving toward requiring the full Medicaid statutory rebate we identified the full rebate and did not include any of this amount in column H (additional funds using the 340B ceiling price).

⁴ Column E less column D. This represents additional rebates to be obtained under HRSA's proposal from manufacturers not already providing voluntary rebates.

⁵ Column B less column E less column G. This represents additional funds available should ADAPs purchase directly from manufacturers rather than receive HRSA's proposed rebates after reimbursing pharmacies.

APPENDIX



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and
Services Administration
Rockville MD 20857

NOV 18 1997

TO: Inspector General, DHHS
FROM: Acting Deputy Administrator
SUBJECT: Office of Inspector General (OIG) Draft Report, "Audit
of State AIDS Drug Assistance Programs' (ADAP) Use of
Drug Price Discounts." (CIN A-01-97-01501)

Attached is HRSA's response to your memorandum dated August 4,
1997, requesting comments on the subject draft report.

Questions may be referred to Michael Herbst on 443-5256.


Thomas G. Morford

Attachment

HEALTH RESOURCES AND SERVICES ADMINISTRATION COMMENTS ON
THE OIG DRAFT REPORT, "AUDIT OF STATE AIDS DRUG ASSISTANCE
PROGRAMS' USE OF DRUG PRICE DISCOUNTS."
(CIN: A-01-97-01501)

GENERAL COMMENTS:

HRSA finds the draft report informative and supportive. It is apparent that many of the comments provided to the OIG by HRSA representatives on an informal basis were incorporated into the report. However, HRSA still considers several specific points to be technically inaccurate or incorrect. The stated inaccuracies, if allowed to remain, could seriously impede implementation of the recommendations provided by the report.

The report describes the multiple pressures that most ADAPs are experiencing related to rapid growth and changing clinical standards for HIV/AIDS treatment. It would be helpful if the report also noted that, as a consequence of the dynamic environment in which they operate, the description of each program is a snapshot taken at a fixed point in time. Consequently, changes are likely to have since occurred.

The report acknowledges that ADAPs were established with funding from HRSA in 1987, prior to passage of the CARE Act. However, this background information does not explain that these programs were originally, and quite logically, set up by States to reimburse providers of prescriptions rather than to purchase and dispense medications directly. There were at least three important reasons for this approach. First, funds were awarded to State health departments, and many lacked the experience, infrastructure, personnel, or other resources needed to purchase and dispense drugs to individuals. Second, ADAP clients were typically dispersed throughout a State, requiring a distribution system with broader reach than one or a few dispensing sites. Third, all States had experience with reimbursement models based on how Medicaid prescription benefits were typically provided.

Personnel ceilings and cutbacks, infrastructure limitations, funding and other resource constraints are factors in State decisions to continue use of reimbursement models to operate ADAPs. The reauthorized CARE Act limits the amount available for administration, planning and evaluation to no more than a combined total of 15 percent of the grant award. For many States with reimbursement models, the substantial up-front costs of overhauling operating structures, administrative procedures, and information management systems in order to directly purchase and dispense drugs has been estimated by grantees to exceed the resources available.

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It is helpful that the report identifies voluntary manufacturers' rebates as an example of cost recovery strategies in the introduction of the report (page 1), notes them again in the general discussion of ADAPs that do not participate in the 340B Program (nonparticipating ADAPs) (page 6), and explains how rebates were accounted for in the pricing analysis. However, the report does not note or describe the extent to which nonparticipating ADAPs were obtaining voluntary manufacturers' rebates, or the use of other cost-savings strategies. The HIV/AIDS Bureau is concerned that readers may mistakenly conclude that nonparticipating ADAPs have not been active in aggressively seeking to control costs.

Among the 35 ADAPs that did not participate in the Drug Discount Program during 1996, 27 (or 77%) were obtaining voluntary rebates. In 1997, that number has increased significantly. Of the 30 ADAPs that do not participate, only four (13%) do not obtain voluntary rebates on all or most covered drugs (IA, SD, WV, WY). Together, these four States' ADAP allocations represent less than .4 percent of the \$167 million earmarked by Congress for ADAPs in 1997.

In the section of the report describing specific ADAP models, the report acknowledges instances where significant program changes have taken place since the time the audit was conducted. However, the discussion of the California ADAP does not include an update of important changes that were in progress at the time of the audit, and which the State has continued to implement. These include securing manufacturers' rebates mandated by the State legislature.

One of the major reasons that pharmacies negotiate contracts with prime vendors other than the cost issue, is to keep inventories low in the pharmacy and shorten the time frame for receiving medications from the vendor. Ordering 340B drugs as prescriptions are presented can reduce diversion. The Texas program is a good example of utilizing a prime vendor method.

OIG RECOMMENDATION:

HRSA should require ADAPs to develop drug purchasing and distribution mechanisms that enable participation in the 340B Drug Pricing Program unless the ADAPs demonstrate that participation is not cost efficient or not possible under ODP current guidelines.

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HRSA RESPONSE:

We concur. A reference, however, to the pending rebate option should be included in the recommendation. The action planned to implement this will include development of guidelines and placing a condition of award on Title II grantees starting in FY 1998. This grant condition would require their participation in the 340B program (either through up front discounts or the pending rebate option) or a demonstration that the grantee achieves pricing as good as or better than 340B pricing through other mechanisms.

We recommend inclusion of the following edit which is in bold italics after, "...Pricing Program," "***...including, the pending, rebate option proposed in a Federal Register notice published August 29, 1997.***" The intent of the proposed rebate notice is to respond to the fact that most ADAPs were originally established as reimbursement programs and, for many of them, the existing up-front discount option is not workable, unless they completely restructure existing systems. HRSA continues to work closely with all ADAPs to encourage 340B participation.

OIG RECOMMENDATION:

HRSA should develop new guidelines to allow ADAPs to participate in the 340B Drug Pricing Program with multiple pharmacy service providers (contract or otherwise) and work with ADAPs to implement the new guidelines.

HRSA RESPONSE:

We do not concur. From the inception of the 340B Program, ODP has considered numerous pharmacy delivery systems that entailed the use of multiple pharmacy service providers. All of these systems were rejected because of the potential of diversion inherent in these systems. HRSA does not believe that sufficient safeguards against diversion necessary to meet the requirements of Section 340B can be incorporated into these systems. HRSA believes that the only feasible system which can allow this type of access to multiple pharmacy service providers is the rebate option proposed in the Federal Register. HRSA is working closely with the ADAP program, the pharmaceutical industry and all concerned parties in the implementation of the rebate option so that the maximum savings can be realized.

OIG RECOMMENDATION:

HRSA should authorize the judicial use of grant money to conduct localized reviews, as needed, to deter and detect drug diversion.

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HRSA RESPONSE:

We do not concur. The recommendation, as written, is too imprecise to fully understand. We nonconcur with this recommendation if the OIG intends that Title II grantees conduct these reviews with such grant funds. Such activity would be administrative in nature, and grantees are already operating under severe legislative restrictions on uses of funds for administration. HRSA is open to discussions with the OIG on the perceived need for such reviews, and the possible use of 1% evaluation funds or other sources for this purpose.

It would be helpful to have some clarification of what "grant money" is being referenced in this recommendation, and whether the recommendation to conduct reviews is directed to States or to HRSA. All Title II appropriated funds (with the exception of the legislatively-mandated up to three percent set aside for the Special Projects Of National Significance Program and one percent set asides for technical assistance and evaluation), including those earmarked by Congress for ADAP, are awarded to grantees under a formula specified in the CARE Act. There are significant limitations on the use of those funds for evaluation and administrative activities (see Section 2618 (c)(3)(4) and the fourth paragraph under General Comments).

OIG RECOMMENDATION:

HRSA should work with HCFA to devise a mechanism to share 340B ceiling prices or rebates (without disclosing average manufacturer prices (AMP)) with eligible entities which express a need for the information (e.g., perform cost effectiveness analysis and verify the receipt of appropriate rebates or 340B ceiling prices) while maintaining confidentiality.

HRSA RESPONSE:

We concur. The 340B ceiling price is calculated on a quarterly basis, using a statutory formula. This formula includes the average manufacturer's price (AMP), which is confidential. HCFA's position is that if ceiling prices were released, the confidentiality of the AMP could be compromised. HCFA is required by statute to maintain the confidentiality of such drug pricing information, except when necessary to implement the program. Therefore, HRSA believes that a policy decision could be made to make the ceiling prices available under controlled circumstances that would ensure confidentiality of the AMP. This issue has been revisited several times with HCFA since the inception of the program. A meeting was held with representatives of HCFA, OGC and the ODP on September, 11, 1997.

-5-

It was decided that the best course of action was to elevate this issue to the Agency Administrator level for a final decision on the issue. A letter to HCFA has been prepared for the Administrator's signature.

OIG RECOMMENDATION:

HRSA should continue its efforts to finalize guidelines establishing a rebate process for ADAPs.

HRSA RESPONSE:

We concur. HRSA has published a notice in the Federal Register, for comment (62 Fed. Reg. 45823, August 29, 1997) recognizing 340B rebates for State ADAPs receiving funds under Title XXVI of the PHS Act. The comment period for the proposed Federal Register notice closed on September 29, 1997. The ODP is in the process of developing responses to comments received and revising the final notice, if necessary.

TECHNICAL COMMENTS:

Office of Audit Services Note: These Technical Comments have been deleted because we have made appropriate revisions and they are no longer relevant.