

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**AIDS DRUG ASSISTANCE PROGRAM  
COST CONTAINMENT STRATEGIES**



**JUNE GIBBS BROWN  
Inspector General**

**SEPTEMBER 2000  
OEI-05-99-00610**

## **OFFICE OF INSPECTOR GENERAL**

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

### **Office of Evaluation and Inspections**

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Region V prepared this report under the direction of William Moran, Regional Inspector General and Natalie Coen, Deputy Regional Inspector General. Principal OEI staff included:

#### **REGION**

Ann Maxwell, *Project Leader*  
Madeline Carpinelli, *Program Analyst*  
Chip Schonenberger, *Intern*

#### **HEADQUARTERS**

Elise Stein, *Director, Public Health and  
Human Services Staff*

To obtain copies of this report, please call the Chicago Regional Office at 312-353-9867.  
Reports are also available on the World Wide Web at our home page address:

<http://www.hhs.gov/oei>

# EXECUTIVE SUMMARY

---

## PURPOSE

Compare the prices that State AIDS Drug Assistance Programs are paying for drugs to the Federal ceiling prices listed in the Federal Supply Schedule.

---

## BACKGROUND

The Ryan White Comprehensive AIDS Resource Emergency (CARE) Act requires that a portion of Title II State grants are allocated to establish AIDS Drug Assistance Programs (ADAPs). The ADAPs provide medications to low-income individuals living with HIV/AIDS who have limited or no coverage from private insurance or Medicaid. Overall, Federal contributions have risen dramatically from the original appropriation of \$52 million in fiscal year (FY) 1996 to \$528 million in the FY 2000 budget.

The ADAPs are facing fiscal challenges from increasing demand due to growing numbers of low-income people living with HIV and the increased cost of drug treatments due to a changing standard of care. The Public Health Service treatment guidelines recommend combination antiretroviral therapies that typically range between \$10,000 and \$12,000 a year per client. In this environment, cost containment has emerged as a key means to address the issue of client access.

One of the principle methods ADAPs have to contain drug costs is the 340B Drug Pricing Program. This program provides drug price ceilings to ADAPs that purchase their drugs through a central purchaser as well as certain other federally funded entities. This program also provides a rebate option for ADAPs who do not have a central purchaser.

The Drug Pricing Program was enacted by Section 602 of the Veterans Health Care Act of 1992. Section 603 of the same law mandated minimum drug discounts for four large Federal agencies, known as the Big 4. Section 603 prices, known as the Federal ceiling prices, are available to the specified agencies through the Federal Supply Schedule. The ceiling price calculations stipulated in Section 602 and 603 are not equivalent.

---

## FINDINGS

### **ADAP ceiling prices are, on average, 16 percent higher than the Federal ceiling prices**

The ceiling prices limiting drug expenditures for ADAPs are, on average, 16 percent higher than the Federal ceiling prices limiting drug costs for the Big 4. As a result,

ADAPs will pay an average of 29 cents more per pill and 32 dollars more per bottle than the Big 4 agencies pay for the same drug.

### **ADAPs could have saved nearly \$58 million in 1999 if allowed to purchase the 10 drugs at Federal ceiling prices**

Comparing the actual per drug expenditures of the ADAPs to what they would have paid if they had access to Federal ceiling prices results in \$57.5 million in Federal savings for ADAPs in 1999. Considering expenditures from all sources of funding, ADAPs could have saved \$72 million given access to Federal ceiling prices. The \$57.5 million in Federal savings could have been used to purchase additional life-saving pharmaceuticals to meet the therapeutic needs of several thousand more individuals living with HIV/AIDS.

When broken out by the type of Drug Pricing Program participation, direct purchase States (22 ADAPs) would save \$14.4 million given access to Federal ceiling prices, and rebate States (22 ADAPs) would save \$39 million. For the five States not participating in the Drug Pricing Program, the savings equal \$4 million, bringing the total to \$57.5 million in Federal savings.

---

## **RECOMMENDATIONS**

### **The Health Resources and Services Administration (HRSA) should seek legislation to change the 340B ceiling price calculation to the Federal ceiling price calculation**

As indicated in our findings, making this calculation change would result in \$57.5 million in annual Federal savings for ADAPs. Also, although it was not in the scope of our study to provide a precise estimate regarding the savings available to all 340B Drug Pricing Program eligible entities, a 16 percent reduction in the ceiling price for pharmaceuticals could save these entities \$240 million in Federal funds.

While this represents significant programmatic savings, 340B drug expenditures in total only represent one percent of the domestic pharmaceutical market. The Big 4 agencies, already covered under Section 603, represent just another one and a half percent of the market. Given the limited scope of the proposed changes, it seems likely that any pharmaceutical industry loss due to lower Federal prices to 340B eligible entities could be regained in additional sales volume. At the time this study was conducted, 11 ADAPs had waiting lists while the demand for combination therapies of two or three drugs continues to accelerate. A potential benefit for the manufacturers is a simplified, uniform Federal pricing system to track and report, with price-changing data submissions and recalculations required only once a year.

Even though the Big 4 and ADAPs would access the same Federal ceiling prices for outpatient covered drugs, we recommend that the programs stay discrete. The prime vendor could negotiate contracts below the 603 ceiling prices for the 340B entities similar to the way the VA negotiates multi-year contracts for users of the Federal Supply Schedule.

### **To allow ADAPs to negotiate the lowest prices possible, HRSA should seek legislation to exempt all sales to 340B covered entities from the calculation of Non-Federal Average Manufacturers Price**

We recommend that HRSA seek to add exclusionary language to the statutes codifying the 340B Drug Pricing Program (42 USC 256B) stating that any price negotiated below the 340B statutory ceiling price would be excluded from the calculation of the non-Federal Average Manufacturer Price. Currently, sales *at* the 340B ceiling price are excluded from this calculation, but sales *below* the ceiling are considered commercial sales by the VA and are included. Defining sales below the ceiling prices as commercial sales lowers average commercial prices. This also lowers the Big 4, Federal ceiling prices since they are a percentage of average commercial prices. The linkage between these two pricing schedules creates a disincentive for manufacturers to offer below 340B ceiling prices since these have the potential to reduce Federal ceiling prices. The Prime Vendor cannot successfully negotiate prices lower than the 340B ceiling, currently, or lower than the Federal ceiling, potentially, until this is changed.

### **HRSA should continue to work with rebate and non-participating ADAPs to devise ways to grant them access to up-front drug discounts**

Currently, ADAPs that utilize a multiple contract pharmacy model for the purchase and distribution of pharmaceuticals are not eligible to access the 340B Drug Pricing Program ceiling prices. The ADAPs using this model would also not be able to take advantage of any savings gained by obtaining Federal ceiling prices. In light of this, we recommend that HRSA continue to work with rebate and non-participating ADAPs to devise ways to grant them access to direct purchase pricing discounts.

---

## **AGENCY COMMENTS**

The HRSA concurred with the report's findings and recommendations. They also offered suggestions for clarifying the report and making other technical changes. We appreciate their suggestions and, where appropriate, we changed the report to reflect their comments. The complete text of HRSA comments can be found in Appendix C. Further, staff from the office of the Assistant Secretary of Planning and Evaluation (ASPE) expressed concerns regarding our first recommendation.

The concern raised by ASPE staff has to do with the larger policy implications of our first recommendation. In particular, they are concerned that allowing 340B entities to utilize the Section 603 Federal ceiling price might affect the ability of the VA and the Big 4 to maintain the low prices they currently obtain. We understand their concern about the negotiations. In fact, it was our concern with this very issue that lead us to recommend that 340B pricing be linked to the statutorily defined Federal ceiling price as opposed to the negotiated Federal Supply Schedule (FSS) contract prices the VA and the Big 4 actually pay for drugs. The Federal ceiling price acts only as an upper ceiling to the FSS prices. In reality, the VA uses its considerable volume to negotiate prices below the Federal ceiling. Allowing 340B entities to utilize the same ceiling calculation as the VA and the Big 4 merely provides them with an equitable starting point. Discussions with the VA confirmed that this is a realistic recommendation in consideration of larger policy implications.

# TABLE OF CONTENTS

	<b>PAGE</b>
<b>EXECUTIVE SUMMARY</b> .....	1
<b>INTRODUCTION</b> .....	6
<b>FINDINGS</b>	
ADAP Ceiling Prices Higher Than Federal Ceiling Prices .....	16
Access to Federal Ceiling Prices Would Save ADAPs \$57.5 Million .....	17
Direct Purchase ADAPs Save \$14 Million; Rebate ADAPs Save \$39 Million .....	18
<b>RECOMMENDATIONS</b> .....	21
<b>AGENCY COMMENTS</b> .....	29
<b>APPENDICES</b>	
A: Projected Savings if ADAPs Purchased Drugs at Federal Ceiling Prices .....	31
B: Names and National Drug Codes of the 10 Drugs Reviewed .....	33
C: Agency Comments: HRSA .....	34
D: Related Office of Inspector General Reports .....	39

# INTRODUCTION

---

## PURPOSE

Compare the prices that State AIDS Drug Assistance Programs are paying for drugs to the Federal ceiling prices listed in the Federal Supply Schedule.

---

## BACKGROUND

### Ryan White CARE Act

In 1990, Congress passed the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act in response to the AIDS epidemic and its impact on individuals, families, communities, cities and States. The Ryan White programs provide health care and support services to persons with HIV/AIDS who would otherwise have no access to health care. The Health Resources and Services Administration (HRSA) directs Ryan White resources to various local entities through the Act's four titles and Part F.

Ryan White programs constitute slightly over \$1.6 billion of the approximately \$8.2 billion in Federal HIV/AIDS appropriations for fiscal year (FY) 2000. The CARE Act is the largest source of Federal funding specifically directed to provide primary care for persons living with HIV/AIDS. The Ryan White CARE Act was re-authorized in 1996 through September 30, 2000. It is currently being considered for its second re-authorization.

### AIDS Drug Assistance Programs

Under Title II of the CARE Act, Ryan White provides formula grants to States to improve the quality, availability and organization of health care services to persons with HIV/AIDS. Section 2616(a) requires allocation of a portion of those funds to establish AIDS Drug Assistance Programs (ADAPs). The ADAPs provide medications to low-income individuals living with HIV/AIDS who have limited or no coverage from private insurance or Medicaid. State ADAPs estimate that they served 64,460 clients in any given month of FY 1999 and approximately 108,600 clients in total.

Federal support for ADAPs has grown significantly. In the FY 2000 budget, Congress earmarked \$528 million for ADAP. This is an increase of 15 percent over the \$461 million for FY 1999. Overall, Federal contributions have risen dramatically from the original appropriation of \$52 million in FY 1996. In 1992, the year the Veterans Health Care Act was passed to limit drug costs, only 47 States had adopted a pharmaceutical

option. Prior to 1996, when the ADAP provision was created, grantees elected whether or not to have a pharmaceutical option. Pharmaceutical expenditures for the 47 States that chose the option totaled \$32 million. In addition to the Congressionally allocated Title II base award, ADAPs often receive contributions from State general revenue funds and Ryan White Title I grants to Eligible Metropolitan Areas.

Title II ADAPs operate within a Federal-State partnership which allows each State maximum flexibility to create a system that fits the needs of their HIV/AIDS population. State ADAPs decide on the administrative structure, the criteria for program eligibility, the drug formulary and the drug purchasing and distribution system. This has led to wide variations between States in the number of patients served, the particular drugs available and the prices paid for those drugs.

### **ADAP Cost Containment**

The ADAPs are facing fiscal challenges from: 1) increasing demand due to growing numbers of low-income people living with HIV and, 2) increasing costs of drug treatments due to a changing standard of care. The Public Health Service (PHS) guidelines recommend combination antiretroviral therapies that typically range between \$10,000 and \$12,000 a year per client. In this environment, cost containment has emerged as a key means to address the issue of client access.

In 1997 appropriations language (H.R. 104-863 to accompany H.R. 3610), Congress stated that they expect “that all States receiving AIDS drug assistance funding will employ cost-savings strategies to maximize assistance to HIV patients.” The HRSA maintains similar expectations. The HRSA’s Notice of Grant Awards states:

If your organization purchases or reimburses for outpatient drugs, an assessment must be made to determine whether the organization’s drug acquisition practices meet Federal requirements regarding cost-effectiveness and reasonableness (See 42 CFR Part 50, Subpart E, and OMB Circulars A-122 and A-87 regarding cost principles). If your organization is eligible to be a covered entity under Section 340B of the Public Health Service Act and the assessment shows that participating in the 340B Drug Pricing Program and its Prime Vendor Program is the most economical and reasonable manner of purchasing or reimbursing for covered outpatient drugs (as defined in section 340B), failure to participate may result in a negative audit finding, cost disallowance or grant funding offset.

This concern with cost effective spending is part of a larger public debate on the cost of

drug prices. Many elected officials are calling into question the appropriateness of current government acquisition and reimbursement prices. For example, according to the National Conference of State Legislatures, 23 States are considering legislation that strives to limit the cost of drugs purchased in their State. Seven of these legislative proposals take into consideration the drug prices on the Federal Supply Schedule (FSS) in establishing their price ceilings.

## **Drug Discounting Legislation**

In 1990, Congress identified a problem with increasing drug prices and enacted the Omnibus Budget Reconciliation Act (OBRA 1990). This law attempted to limit drug costs for the Medicaid program, establishing the Medicaid Drug Rebate Program. This program requires manufacturers to give Medicaid a rebate that is the greater of 15.1 percent of the Average Manufacturer's Price (AMP) or AMP minus the manufacturer's "Best Price" (BMP), whichever is lowest. The AMP is the average unit price paid by wholesalers to manufacturers. The BMP is the lowest price at which the manufacturer sells the drug to any purchaser.

As originally enacted, the calculation of the BMP included sales to Federal health care programs. As a result, drug manufacturers were reluctant to sell drugs to Federal health care programs at the very advantageous prices they had in the past because it could increase the rebates they had to pay to Medicaid, which represents a significant portion of the US pharmaceutical market. For this reason, the implementation of OBRA 1990 resulted in overall price increases for drugs purchased by Federal health care programs as well as inflation in the commercial market.

In order to remove the disincentive for manufacturers to give Federal programs the best possible price, the Veterans Health Care Act of 1992 (VHCA) was enacted. The VHCA also attempted to establish price controls to limit the cost of drugs to Federal purchasers and certain grantees of Federal agencies. In particular, Section 601 of VHCA corrected the pricing problems created by OBRA 1990 by excluding sales to Federal agencies from the calculation of the BMP. Section 602 of the Act enacted section 340B of the Public Health Services Act which provides drug price ceilings to certain grantees of the Public Health Service, including ADAPs. Section 603 of VHCA mandated minimum drug discounts for the Department of Veterans Affairs (VA), Department of Defense (DOD), Public Health Service, including the Indian Health Service, and later the Coast Guard. These agencies are commonly known as the Big 4. It additionally required that the four agencies be offered access to covered drugs and their statutorily discounted prices through the Federal Supply Schedule.

## Section 602: 340B Drug Pricing Program

Section 602 of VHCA enacted Section 340B of the Public Health Services Act. This statute requires manufacturers, as a condition for the receipt of Medicaid matching funds, to sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services agreeing to charge a price for covered drugs not to exceed the amount determined by statutory formula. This formula is roughly the AMP decreased by the Medicaid unit rebate amount. The Health Care Financing Administration (HCFA) recalculates the ceiling price, using the specified statutory formula, on a quarterly basis for the 340B Drug Pricing Program.

The ADAPs are included in Section 602's list of 'covered entities', making them eligible for 340B pricing discounts. Although the 340B program discounts are statutorily defined, participation remains voluntary. Those wishing to participate must comply with the following statutory requirements to access 340B discounts:

- 1.) Not request a discount for a drug subject to a Medicaid rebate;
- 2.) Not resell or otherwise transfer a discounted drug to a person who is not a patient of the entity;
- 3.) Maintain records of purchases and permit the Secretary and manufacturers to audit entity records pertaining to the drugs in question, in accordance with procedures established by the Secretary, to assure compliance with the first two requirements;
- 4.) Repay the manufacturer the amount of 340B discounts received for any violations of the first two requirements, if the manufacturer seeks restitution.

### ADAPs Participation in the 340B Drug Pricing Program

The CARE Act allows States significant flexibility in the design of their ADAP program. Generally, States' purchasing/distributing systems divide them into two categories: direct purchase and rebate States. However, State ADAPs operate in dynamic environments, so the description of each program that follows is a snapshot taken at a fixed point in time.

A direct purchase State purchases the drugs centrally through a State pharmacy, purchasing agent or public agency/hospital. At the time this study was conducted, twenty-three ADAPs participated in the 340B direct purchasing option<sup>1</sup>. A rebate State contracts with a pharmacy network/pharmacy benefits management company for the purchase of drugs and then reimburses them. At the time this study was conducted, twenty-four ADAPs received standardized rebates on drugs purchased from pharmacies through the 340B rebate option. Five ADAPs obtained voluntary manufacturer rebates to help contain drug costs, but elected not to participate in the 340B program.

<sup>1</sup> As of August 2000, only 22 ADAPs participate in the direct purchase option.

The remaining two ADAPs (Washington, DC and Guam) had instituted other purchasing mechanisms.

Section 340B contains no explicit language as to whether the required reduction in price should be obtained by a point-of-purchase (direct purchase) or through manufacturer rebates. When initially enacted, section 340B was only an option for the direct purchase States with a centralized purchasing agent. However, many ADAPs were initially established to operate under a pharmacy reimbursement model similar to Medicaid, without a centralized purchaser. This structure prevented those States' participation in the discount program. The HRSA issued a notice in the Federal Register on June 29, 1998 recognizing a rebate option for State ADAPs under 340B. States selecting this option would now receive the full statutory Medicaid rebate, lessening the burden on them to negotiate with individual manufacturer's for voluntary rebates.

It is generally believed that participation in the 340B direct purchasing option is currently the best option for ADAPs to maximize savings on pharmaceutical purchases. The ceiling price for the 340B direct purchasing option is approximately the AMP minus the Medicaid unit rebate amount. The ADAPs that utilize the 340B rebate option also obtain the Medicaid unit rebate amount from manufacturers, but only after reimbursing retail pharmacies at the average wholesale price (AWP), which tends to be higher than the AMP. Further, several Office of Inspector General (OIG) evaluations have indicated that government prices based on AWP are considerably more than prices available to commercial purchasers.

For those ADAPs not participating in the 340B program, one reason often cited is that the implementing guidelines that limit an entity to one contract pharmacy are too restrictive, limiting client access to needed drugs. Other ADAPs believe their drug purchasing and distribution arrangements provide them with lower costs than can be obtained by the 340B program, once all administrative costs are taken into consideration.

The HRSA published a proposal in the Federal Register on October 22, 1998 that would have made participation in the 340B program a grant requirement for eligible entities. After receiving negative feedback, HRSA decided that although it will not be a grant requirement, it is a program expectation.

### **Prime Vendor Provision**

Another 340B provision (340 (a)(8)) mandates the Secretary to establish a Prime Vendor Program for covered entities. The prime vendor would assist covered entities not only in accessing the 340B manufacturer drug price reductions, but also in negotiating competitive pricing for wholesaler drug distribution. In September 1999, HRSA announced its contract with Bergen Brunswick Drug Company (BBDC) making it the first prime vendor for the 340B Drug Pricing Program.

As prime vendor, BBDC will negotiate lower prices with about 600 pharmaceutical companies based on the large nationwide buying power of the 12,000 entities eligible to participate. Under the contract, BBDC will consolidate drug sales and delivery, resulting in lower distribution costs, reduced turn around time for delivery of drugs and decreased inventory costs.

The new Prime Vendor Program will offer ADAPs participating in the 340B direct purchasing option another cost containment strategy. Participation is voluntary, but the benefits to participants will be greatest if all eligible entities register to be prime vendor customers. Those ADAPs utilizing the rebate option and those not participating in the 340B Drug Pricing Program are not eligible to participate in the Prime Vendor Program for the same reasons they are not eligible for up-front pricing discounts. Intended as the primary vehicle for future drug discounting, HRSA anticipates the Prime Vendor Program to provide the best available pricing for its eligible entities.

### **Section 603: Federal Ceiling Prices and the Federal Supply Schedule**

As previously stated, Section 603 of VHCA mandated minimum drug discounts for four Federal agencies known as the Big 4. Specifically, the law states that prices to the Big 4 may not exceed 76 percent of the non-Federal average manufacturer price (non-FAMP). These statutorily discounted prices are typically referred to as the Federal ceiling prices. The law additionally requires that the four agencies be offered access to covered drugs and their Federal ceiling prices through the Federal Supply Schedule.

The FSS provides a schedule of contracts and prices for covered and non-covered drugs that allow agencies to purchase various quantities of pharmaceuticals while still obtaining the discounts associated with bulk purchasing. General Services Administration Administrative Order 4800.2E lists who has access to the FSS. While it includes the Public Health Service, it excludes Federal grantees such as ADAPs.

The VA manages several Federal Supply Schedules dealing with health care commodities for the entire Federal Government, including Schedule 65 I B for pharmaceuticals. In this capacity, it negotiates contracts using a non-competitive FSS negotiation procedure. The FSS contracted prices of covered drugs for the Big 4 may not exceed the statutory Federal ceiling prices stipulated in Section 603 of VHCA. To assure that the statute is being executed properly, the VA annually recalculates all Federal ceiling prices based on manufacturers' annual reports of non-FAMP for each covered drug. However, the contract prices for other entities allowed to use the FSS are usually negotiated based on 'most favored customer price' disclosures and may exceed the statutory ceiling. These negotiated prices are called the FSS Other Government Agency contract prices. These prices are frequently what non-Big 4 agencies authorized to use the FSS pay for drugs.

Of course, if a manufacturer wishes, it may maintain a single price list offering Big 4 or better prices to all FSS ordering activities. Many manufacturers do this to avoid having two price lists.

### **Non-Federal Average Manufacturer Price**

Section 603 of VHCA created a Big 4 Federal ceiling formula based on the non-FAMP. Non-FAMP is defined as “the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account (A) any prices paid by the Federal Government, or (B) any prices found by the Secretary to be merely nominal in amount.” In other words, non-FAMP is the manufacturers weighted average of commercial, non-Federal sales per unit.

The VA has determined that sales through a wholesaler *at* the 340B ceiling price should be excluded from the calculation of non-FAMP since they are statutorily defined prices. However, the VA considers any sales to 340B entities *below* the ceiling price as commercial sales, and includes these sales in the calculation of non-FAMP. This interpretation of non-FAMP by the VA has hindered 340B entities’ ability to successfully negotiate drug prices that are below the ceiling. Manufacturers do not want to sell at below 340B ceiling prices because those sales, unlike sales at the ceiling price which are exempt, will be reported as part of the non-FAMP. The inclusion of extremely low prices in the non-FAMP lowers the non-FAMP and subsequently the Federal ceiling prices that are calculated from it. In this way, sales to 340B entities below the ceiling prices negatively impacts the price manufacturers must give the Big 4. This creates a disincentive to provide the lowest possible prices to 340B entities.

### **Related Work by the Office of Inspector General**

The Office of Inspector General has released two reports regarding ADAP cost containment policies in the past few years. The first report, *Audit of State AIDS Drug Assistance Programs’ Use of Drug Price Discounts* (A-01-97-01501), focused on whether HRSA ensured that ADAPs effectively utilized available discount drug pricing programs. They concluded that participation in the 340B direct purchase option by all ADAPs could save the program a considerable amount of money and allow them to provide needed drugs to a larger number of individuals living with HIV/AIDS. The second report, *Audit of the Utilization of the Public Health Service 340B Drug Pricing Program* (A-01-98-01500), reviewed whether all eligible PHS funded entities effectively utilized the 340B Drug Pricing Program. They found that 66 percent of the eligible HRSA grantees in 1998 did not participate in the program.

The OIG has also conducted a variety of studies concerning Medicare payments for prescription drugs. Most notably, *Comparing Drug Reimbursement: Medicare and*

*Department of Veterans Affairs (OEI-03-97-00293)* compared Medicare drug allowances and the prices available to the VA. This report found that Medicare could save \$1 billion in 1998 if the allowed amounts for the 34 drugs studied were equal to the prices obtained by the VA.

---

## **SCOPE AND METHODOLOGY**

This inspection is a review of the 340B ceiling prices and the prices actually paid by AIDS Drug Assistance Programs for 10 commonly prescribed antiretroviral drugs. Specifically, we compared these prices to the Federal ceiling prices listed in the Federal Supply Schedule.

All of the price comparisons made are for the first three quarters of 1999 since this was the most current data HRSA and many ADAPs had on specific antiretroviral expenditures and rebates at the time data collection was conducted. All savings estimates based on this information have been annualized and only reflect the Federal share of ADAP funding. In FY 1999, Federal funding averaged 80 percent of total ADAP funding. The remaining 20 percent comes from the State general revenue funds and other sources.

Out of the expansive ADAP formularies, we focused on antiretroviral drugs because they constitute the most prescribed and effective drug therapies for treating HIV/AIDS. According to the ADAP Monitoring Project 1999 Annual Report, antiretroviral expenditures comprised 88 percent of overall ADAP spending in June 1998. We selected 10 brand name, single source drugs of the possible 16 Food and Drug Administration approved antiretroviral drugs. The 10 drugs we reviewed and their National Drug Codes are listed in Appendix B.

We based the comparison of prices on the drug acquisition cost. For the purposes of this study, we define drug acquisition cost as the basic cost of the drug to the ADAP. This includes all discounts, rebates or any other benefits. It also includes any additional fees charged by wholesalers or other contracted middle-men. For example, the Texas ADAP contracts with a prime vendor to purchase drugs. The prime vendor supplies the ADAP with all the drugs on its formulary for 340B ceiling prices plus a one percent distribution fee.

Our definition of acquisition cost does not incorporate the overall program costs of delivering pharmaceuticals to eligible clients. This narrow definition of drug cost was necessary to control for the differences in administrative and drug distribution systems between the ADAPs and the agencies that access the FSS Federal ceiling prices. Further, specific administrative data was unavailable since ADAPs typically do not break-out overhead costs, such as storage and distribution, per drug.

Unfortunately, this narrow definition of drug cost does not entirely control for the

difference between the rebate ADAPs and the Big 4 agencies that access the Federal ceiling prices. The Big 4 agencies, like the direct purchase ADAPs, buy needed pharmaceuticals directly from a manufacturer or wholesaler. This is their acquisition cost. Rebate States, on the other hand, typically reimburse pharmacies for drugs dispensed to ADAP clients at retail drug prices minus a small pharmacy discount. These higher retail prices, to some extent, reflect the pharmacies' role in storing and disbursing the drugs on behalf of the rebate ADAPs. In order to account for the hidden storage and distribution fees incorporated into these prices, a separate analysis was conducted. In this analysis, we subtracted out an industry average for these costs from rebate ADAPs reimbursement expenditures in order to make them more comparable to the Federal ceiling acquisition prices.

To conduct our analysis, we reviewed the ADAP Monthly Report for the first three quarters of FY 1999. This report tracks the unit price, the unit rebate amount, the volume prescribed and the dispensing fees for a limited set of pharmaceuticals. We also reviewed the FY 1998 AIDS Pharmaceutical Assistance Annual Administrative Report, the State ADAP Profiles, and the ADAP portion of Title II applications for FY 1999.

We also gathered information regarding pharmaceutical pricing from HCFA and the VA. The HCFA supplied us with the 340B ceiling prices and the Medicaid unit rebate amount information. The VA provided us with data on the FSS Federal ceiling and the FSS contract prices.

To gather data on actual State ADAP expenditures, we sent a survey to each of the 52 operational ADAPs. Surveys were distributed via facsimile in February 2000 and the survey data was collected between February and April 2000. We received 49 surveys back for a response rate of 94 percent. New Hampshire, Wyoming and Maine were unable to provide us with the information we requested.

The survey requested States to record their ADAP expenditures for the first three quarters of 1999. For each of the 10 drugs, ADAPs listed the unit price, quantity for a 30 day supply, total quantity for the quarter, and dispensing, transaction and administrative fees where applicable. States utilizing the 340B rebate option or States obtaining other manufacturer rebates also reported the unit rebate amount, total rebate amount and the number of units that received a rebate. The survey also asked States to describe their ADAP's structure for purchasing and distributing drugs in order to get a contextual understanding of drug purchasing expenses.

We conducted extensive follow-up on the survey. On March 1, 2000, we hosted a national teleconference arranged by the National Alliance of State and Territorial AIDS Directors for ADAP Directors. The purpose of the teleconference was to discuss the complexities of individual programs and to reach agreement on how to uniformly report data. We spoke individually with State programs where necessary for clarification.

We have taken precautions not to disclose any information that would allow the reader to trace back to the manufacturers price since this is proprietary information. Towards this end, all estimates have been rounded. We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

# FINDINGS

## **ADAP ceiling prices are on average 16 percent higher than Federal ceiling prices**

The ceiling prices limiting drug expenditures for ADAPs are, on average, 16 percent higher than the Federal ceiling prices limiting drug costs for the Big 4. For the 10 sample drugs the ceiling prices available to ADAPs during the first three quarters of 1999 are at least 12 percent more than the Federal ceiling prices and range up to 21 percent more. As a result, ADAPs that take advantage of the ceiling prices offered by the 340B drug pricing program will pay anywhere from 9 cents to 70 cents more per pill than the Big 4 pays for the same drug. On average, ADAPs will pay 29 cents more per pill and 32 dollars more per bottle than the Big 4 agencies pay for the same drug.

The formulas for both 340B and Federal ceiling calculations are stipulated in the Veterans Health Care Act of 1992. The intention of this legislation was to place limits on the prices of drugs procured by Federal purchasers. Yet the ceiling price calculations stipulated for each program are different resulting in prices that are consistently higher for entities covered under Section 602. Section 602 of VHCA lays out a statutory calculation for the ceiling prices available to ADAPs that is roughly equivalent to AMP, disregarding Federal sales, minus the Medicaid unit rebate amount. This rebate ranges from 11 to 15 percent. The statutory formula laid out in Section 603 stipulates that Big 4 are required to receive a minimum 24 percent discount off the non-Federal Average Manufacturer Price which is the AMP disregarding Federal sales. Thus, ADAPs are receiving 11 to 15 percent off a non-FAMP equivalent while the Big 4 are guaranteed 24 percent off non-FAMP.

While Section 602 and 603 ceiling prices determine the highest amount that covered entities can pay for pharmaceuticals, there is nothing in the law prohibiting the negotiation of prices lower than the stipulated ceiling prices. In fact, Section 602 (10) reads, “Nothing in this statute shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price.” However, only 4 of the 22 ADAPs in the direct pricing program indicated that they had been able to negotiate below 340B ceiling prices. The VA is typically able to contract below their ceiling price for approximately one-third of the covered pharmaceuticals. Even with this potential, ADAPs are at a disadvantage given that they start their negotiations from a higher ceiling, do not individually command enough volume to demand large concessions and manufacturers’ have a disincentive to negotiate below ceiling prices with ADAPs since these prices will be included in non-FAMP.

## **ADAPs could have saved nearly \$58 million in 1999 if allowed to purchase the 10 drugs at Federal ceiling prices**

Comparing the actual per drug expenditures of the ADAPs to what they would have paid if they had access to Federal ceiling prices, results in \$57.5 million in Federal savings for ADAPs in 1999. This savings represents 22 percent of the \$266 million paid for these drugs with Federal funding in 1999. Considering expenditures from all sources of funding, State, local and Federal, ADAPs could have saved \$72 million if given access to Federal ceiling prices.

A general estimate of ADAP savings for all drugs can be obtained from analyzing the FY 1998 AIDS Pharmaceutical Assistance Annual Administrative Report. In this annual document, ADAPs reported drug expenditures of \$538 million on 576 pharmaceuticals. The Federal portion of that spending would be approximately \$432 million. If ADAPs were able to obtain the 16 percent average amount of savings indicated by our analysis, the estimated savings would be \$69 million. Again, we would expect this savings estimate to have increased since FY 1998 given that prescription drug costs are the fastest growing segment of health care costs. Since 1993, they have risen at a 12 percent annual rate. The ADAP increases in drug expenditures are consistent with this national trend. The March 1999 National ADAP Monitoring Project indicates that national per client ADAP expenditures increased by 12 percent between 1997 and 1998. A 12 percent increase in costs would place the estimated FY 1999 savings for all drugs at \$77.3 million.

### **The majority of savings derives from 3 of the 10 pharmaceuticals**

The ADAPs could have saved \$36.8 million, representing over half of the total savings estimate, if they were able to purchase just 3 of the 10 drugs at the Federal ceiling prices. Purchasing Viracept at Federal ceiling prices would have saved \$14 million. The ADAPs could have saved another \$13 million by purchasing Combivir at Federal ceiling prices and \$9.6 million on D4T purchases. The median savings for all 10 drugs is \$4 million.

For Combivir and Viracept, the large potential savings reflect the fact that these are expensive, heavily prescribed pharmaceuticals. Any reduction in cost will have significant program savings. According to the data we received for the first three quarters of 1999, approximately 139,000 bottles of Combivir were procured by the ADAPs. This represents the third largest volume of any of the 10 drugs. Viracept had the fourth highest volume at 136,000 bottles. Viracept and Combivir are also among the most expensive of the drugs we reviewed.

While D4T was the most heavily prescribed drug of the 10 we analyzed with 175,000 bottles, it is also the pharmaceutical with the largest difference between the 340B price

and the Federal ceiling price. The 340B ceiling price for D4T is 21 percent higher than the FSS Federal ceiling price.

### **ADAPs could have served thousands more people living with HIV/AIDS**

The \$57.5 million savings could have purchased additional pharmaceuticals to meet the pharmaceutical needs and improve the lives of several thousand more individuals living with HIV/AIDS. Using the estimate of \$12,000 a year for combination antiretroviral therapy, the savings could have purchased an complete regimen for almost 5,000 additional clients in 1999.

Focusing solely on the three drugs with the most savings, Viracept, Combivir and D4T, also results in a substantial increase in patient access to life-saving therapeutics. The \$57.5 million in savings could have purchased an additional 414,000 bottles of D4T at Federal ceiling prices. This translates into a prescription of a bottle per month for 34,500 patients. Alternately, the \$57.5 million in savings could have purchased 176,000 additional bottles of Combivir for 14,700 patients' annual needs or 166,400 bottles of Viracept for 14,000 patients.

Demand already exists for the greater capacity that these savings would create. According to the Kaiser Family Foundation's ADAP Monitoring Report, as of July 1999, there are 11 ADAPs with waiting lists of eligible clients. Other ADAPs have capped the amount of expenditures per patient or created an enrollment cap in order to deal with the inequity between demand and available resources.

Demand for HIV/AIDS pharmaceuticals continues to increase. The standard of care for persons living with HIV/AIDS is increasingly reliant on drug therapy. The National Institutes of Health/PHS *Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents* calls for the use of combination antiretroviral therapy comprised of at least three drugs. Additionally, the numbers of HIV-infected, low-income, traditionally underserved, population are climbing. This in combination with the fact that approximately 75 percent of the HIV population has no private health insurance will continue to place increasing demands on the ADAPs to provide more pharmaceuticals.

---

### **Given access to Federal ceiling prices, ADAPs enrolled in the direct purchase option would save \$14 million. ADAPs utilizing the rebate option would save \$39 million**

All State ADAPs showed significant savings when the prices they paid for drugs were compared to the Federal ceiling prices. When broken out by the type of 340B participation, direct purchase States (22 ADAPs) would save \$14.4 million and rebate States (22 ADAPs) would save \$39 million. For the five non-participating States, the

savings equals \$4 million, bringing the total to \$57.5 million in Federal savings. Appendix A contains a break-out of program saving by State ADAP.

### **Even though Direct purchase States access the 340B ceiling price, there are significant program savings when compared to the Federal ceiling prices**

Even though direct purchase States buy drugs at the best price available to ADAPs, they would be paying \$14.4 million less if granted access to the Federal ceiling prices. The three direct States that would produce the largest savings are Louisiana, Puerto Rico and Texas. These are three of the largest ADAP programs operating. The savings in these three States would total \$7.4 million. The range of savings for direct purchase States is \$23,000 in Delaware to \$3 million in Texas with median savings of \$436,000.

### **Comparing rebate States drug expenditures to the Federal ceiling prices results in the most program savings for the drug assistance program**

Rebate States would have saved \$39 million if granted access to the Federal ceiling prices. The three rebate States producing the most savings are California, New Jersey and New York, with combined savings of \$29 million. Their savings represent 75 percent of the total \$39 million in savings from rebate States and could impact the nearly 40,000 clients enrolled in those States. The range of savings for rebate States was \$22,000 in Alaska to \$13.7 million in New York, with median savings of \$575,000.

The excessive amount rebate States pay for drugs is related to the reimbursement model they utilize. Rebate ADAPs reimburse pharmacies at the average wholesale price (AWP), or the suggested list price for retailers set by manufacturers, minus a pharmacy discount. Our data showed a range of pharmacy discounts of 10 to 16 percent. The average discount obtained was 12.2 percent. In addition to these pharmacy discounts, rebate ADAPs receive the Medicaid unit rebate amount from manufacturers on a quarterly basis. Direct purchase ADAPs also use the Medicaid URA to discount the cost of drugs, but it is subtracted from the lower AMP, the average manufacturers price, prior to the drug purchase.

For the 10 drugs we examined, we found AWP, the base drug price paid by rebate ADAPs, to be 25 percent higher than AMP. This finding parallels an analysis of pharmaceutical pricing by the National Association of Chain Drug Stores. They found that in 1999 only 75.7 percent of the cost of a prescription went to the manufacturer.

In order to reduce drug expenditures, rebate and nonparticipating ADAPs have instituted various additional cost containment measures. These efforts include obtaining pharmacy or additional manufacturer discounts, voluntary rebates and the subsidy of private

insurance premiums or co-payments<sup>2</sup>. The \$39 million savings projection takes into account pharmacy discounts and all manufacturer rebates. It does not take into account savings obtained through the subsidy of private insurance since this cost containment measure would still be viable if ADAPs were granted access to Federal ceiling prices. Nine States<sup>3</sup> supplied us with information regarding savings achieved through the subsidy of private insurance. The savings gained from providing insurance in these nine States totaled \$4.3 million.

In order to analyze the impact of hidden distribution fees on our comparison, we performed a separate analysis of rebate ADAPs. This comparison took into consideration the fact that the prices rebate ADAPs pay may include storage and distribution costs whereas the Federal ceiling prices do not. Thus, we subtracted a standard distribution fee from the drug prices reported to us by the rebate States.

The National Association of Chain Drug Stores estimates 2.3 percent of the retail price of drugs goes to wholesalers for storage and distribution costs. On the other hand, Bergen Brunswick believed that recent trends in the commercial pharmaceutical industry have led to most wholesalers charging distribution fees of 1 percent or less. Finally, the VA has a negative distribution fee negotiated in exchange for maintaining their business. Prior to the negative fee, the VA was paying .03 percent per bottle in distribution fees. We selected the 2.3 percent estimate to provide rebate ADAPs with the most generous allotment for distribution fees. In this analysis, we found that rebate States would still save \$35 million if granted access to Federal ceiling prices. States not participating in the 340B program would still save \$3.4 million.

<sup>2</sup> Direct purchase ADAPs can also implement a health insurance component within their program.

<sup>3</sup> Of the nine ADAPs that reported insurance data, 6 were rebate ADAPs, 2 were non-participating ADAPs and one was a direct purchase ADAP.

# RECOMMENDATIONS

Two primary concerns regarding the cost effectiveness of ADAP expenditures are drug acquisition and drug distribution. In many ways these two issues are intertwined since the method of distribution can determine an acquisition model. In this inspection, we focused primarily on the base acquisition cost of the drugs in order to compare prices across government programs. While we recognize that this is a simplified picture and did take steps to estimate distribution expenditures, we strongly feel that lower acquisition costs would be advantageous to the program and its ability to provide life-saving drugs to low-income individuals living with HIV/AIDS. Once this option for low cost drugs is made available to ADAPs, the more complicated comparison of distribution systems can be made and the most economical, efficient and accessible means to distribute HIV/AIDS pharmaceuticals can begin to be addressed.

Fundamentally, any program savings translates into an enhanced ability to serve those in need. Access to Federal ceiling prices would result in overall program savings of \$72 million. This level of savings could provide a year's regimen of combination therapies to thousands of additional clients. In fact, demand already exists for the greater capacity that would be created with these savings. Facing an increasing rate of HIV infection among low-income individuals, several ADAPs have been forced to institute program limitations in the form of waiting lists, enrollment caps and per client expenditure limits in order to deal with the inequity between demand and available resources.

---

## **HRSA should seek legislation to change the 340B ceiling price calculation to the Federal ceiling price calculation**

We recommend that HRSA work towards legislatively changing the calculation of the 340B drug price ceiling in the public health statutes to the statutory formula mandated in Section 603 of the Veterans Health Care Act of 1992. Changing this ceiling calculation would create significant Federal savings of \$57.5 million for ADAPs. While our study focused on ADAP cost savings, ADAPs are only one of the entities that would be impacted by changing the 340B ceiling prices. However, there is no logical reason to carve out ADAPs from the rest of the 340B eligible entities since all of the entities are purchasing drugs with Federal dollars. Further, there is no reason why all federally appropriated funds covered by the law should not be spent in the most economical way in order to serve additional medically needy clients. Although it was not in the scope of our study to provide a precise estimate regarding the savings available to all 340B Drug Pricing Program eligible entities, a 16 percent reduction in the ceiling price could save these entities \$240 million in Federal funds.

Technically, there are three parts to the 603 pricing formula. The base calculation is AMP minus 24 percent. The second part of the calculation is an annual adjustment using the Consumer Price Index for urban consumers. This is intended to ensure that the ceiling prices do not increase more than the rate of inflation. The third part of the calculation is a dual calculation performed starting the second year of a multi-year contract. This calculation compares the inflation adjusted AMP minus 24 percent to the previous year's FSS contract prices adjusted for inflation. The lower of the two prices becomes the new Federal ceiling price. We recommend that only the first two aspects of the calculation be utilized to create a ceiling price for the 340B entities. Since the dual calculation entails using prices from the previous years' FSS contracts, it would create a link between the pricing of these two groups. We are concerned that this linkage could have a detrimental effect on the ability of the VA to negotiate the lowest possible prices for the FSS.

Changing the ceiling calculation would further the legislative intent of VHCA to limit the prices of drugs to government purchasers. Although VHCA successfully established ceiling prices to limit costs for a specified group of entities, it failed to produce a single discount ceiling for all Federal purchases made by these organizations. Section 603 covers direct Federal purchasers while Section 602 generally covers entities that make pharmaceutical purchases with Federal dollars. Despite the fact that both are expending Federal dollars, entities covered by 602 are provided with a smaller discount. We recommend that the current inequity within the law be rectified by standardizing the ceiling calculation for all entities covered under Sections 602 and 603 of VHCA. Section 603 ceiling prices already cover the Public Health Service and "any entity that receives funds under the Public Health Service Act."

Limiting pharmaceutical costs is even more critical today than when VHCA was passed in 1992. Medical advances have produced drugs that are often the therapy of choice for persons living with HIV/AIDS. These medications have the power to improve quality of life by inhibiting the progression of the disease and to prolong life. The PHS recently issued guidelines promoting the use of combination antiretroviral drug therapy for treating persons living with HIV as well as AIDS. As a result of this reliance on drug therapy, pharmaceutical purchases have been increasing at a dramatic rate.

Changing the calculation would be beneficial because the 340B prices would no longer be tied to the Medicaid rebate calculation. Currently, the Section 602 calculation is AMP minus the Medicaid URA. Medicaid is a reimbursement program whereas the 340B Drug Pricing Program is intended to provide an up-front discount off the purchase price<sup>4</sup> of pharmaceuticals. This difference in structure has led to technical problems regarding

<sup>4</sup> A 340B rebate option was designed to specifically accommodate those ADAPs with a reimbursement structure. Only ADAPs are eligible to participate in this option. At the time this study was conducted, 23 ADAPs participated in the rebate option.

calculating the ceiling prices. Medicaid allows changes to the Medicaid URA data to be implemented retroactively. Since the 340B provides an immediate discount at point of purchase, many of these retroactive changes are never reflected in the discount they are provided. Adjustments have proven difficult to identify and implement. On the other hand, Section 603 pricing, administered by the VA, is similar to the 340B program in that it is an up-front, time of purchase discount program. Further, the VA has reliable, easily validated data that is tracked as pricing changes occur.

Making this change will impact the manufacturers in several ways. Primarily, the change would allow all 340B covered entities to access outpatient covered drugs at the lower 603 Federal ceiling prices. Beyond the 52 ADAPs, there are close to 12,000 eligible 340B entities. However, it has been estimated that only 66 percent of them participate in the 340B Drug Pricing Program. In total, pharmaceutical expenditures by 340B entities in 1999 represented approximately 1 percent of the domestic pharmaceutical market. The Big 4 agencies, already covered under Section 603, represent just another one and a half percent of the market. By means of comparison, Medicaid comprised 10 percent of the market. A potential benefit for the manufacturers is a simplified, uniform Federal pricing system to track and report, with price-changing data submissions and recalculations required only once a year. Currently, manufacturers report quarterly data to HCFA and face quarterly recalculation of drug prices for the 340B drug pricing program.

Given the limited scope of the proposed changes, it seems likely that any loss due to lower Federal prices to these 12,000 entities could be regained in additional sales volume. At the time this study was conducted, five ADAPs had waiting lists while the demand for combination therapies of two or three drugs continues to accelerate. Further, the incremental costs of producing additional drugs is minimal. Most of the investment typically occurs during the research and development phases. However, in the case of these 10 drugs, even these expenses have been mitigated by the Federal subsidy of basic research and clinical trial testing. Given these facts, manufacturers should be able to produce more drugs without significantly eroding their profit margin and their ability to recoup their initial investments.

This recommended change could also mean some adaptations for the VA. The VA calculates the Federal ceiling price for the Big 4 annually based on manufacturer's reports. To maximize efficiency, it would be beneficial if the VA would enter into a data sharing agreement with HRSA to annually provide this ceiling price information to them. Although both the Big 4 and 340B eligible entities would have access to the same ceiling prices for outpatient covered drugs, the programs would stay discrete. The entities benefitting from 602 and 603 are very different in ownership and control, creating great differences in the administration of the two programs. Further, HRSA's prime vendor is perfectly situated to negotiate contracts at or below the 603 ceiling price for the 340B covered entities similar to the way the VA negotiates annual contracts for users of the FSS including the Big 4.

While the legislative process to accomplish these changes is underway, HRSA should encourage the prime vendor to negotiate prices that resemble those the Big 4 currently receive. Maximum impact could be achieved by focusing on the drugs or the State ADAPs that we found to have the largest potential for program savings.

---

## **To allow ADAPs to negotiate the lowest prices possible, HRSA should seek legislation to exempt all sales to 340B covered entities from the calculation of Non-Federal Average Manufacturers Price**

To accomplish this, we recommend that HRSA seek to add exclusionary language to the statutes codifying the 340B drug pricing program (42 USC 256B) stating that any price negotiated by the prime vendor or any 340B eligible entity below the 340B statutory ceiling price would be excluded from the calculation of the non-FAMP. Currently, sales *at* the 340B ceiling price are excluded from the non-FAMP calculation, but sales *below* the ceiling are considered commercial sales by the VA and are included in the calculation.

The inclusion of sales below the 340B ceiling price in non-FAMP creates disincentives for manufacturers to negotiate prices that are lower than ceiling prices for ADAPs. The VA considers sales to 340B entities below the 340B ceiling price as commercial sales, and therefore, includes them in the calculation of non-FAMP. Non-FAMP is fed into the VA's calculation of the Federal ceiling prices. The inclusion of extremely low prices, such as prices below the 340B ceiling, could lead to lower ceiling prices for the large volume purchased by the Big 4. This potential of ratcheting down Federal ceiling prices discourages manufacturers from offering lower than ceiling prices to 340B entities.

The inclusion of sales below the 340B ceiling price in non-FAMP does not appear to support the intent of VHCA or Congressional mandates. The VHCA specifically does not prohibit manufacturers from offering prices below the ceiling. Section 340B (10) states that there is "no prohibition on a larger discount" from manufacturers to 340B eligible entities. In light of this, the Congress has encouraged covered entities to aggressively seek drug price reductions as a means to expend their resources in the most economical way feasible. Further, Congress excluded Federal sales from the calculation of Best Manufacturers Price in Section 601 of VHCA in order to correct a similar pricing disincentives faced by government purchasers due to the implementation of the Medicaid Rebate Program.

This non-FAMP issue presents a major barrier to HRSA's Prime Vendor in their ability to negotiate the lowest possible prices. If lower than ceiling price sales to 340B entities continue to be included in non-FAMP, the prime vendor cannot successfully negotiate for prices lower than the 340B ceiling, currently, or lower than the 603 ceiling potentially.

Several manufacturers have made it clear to HRSA that they will not offer deeper discounts to 340B eligible entities until the non-FAMP issue is resolved. The ability to offer considerable discounts is pivotal to the success of the Prime Vendor Program since it is a voluntary program. The more entities it can persuade to join the program by offering lower than ceiling prices, the larger its bargaining power, and the more price concessions it can negotiate on behalf of the ADAPs.

Excluding below ceiling prices from non-FAMP will also provide consistency in the interpretation of ceiling calculations across the Federal Government. The HCFA excludes all 340B sales, ceiling and below, from their calculation of AMP for the Medicaid Rebate Program. The VA, on the other hand, includes any 340B sale below the statutory ceiling in its calculation of non-FAMP. The AMP, as used by HCFA, and non-FAMP should be equivalent since each is calculated to represent the average, non-Federal price paid to manufacturers by wholesalers.

Over the years, HRSA has requested that the VA change their reporting procedure so that it does not interfere with the 340B Drug Pricing Program. Specifically, they have asked the VA to permit drug manufacturers to exclude all sales to 340B covered entities when they report to the VA on their non-FAMP. This repeated administrative request from HRSA has proved ineffective, therefore, we recommend a statutory change excluding *all* 340B sales from the calculation of non-FAMP.

---

## **HRSA should continue to work with rebate and non-participating ADAPs to devise ways to grant them access to up-front drug discounts**

Rebate and non-participating ADAPs utilize a reimbursement model for the purchase and distribution of pharmaceuticals that prevents them from being eligible for up-front drug discounting. They are ineligible for the direct purchase option of the 340B program and they will not be able to take advantage of any savings negotiated by the prime vendor. Further, their current structure would prevent them from accessing the Federal ceiling prices if that legislative change was enacted.

There are several ways HRSA could work with rebate States to allow them to access direct purchase discounts:

***1) HRSA should continue to provide incentives and technical assistance for States to join the direct pricing/Prime Vendor option.***

We recognize that HRSA has in the past and continues to strongly encourage all ADAPs to participate in the 340B direct purchase option. On October 22, 1998, HRSA released a Federal register notice stating that participation in the 340B program would be a

condition of the grant. While HRSA decided this approach would be too administratively burdensome, they did make participation in the 340B program ‘expected.’ The Notice of Grant Awards now indicates that if participating in the direct purchase or Prime Vendor option is determined to be the most economical means to purchase drugs, “Failure to participate may result in a negative audit finding, cost disallowance or grant funding offset.”

The HRSA should work with the remaining rebate and non-participating ADAPs to educate them to the significant program savings available through the current up-front drug pricing program and the even more dramatic savings potentially available through accessing Federal ceiling prices. A 1999 evaluation found that “both non-participating and participating entities could benefit from education efforts to help them to better understand the program.” Where feasible, HRSA could help ADAPs develop cost-effective, creative solutions to restructuring their program. Best practices models could be disseminated and used as a starting point to create a system geared to meet the needs of each ADAP as well as the eligibility requirements for participation in up-front pricing discounts.

While not suitable for all State ADAPs, one possible way to transform a reimbursement system into a system with a single central purchaser, without sacrificing wide distribution, would be to engage a mail-order pharmacy. Mail-order pharmacies typically have a 2 day turn-around and can ship to any address in the State. Further, mail-order pharmacies are high-volume operations and can locate where costs are low, keeping administrative expenses low. Illinois recently moved to a mail-order system in order to access 340B ceiling prices. They pay the pharmacy a \$15.93 per transaction charge. This includes all labor and administrative cost as well as dispensing fees.

## ***2) HRSA should revisit the potential of allowing multiple contract pharmacies.***

Despite HRSA’s efforts to encourage participation in the direct purchase option, there remain serious administrative, fiscal, technical and political barriers to altering some State’s structures to comply with program eligibility rules. The largest obstacle for most rebate and non-participating ADAPs is the program guidance requiring a single State or contract pharmacy. The ADAPs with a reimbursement model make use of vast retail pharmacy networks that purchase and distribute pharmaceuticals on their behalf. Restructuring this system could mean having to develop internal means to purchase, warehouse and distribute drugs. It could also mean less convenient access for their clients.

In order to achieve maximum participation in drug price savings, HRSA should support the submission of proposals for multiple contract pharmacies and review them for potential receipt of up-front pricing discounts. On August 23, 1996, HRSA set forth program guidance allowing ADAPs to use contract pharmacy services. It is this program

guidance, not the law, that holds ADAPs to a single contract pharmacy in order to be eligible for 340B direct pricing. However, the guidance also states that HRSA will evaluate “ the feasibility of permitting covered entities to contract with more than one site and contractor.”

In order to support the submission of multiple contract pharmacy proposals, HRSA should create a system of review for such proposals. They should also provide guidance regarding the level of drug diversion and client eligibility safeguards needed to reasonably consider allowing a multiple contract pharmacy model. Some of these considerations are already outlined in Appendix A, Suggested Contract Provisions, of the Contract Pharmacy Services guidance. This document could be expanded to include more specific monitoring and reporting standards for rebate and non-participating ADAPs to adhere to if they were seeking up-front pricing discounts.

The potential for drug diversion in a multiple pharmacy model is a concern. Despite the fact that the 340B statute contains explicit prohibitions against drug diversion and duplicate discounting, the Pharmaceutical Research and Manufacturers of America filed a lawsuit in 1996 to prevent 340B covered entities from contracting with pharmacies. They claimed that “companies cannot adequately protect themselves from diversion of low-price drugs to non-covered patients.” In response, HRSA indicated that the Department was unaware of any documented instances of intentional drug diversion. They also pointed out that the law stipulates that the drug manufacturers and the government have the right to audit records of the organizations using the program and that entities are responsible for reimbursing manufacturers for any losses due to drug diversion.

To respond to drug diversion concerns, HRSA could offer specific technical assistance to States concentrating on effective ways to safeguard against drug diversion. This could entail providing technical assistance regarding effective drug tracking and reporting systems and techniques to strengthen eligibility screening. The HRSA has already established an initiative to improve ADAP infrastructure by focusing on the development of centrally administered, integrated data systems. A 1998 OIG study of ADAP monitoring systems, *The Ryan White Evaluation Systems: ADAP* (OEI-05-98-00390), found that drug assistance programs in the eight States visited have centralized computer systems that sufficiently track client enrollment and eligibility as well as monitor pharmacy claims information. Activity reports from these databases are typically reviewed on a monthly, sometimes weekly, basis.

The rebate option was instituted to allow States with a reimbursement structure to access standardized savings greater than those they were able to negotiate on their own. While this cost saving measure along with others such as the subsidy of private insurance has resulted in program savings, our analysis indicates even greater savings would be achieved if the rebate ADAPs could access up-front price discounts similar to those granted the Big 4. Even when estimated distribution fees are subtracted from rebate and

non-participating States' drug expenditures, they would still save \$38.4 million at Federal ceiling prices. It is necessary to achieve the aim of the 340B program and adhere to Congressional mandates that Federal funds are used in the most cost effective way possible that rebate and non-participating States be given every opportunity to access low cost drugs.

# AGENCY COMMENTS

The HRSA concurred with the report's findings and recommendations. They also offered suggestions for clarifying the report and making other technical changes. We appreciate their suggestions and, where appropriate, we changed the report to reflect their comments. The complete text of HRSA comments can be found in Appendix C. Further staff from the office of the Assistant Secretary of Planning and Evaluation (ASPE) expressed concerns regarding our first recommendation. We will address their concerns in this section.

In response to our first recommendation, HRSA indicated that they will actively review the need for such a legislative change and make an appropriate recommendation to the Department. They agreed that changing the calculation of the 340B ceiling pricing to the Section 603 pricing formula could further stretch Federal dollars to serve additional patients whose current needs remain unmet. Further, they indicated that linking the 340B pricing calculation to Section 603, a pricing mechanism intended for up-front discounted purchasing, would result in more accurate and timely data for the pricing calculations.

The HRSA agreed with our second recommendation reiterating the fact that the inclusion of sales to 340B covered entities below the current 340B statutory ceiling price into the non-Federal Average Manufacturer Price may cause manufacturers to avoid negotiations that would provide further discounts to the 340B covered entities.

Regarding the third recommendation, HRSA pointed out several ongoing activities to promote ADAP participation in the 340B direct purchase option, including the implementation of the Prime Vendor Program. We commend their efforts in this area. The HRSA cautioned, however, that one potential solution offered, that of transforming reimbursement systems into direct purchase systems via mail order pharmacies was not necessarily the perfect solution for every State ADAP. They pointed out that States often face unique concerns and constraints that would make a mail order system unworkable. We agree with HRSA's assessment.

One technical concern HRSA expressed was with our calculation of the percentage of Federal funding for ADAPs. We report that Federal funding comprised 80 percent of total ADAP funding. This figure is based on data HRSA supplied to us from the ADAP portion of the FY 1999 Title II Grant Applications. The HRSA used data from the same source to arrive at a 74 percent Federal share. The HRSA percentage is calculated using a denominator they have titled 'Total ADAP Resources' which not only includes Federal, State and other funding, but a category of cost-savings strategies. Our denominator excludes the category 'cost-savings strategies' since it is our understanding that these are ADAP resources, but they do not constitute an ADAP funding source.

The concern raised by ASPE staff has to do with the larger policy implications of our first recommendation. In particular, they are concerned that allowing 340B entities to utilize the Section 603 Federal ceiling price might affect the ability of the VA and the Big 4 to maintain the low prices they currently obtain. We understand their concern about the negotiations. In fact, it was our concern with this very issue that lead us to recommend that 340B pricing be linked to the statutorily defined Federal ceiling price as opposed to the negotiated Federal Supply Schedule (FSS) contract prices the VA and the Big 4 actually pay for drugs. The Federal ceiling price acts only as an upper ceiling to the FSS prices. In reality, the VA uses its considerable volume to negotiate prices below the Federal ceiling. Allowing 340B entities to utilize the same ceiling calculation as the VA and the Big 4 merely provides them with an equitable starting point. Discussions with the VA confirmed that this is a realistic recommendation in consideration of larger policy implications.

**Projected Savings if ADAPs Purchased Drugs at Federal Ceiling Prices  
By State for CY 1999**

<b>States</b>	<b>Federal Savings</b>	<b>State/Other Savings</b>	<b>Total Savings</b>
<b>Direct Purchase States</b>			
TEXAS	\$3,188,827.19	\$227,411.05	\$3,416,238.24
LOUISIANA	\$2,121,753.07	\$0.00	\$2,121,753.07
PUERTO RICO	\$2,110,284.76	\$445,620.56	\$2,555,905.32
COLORADO	\$1,153,847.63	\$298,881.17	\$1,452,728.81
ILLINOIS	\$837,363.66	\$410,718.12	\$1,248,081.79
VIRGINIA	\$833,214.59	\$78,838.64	\$912,053.23
GEORGIA	\$825,576.97	\$151,860.11	\$977,437.08
SOUTH CAROLINA	\$692,909.46	\$63,876.75	\$756,786.21
ALABAMA	\$514,536.07	\$13,944.96	\$528,481.03
KENTUCKY	\$488,075.56	\$19,486.20	\$507,561.76
NEVADA	\$487,965.83	\$190,141.56	\$678,107.38
ARIZONA	\$384,879.54	\$94,855.93	\$479,735.47
MISSISSIPPI	\$234,993.81	\$41,703.30	\$276,697.11
NEW MEXICO	\$130,204.14	\$141,954.05	\$272,158.19
TENNESSEE	\$124,160.02	\$0.00	\$124,160.02
HAWAII	\$109,362.24	\$25,360.28	\$134,722.51
IOWA	\$99,532.64	\$0.00	\$99,532.64
NEBRASKA	\$68,254.93	\$0.00	\$68,254.93
FLORIDA	\$40,509.68	\$6,055.50	\$46,565.18
MONTANA	\$38,113.22	\$0.00	\$38,113.22
DELAWARE*	\$23,018.90	\$0.00	\$23,018.90
DC**	-\$41,153.55	-\$3,711.95	-\$44,865.50
<b>Subtotal</b>	<b>\$14,466,230.36</b>	<b>\$2,206,996.22</b>	<b>\$16,673,226.58</b>
<b>340B Rebate States</b>			
NEW YORK	\$13,694,595.49	\$1,009,649.49	\$14,704,244.98
CALIFORNIA	\$9,544,078.82	\$5,797,408.79	\$15,341,487.62
NEW JERSEY	\$6,121,303.64	\$896,065.96	\$7,017,369.60
MARYLAND	\$1,552,366.18	\$64,337.19	\$1,616,703.37
WASHINGTON	\$1,301,611.64	\$530,284.75	\$1,831,896.38
MASSACHUSETTS	\$1,084,651.14	\$257,847.26	\$1,342,498.40
CONNECTICUT	\$962,850.38	\$72,194.68	\$1,035,045.06
MISSOURI	\$877,743.98	\$376,592.56	\$1,254,336.54
OHIO	\$869,197.74	\$514,594.06	\$1,383,791.80
INDIANA	\$620,301.59	\$0.00	\$620,301.59

WISCONSIN	\$591,099.36	\$147,178.48	\$738,277.85
NORTH CAROLINA	\$559,687.70	\$770,377.28	\$1,330,064.98
OKLAHOMA	\$286,704.96	\$110,595.67	\$397,300.63
KANSAS	\$252,476.92	\$0.00	\$252,476.92
UTAH	\$243,022.91	\$24,545.63	\$267,568.54
RHODE ISLAND	\$228,868.96	\$0.00	\$228,868.96
OREGON	\$210,505.73	\$0.00	\$210,505.73
WEST VIRGINIA	\$163,381.51	\$12,491.40	\$175,872.91
IDAHO	\$75,164.09	\$34,023.68	\$109,187.77
VERMONT	\$40,994.05	\$33,059.72	\$74,053.77
NORTH DAKOTA	\$34,450.13	\$0.00	\$34,450.13
ALASKA	\$21,886.31	\$1,622.06	\$23,508.38
<b>Subtotal</b>	<b>\$39,336,943.24</b>	<b>\$10,652,868.67</b>	<b>\$49,989,811.91</b>
<b>Non-Participating States ***</b>			
PENNSYLVANIA	\$1,945,523.68	\$1,291,223.10	\$3,236,746.78
MICHIGAN	\$657,021.25	\$0.00	\$657,021.25
MINNESOTA	\$586,286.47	\$29,309.66	\$615,596.14
ARKANSAS	\$515,510.43	\$0.00	\$515,510.43
SOUTH DAKOTA	\$47,138.80	\$0.00	\$47,138.80
<b>Subtotal</b>	<b>\$3,751,480.63</b>	<b>\$1,320,532.76</b>	<b>\$5,072,013.39</b>
<b>Total Savings****</b>	<b>\$57,554,654.23</b>	<b>\$14,180,397.65</b>	<b>\$71,735,051.88</b>

Notes: \*Delaware is registered as a rebate State with HRSA, but the bulk of its purchases are made through a Disproportionate Share Hospital which purchases the drugs directly at the 340B ceiling price. For the purposes of this analysis, it was counted as a direct purchase State.

\*\*The District of Columbia's negative savings reflects the fact that they procure their drugs through the Department of Defense at Big 4 contract prices. Big 4 contract prices are often lower than Federal ceiling prices given the tremendous bargaining power of the Big 4. Washington DC was included in the direct purchase category because this category most closely resembles how DC obtains drugs and the prices they pay.

\*\*\*Non-participating ADAPs often negotiate their own rebates from pharmaceutical manufacturers. Michigan and Minnesota receive voluntary rebates from pharmaceutical manufacturers. Pennsylvania receives State mandated rebates from pharmaceutical manufacturers. These rebates have been calculated into our savings estimates. Arkansas became a direct purchase State in September 1999, at the end of our sampled time.

\*\*\*\* New Hampshire, Wyoming and Maine were unable to provide us with the information we requested. The Virgin Islands only became eligible for the 340B Drug Pricing Program in October 1999. We believe that the total savings would be even greater had pricing information from these ADAPs been included.

**Names and National Drug Codes of the 10 Drugs Reviewed**

<b>Pharmaceutical Brand Name (Generic Name)</b>	<b>National Drug Code</b>
<b>Crixivan (Indinavir)</b> 400 mg, 180 units	<b>00006057362</b>
<b>Invirase (Saquinavir)</b> 200mg, 270 units	<b>00004024515</b>
<b>Sustiva(Efavirenz)</b> 200mg, 90 units	<b>00056047492</b>
<b>Viracept (Nelfinavir)</b> 250mg, 270 units	<b>63010001027</b>
<b>Zidovudine (AZT)</b> 100mg, 100 unit	<b>00173010855</b>
<b>Epivir (3TC)</b> 150mg, 60 units	<b>00173047001</b>
<b>Videx (ddl)</b> 100mg, 60 units	<b>00087665201</b>
<b>D4T (Zerit)</b> 40mg, 60 units	<b>00003196701</b>
<b>Combivir (AZT/3TC)</b> 150mg/300mg, 60 units	<b>00173059500</b>
<b>Fortovase (Saquinavir)</b> 200mg, 180 units	<b>00004024648</b>

Note: The original survey requested information on 11 drugs. The 10 drugs listed here and Norvir (NDC#00074663322). The National Drug Code for Norvir used on our survey was not issued until June 1999. It was often not clear in the data received which NDC of Norvir the information corresponded to, therefore we did not use any of the data related to this pharmaceutical.

Agency Comments

---



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Health Resources and  
Services Administration  
Rockville MD 20857

TO: Inspector General, OS

FROM: Deputy Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Report "AIDS Drug Assistance Program Cost Containment Strategies," OEI-05-99-00610

In response to the Inspector General's July 11 memorandum, are the Health Resources and Services Administration's comments to the subject draft report.

Staff questions may be referred to Jeanelle Kallevang on (301) 443-6507.

Handwritten signature of Thomas G. Morford.

Thomas G. Morford

Attachment

## Agency Comments

---

Health Resources and Services Administration (HRSA) Comments to the Office of Inspector General (OIG) Draft Report “AIDS Drug Assistance Program Cost Containment Strategies” OEI-05-99-00610

### GENERAL COMMENTS

The draft report is informative and supportive of AIDS Drug Assistance Programs (ADAPs). However, to be accurate the Health Resources and Services Administration (HRSA) recommends that the report include the information that State ADAPs operate in dynamic environments and that the description of each program is a snapshot taken at a fixed point in time. For example, the study period for this report included only the first three quarters of 1999. Therefore, to describe ADAPs as they existed during the study period, we recommend that OIG change the word “currently” to “at the time this study was conducted,” everywhere the word “currently” appears in the report.

### OIG RECOMMENDATION

The Health Resources Services Administration should seek legislation to change the 340B ceiling price calculation to the Big 4 ceiling price calculation.

### HRSA COMMENT

We concur. We will actively review the need for such a legislative change and make an appropriate recommendation to the Department. Implementation of the 340B Drug Pricing Program has been tied to the Medicaid program for calculation of the ceiling price. Medicaid is a reimbursement program and changes to the data utilized to calculate the Medicaid Unit Reimbursement (URA) are allowed to occur retroactively. The 340B price is an immediate, up-front, at the time of purchase selling price and these changes are often not captured or included in the calculation. Adjustments are difficult to identify and implement. The “Big 4” Section 603 price schedule administered by the Veterans Administration (V.A.) is similar to the 340B drug pricing program in being an up-front, at the time of purchase discount program. Changes as they occur are tracked by the V.A. and this can be easily communicated to HRSA for the 340B program. The Federal dollars, provided to the 340B covered entities through grant funding, may be further stretched to serve additional patients and provide additional services with this change in the legislation. The impact of this legislative change is not limited to the ADAPs, but would extend to all 340B covered entities. The impact is potentially larger and may have a significant impact on providing access to both health care services and pharmaceuticals to individuals with current unmet needs.

## Agency Comments

---

### OIG RECOMMENDATION

To allow ADAPs to negotiate the lowest prices possible, HRSA should seek to statutorily exempt all sales to 340B covered entities from the calculation of Non-Federal Average Manufacturers Price (nonFAMP).

### HRSA COMMENT

We concur. The inclusion of sales to 340B covered entities below the current 340B statutory ceiling price into the nonFAMP may cause manufacturers to avoid negotiations that would provide further discounts to the 340B covered entities.

### OIG RECOMMENDATION

HRSA should continue to work with rebate and non-participating ADAPs to devise ways to grant them access to up-front drug discounts. 1) HRSA should continue to provide incentives and technical assistance for States to join the direct pricing/Prime Vendor option, and 2) HRSA should revisit the potential of allowing multiple contract pharmacies.

### HRSA COMMENT

We concur.

1. HRSA has in the past and continues in the present to encourage the ADAPs to participate in the 340B direct purchase option. The implementation of the HRSA Prime Vendor is anticipated to provide additional savings to those ADAPs participating in both the direct discount option and the Prime Vendor as compared to the rebate and non-participating ADAPs. The potential additional savings possible if the ceiling price is changed to the “Big 4” Section 603 ceiling price would be an additional inducement for the ADAP rebate option States to implement a direct discount option system.

HRSA has provided and will continue to provide incentives and technical assistance for State ADAPs to participate in the Section 340B direct purchase discount program. However, when advising State ADAPs about the Section 340B point of purchase discount, HRSA advises State ADAPs to consider the cost-effectiveness of the entire drug purchasing, dispensing, and administrative system used by the ADAP.

## Agency Comments

---

2. A “Mail Order” Pharmacy has been an option for the ADAPs since the establishment of the 340B Contract Pharmacy Service Provider guidelines. HRSA will continue to explore options that may facilitate ADAPs in utilizing either a Mail Order Pharmacy or multiple contract pharmacy service providers.

The report suggests that one way to easily transform a reimbursement system into a system with a single central purchase, without sacrificing wide distribution, would be to engage mail-order pharmacy service. It is important to note that a system that works well for one State ADAP may not be suitable for another State to incorporate.

A mail-order pharmacy may not necessarily be a perfect solution for every State ADAP for the following reasons:

- 1) A number of ADAPs provide treatments for acute opportunistic infections and pain medication that require immediate and convenient client access.
- 2) Many of the reimbursement State ADAPs utilize the same structure as other governmental programs providing access to medications within the State (i.e., Medicaid) and often both Medicaid and ADAP utilize the same local pharmacy network.
- 3) Clients often move back and forth between Medicaid and ADAP. It is essential that these two programs coordinate and function well together.
- 4) ADAP clients living in public housing projects and high crime inner-city neighborhoods, as well as homeless or those living in temporary housing, would also prove difficult to serve through a mail-order system due to potential shipping loss and theft.

These potential problems would also impact client adherence, another major concern that could impact a client’s overall health, as well as result in additional health care costs (e.g., viral resistance, risk from opportunistic infections, increased emergency room utilization, increased hospitalization, and increased mortality).

### TECHNICAL COMMENTS

Page 8: Under “ADAPs Participation in the 340B Drug Pricing Program,” please insert a new second sentence that says: “State ADAPs operate in dynamic environments, so the description of each program that follows is a snapshot taken at a fixed point in time.”

## Agency Comments

Under the heading, “ADAPs Participation in the 340B Drug Pricing Program,” line 5, that reads “Currently, twenty-three ADAPs participate in the 340B,” add “under the direct discount program” and change twenty-three to twenty-two.

Line 7 states “Twenty-two ADAPs receive standardized rebates,” add “under the 340B rebate option” and change twenty-two to twenty-four.

Page 12: In the second paragraph under “Scope and Methodology”, the report describes funding sources to ADAPs and states that Federal funding typically comprises 80 percent of total ADAP funding. While that may be correct for the States responding to the survey, please add a new sentence at the end of the paragraph: “Overall, though, as reported in the FY 1999 Title II grant applications, State ADAPs estimated 74 percent of funds was from Federal sources, (specifically 64 percent was received from the Federal ADAP earmark, 7 percent from Title II base contribution, 3 percent from Title I contributions, 18 percent from State contributions, 1 percent from other contributions, and 7 percent from other cost-saving strategies).”

Page 17: Under the heading, “ADAPs could have served thousands more people living with HIV/AIDS,” paragraph 4. change the 3rd sentence to read, “The National Institutes of Health/PHS Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents calls for the use of combination Antiretroviral therapy comprised of at least three drugs.” Delete sentence 4 because the guidelines no longer encourage starting persons infected with HIV on aggressive drug therapy earlier in the development of the disease.

Page 25: Delete paragraph 4 that starts with the sentence, “The ADAPs concerned about the drawbacks of a mail-order system could create a mixed system.” This recommendation would require States to develop parallel systems that would be administratively burdensome and not necessarily cost effective.

Appendix A: Include Arkansas and the Virgin Islands in the first chart that lists States that participate in the 340B direct purchase option. Delete Delaware and D.C. as using this option. Delaware participates in the rebate option and D.C. purchases medications under the Federal Supply Schedule.

Include Delaware and Wyoming in the second chart that lists the States that participate in the 340B rebate option.

Include the following information in the 3rd chart that lists the States that do not participate in the 340B purchasing option: Michigan and Minnesota receive voluntary rebates from pharmaceutical manufacturers and Pennsylvania receives State mandated rebates from pharmaceutical manufacturers.

---

**Related Office of Inspector General Reports**

---

The Ryan White Evaluation Systems: AIDS Drug Assistance Programs (OEI-05-98-00390)

The Ryan White Evaluation Systems: Title II Grants to the States (OEI-05-98-00393)

Audit of the Utilization of the Public Health Service 340B Drug Pricing Program  
(A-01-98-01500)

Audit of State AIDS Drug Assistance Programs' Use of Drug Price Discounts (A-01-97-01501)

Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs  
(OEI-03-97-00293)