

**Memorandum**

Date · APR 10 1997

From June Gibbs Brown
Inspector General

Subject Medicaid Pharmacy - Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs (A-06-96-00030)

To

Bruce C. Vladeck
Administrator
Health Care Financing Administration

Attached is our report on the consolidated results of our review of pharmacy acquisition costs for brand name drugs reimbursed under the Medicaid prescription drug program. The report is in response to a request from your Medicaid Bureau that the Office of Inspector General (OIG) perform an audit of the use of average wholesale price (AWP) as part of the Medicaid drug reimbursement policies. The memorandum stated that it would be useful for the OIG to document the size of the difference between AWP and actual invoice prices paid by retail pharmacies to purchase drugs. As you know, most States use AWP, minus a percentage discount which varies by State, as a basis for reimbursing pharmacies for drug prescriptions. Although this discount is most commonly about 10 percent nationally, it has been recognized as not being a sufficient discount to ensure that the reasonable price is paid for drugs. Therefore, the objective of our review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name drugs. Estimates were also developed for the discount below AWP at which pharmacies purchase generic drugs and those results will be summarized in a separate report.

Through use of statistical sampling, we obtained pricing information from 315 pharmacies in 11 States and obtained 18,973 invoice prices for brand name drug products. We estimated that actual acquisition cost was a national average of 18.3 percent below AWP. This estimate combined the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent and excluded the results obtained from non-traditional pharmacies. Using the results of our review, we calculate that as much as \$225 million could have been saved for 100 drugs with the greatest amount of Medicaid reimbursements in Calendar Year 1994, if reimbursement had been based on the findings of this report.

Page 2 - Bruce C. Vladeck

We are recommending that the Health Care Financing Administration (HCFA) work to ensure that States reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report. Additionally, we are recommending that HCFA study any of the other factors (for example dispensing fees) which they believe could significantly impact pharmacy reimbursement. We remain available to assist HCFA in conducting other studies that will aid in the implementation of these recommendations. The HCFA Administrator responded to our draft report in a memorandum dated March 18, 1997. In that memorandum, HCFA agreed with the findings and recommendations of this report.

Please refer to Common Identification Number A-06-96-00030 in all correspondence relating to this report. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

Attachments

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICAID PHARMACY -
ACTUAL ACQUISITION COST OF
PRESCRIPTION DRUG PRODUCTS
FOR BRAND NAME DRUGS**



JUNE GIBBS BROWN
Inspector General

APRIL 1997
A-06-96-00030

SUMMARY

At the request of the Health Care Financing Administration (HCFA), the Office of Inspector General (OIG) conducted a nationwide review of pharmacy acquisition cost for brand name drugs reimbursed under the Medicaid prescription drug program. Since most States reimburse pharmacies for Medicaid prescriptions using a formula which discounts the average wholesale price (AWP), the objective of our review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name drugs. Estimates for generic drugs were also developed but must be compared to Federal upper limit prices. Those results will be discussed as part of a separate report we are preparing.

To accomplish our objective, we selected a random sample of 11 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a statewide managed care program for Medicaid. The sample States were California, Delaware, District of Columbia, Florida, Maryland, Missouri, Montana, Nebraska, New Jersey, North Carolina, and Virginia.

For each of these States, we selected a sample of Medicaid pharmacy providers and obtained invoices of their drug purchases. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, etc.). We included the non-traditional category so as to be able to exclude those pharmacies from our overall estimates. We believed such pharmacies purchase drugs at substantially greater discounts than retail pharmacies, and including them would have inflated our percentages.

We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. We then projected those differences to the universe of pharmacies in each category for each State and calculated an overall estimate for each State. Additionally, we projected the results from each State to estimate the nationwide difference between invoice price and AWP for each category.

We obtained pricing information from 315 pharmacies. Specifically, we obtained 18,973 invoice prices for brand name drugs. We estimated that actual acquisition cost was a national average of 18.3 percent below AWP. The estimate combined the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent and excluded the results obtained from non-traditional pharmacies. Additionally, we calculated a savings of as much as \$225 million for 100 brand name drugs with the greatest amount of Medicaid reimbursements in Calendar Year (CY) 1994, if reimbursement had been based on the findings of this report.

We are recommending that HCFA work to ensure that States reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report. Additionally, we

are recommending that HCFA study any of the other factors (for example dispensing fees) which they believe could significantly impact pharmacy reimbursement. We remain available to assist HCFA in implementing these recommendations.

The HCFA Administrator responded to our draft report in a memorandum dated, March 18, 1997. The HCFA agreed with the findings and recommendations of this report. The full text of HCFA's comments are included in Appendix 3.

TABLE OF CONTENTS

	<u>PAGE</u>
INTRODUCTION	1
BACKGROUND	1
SCOPE	2
FINDINGS AND RECOMMENDATIONS	4
CONCLUSIONS AND RECOMMENDATION	5
HCFA'S COMMENTS	5
APPENDICES	
APPENDIX 1 - SAMPLE DESCRIPTION	
APPENDIX 2 - NATIONWIDE SAMPLE RESULTS	
APPENDIX 3 - HCFA'S COMMENTS	

INTRODUCTION

At HCFA's request, the OIG, Office of Audit Services (OAS), conducted a nationwide review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program. The objective of our review was to develop an estimate of the difference between actual acquisition costs of drugs by the retail pharmacy and AWP for brand name drugs.

BACKGROUND

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or an upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by HCFA. If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using AWP for a drug less a discount percentage. The AWP is the price assigned to the drug by its manufacturer and is listed in either the **Red Book**, **Medispan**, or the **Blue Book**--publications universally used in the pharmaceutical industry. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, HCFA issued a revision to the State Medicaid Manual which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual issuance further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

In November 1990, the Omnibus Budget Reconciliation Act of 1990 was passed which placed a 4-year moratorium on changes to States' reimbursement policies. The moratorium expired on December 31, 1994 and HCFA requested that we, once again, determine the difference between AWP and actual pharmacy acquisition cost.

An article in the June 10, 1996 issue of **Barron's** entitled, "*Hooked on Drugs*," focused additional attention on AWP and its relationship to actual acquisition cost. **Barron's** compared about 300 dose forms of the top 20 Medicare drugs and concluded that the true cost was 10 to 20 percent below AWP for brand name drugs and 60 to 85 percent below AWP for generic

drugs. **Barron's** also reported that industry insiders joke that AWP really means "Ain't What's Paid" indicating that AWP is not a valid reflection on the costs paid by pharmacies for drugs.

SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop an estimate of the difference between the actual invoice prices of brand name prescription drugs to Medicaid pharmacy providers and AWP. Our objective did not require that we identify or review any internal control systems. We did not include generic drugs in this review as reimbursement for generic drugs is limited by the Federal upper limit amounts. We plan to evaluate the adequacy of the Federal upper limit amounts in generic drug reimbursements in a subsequent review.

Our review was limited to ingredient acquisition costs and did not address other areas such as: (1) the effect of Medicaid business as a contribution to other store sales; (2) the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, and physician consultation; and (3) the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead.

To accomplish our objective, we designed a multistage sampling procedure (a detailed description of our sample design is included as **Appendix 1** to this report). State Medicaid agencies were designated as the primary units and Medicaid pharmacy providers as the secondary units. We selected a random sample of 11 States from a universe of 49 States including the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. The States selected were California, Delaware, District of Columbia, Florida, Maryland, Missouri, Montana, Nebraska, New Jersey, North Carolina, and Virginia.

We obtained a listing of all Medicaid pharmacy providers from each sample State. The State agencies were responsible for classifying each pharmacy as a chain, independent or non-traditional. For purposes of this review, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a December 31, 1992 listing of the metropolitan areas and their components. We selected a stratified random sample of 60 pharmacies from each State with 12 pharmacies selected from each of 5 strata--urban-chain, rural-chain, urban-independent, rural-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.) If a stratum had a universe of less than 12, we selected 100 percent of the pharmacies in that stratum. We included the non-traditional category so as to be able to exclude those pharmacies from our estimates. We believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and would inflate our estimate.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1994. We identified the sources of supply as wholesalers, chain warehouse distribution centers, and direct manufacturer purchases. Each pharmacy was initially assigned a month from January through September in order to provide a cross-section of this 9-month time period. However, we permitted some pharmacies to provide invoices from October, November, or December as invoices were not available from the earlier period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which was needed to obtain AWP for the drug. We attempted to obtain NDCs in those instances. We used the **1994 Red Book**, a nationally recognized reference for drug product and pricing information, to obtain NDCs or identify over-the-counter items. One prominent wholesaler, whose invoices contained that wholesaler's item numbers rather than NDCs, provided us with a listing that converted their item numbers to NDCs. If we were unable to identify the NDC for a drug, we eliminated the drug.

We obtained a listing from HCFA that indicated whether a drug is a brand name or generic drug. We used that listing to identify the brand name drugs on the invoices. If a drug was not on the HCFA listing, we used the **Red Book** to determine whether the drug was a brand name drug. We also obtained from HCFA a listing of the top 100 brand name drugs in terms of the amount reimbursed by Medicaid for CY 1994. The listing also included the total units reimbursed for those drugs.

The State of Missouri provided us with a pricing file for the purpose of obtaining AWP for each drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. If a drug from an invoice was not on the pricing file we eliminated that drug.

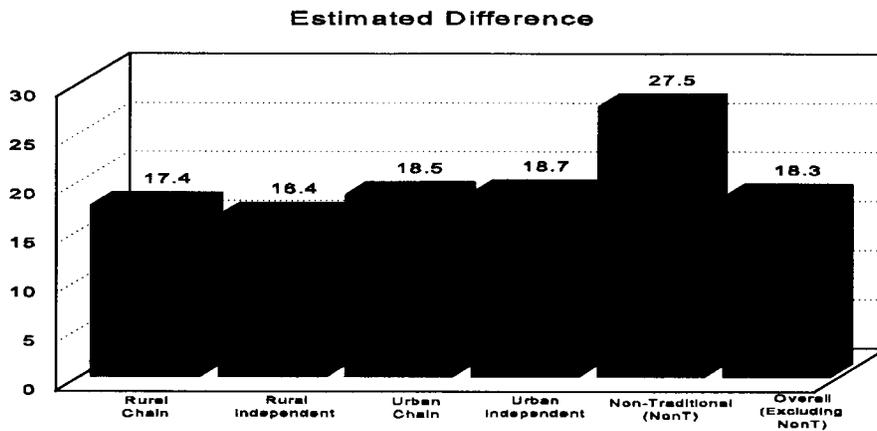
We involved State agency officials in planning the methodology for this review. A meeting was held in Richmond, Virginia, with HCFA officials and Medicaid pharmacy representatives from the sample States to collaboratively design our approach. A second meeting was also held in Richmond, Virginia, involving HCFA officials and pharmacy representatives from the sample States to present the results of our review and discuss how best to present these results to the States.

We used OAS statistical software to calculate all estimates as well as to generate all random numbers. We obtained the total number of pharmacies in the universe and State reimbursement information from the September 1994 issue of **Pharmaceutical Benefits Under State Medical Assistance Programs**. We did not independently verify any information obtained from third party sources. Our review was conducted by our Little Rock, Arkansas OAS Field Office with assistance from our OAS Field Offices in Baton Rouge, Louisiana, Austin, Texas, and Oklahoma City, Oklahoma from September 1994 to September 1995.

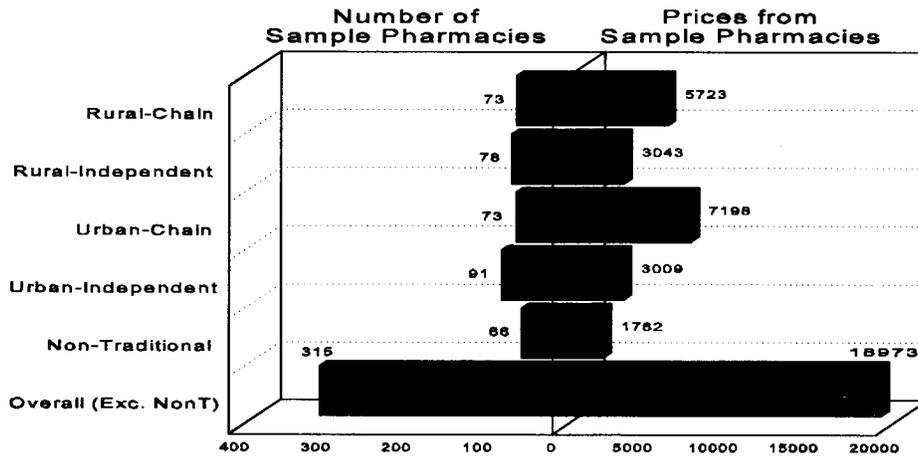
FINDINGS AND RECOMMENDATIONS

We estimated that the invoice price for brand name drugs was a national average of 18.3 percent below AWP. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison to AWP of 18,973 invoice prices received from 315 pharmacies in the 11 State sample. The standard error for this estimate was .66 percent.

The estimates that invoice prices for brand name drugs were discounted below AWP are summarized in the following chart:



The following chart shows the number of pharmacies sampled and the number of prices reviewed by individual category for brand name drugs.



The estimate of the discount below AWP for brand name drugs is significantly greater than the discount allowed under current reimbursement policies in most States. While ingredient cost, or EAC, is not based on AWP in every State or in every situation, EAC is predominantly based on a discounted AWP. The most common amount that AWP is discounted for reimbursement of EAC is 10 percent. Therefore, any change in reimbursement policies consistent with the findings in this report could produce significant savings.

We calculated a savings amount of as much as \$225 million for 100 drugs with the greatest amount of Medicaid reimbursements for CY 1994. The savings amount was determined by multiplying the nationwide utilization for each drug by 8 percent of AWP, with the 8 percent representing the difference between the findings of this report, AWP minus 18 percent, and the predominant EAC, AWP minus 10 percent. We used the AWP for each drug that was in effect January 1, 1994. Using a reduction in AWP of 5 percent rather than 8 percent would result in a savings of as much as \$141 million. The total amount Medicaid reimbursed for the 100 drugs in this calculation was \$2.8 billion in CY 1994.

CONCLUSIONS AND RECOMMENDATIONS

Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost and AWP. We have also calculated that changing reimbursement policy consistent with the findings of our report could have resulted in savings of as much as \$225 million for the 100 most reimbursed drugs in CY 1994. We recognize that these calculations do not incorporate all the complexities of pharmacy reimbursement and that acquisition cost is just one factor in pharmacy reimbursement policy. We believe that any change to that policy should also consider the other factors discussed in the Scope section of our report. However, we also believe that the results of this report are significant enough to warrant a review of pharmacy reimbursement policy. Therefore, we recommend that HCFA work to ensure that States reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report. Additionally, we recommend that HCFA study any of the other factors which they believe could significantly impact pharmacy reimbursement.

HCFA'S COMMENTS

The HCFA Administrator responded to our draft report in a memorandum dated, March 18, 1997. The HCFA agreed with the findings and recommendations of this report. The full text of HCFA's comments are included in Appendix 3.

SAMPLE DESCRIPTION

Sample Objectives:

Develop a nationwide estimate of the extent of the discount below AWP of actual invoice prices to Medicaid pharmacies for brand name drugs .

Population:

The primary sampling population was all States providing coverage of prescription drugs as an optional service under section 1905 (a) (12) of the Social Security Act. Section 1903 (a) of the Act provides for Federal financial participation (FFP) in State expenditures for prescription drugs.

Sampling Frame:

The primary sampling frame was a listing of all States participating in the Medicaid prescription drug program except for Arizona and Tennessee. Arizona was excluded because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid.

Sample Design:

A multistage sample was designed with States as the primary sample units and Medicaid pharmacy providers within those States as the secondary sample units. A simple random sample of States was selected for the primary sample and a stratified random sample of pharmacies was selected for the secondary sample. A sample of 12 pharmacies was selected from each of 5 strata. The 5 strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.) Each pharmacy was assigned a month from 1994 for which to provide invoices. All pharmacies were initially assigned a month from January through September in a method designed to provide a cross-section of the 9-month period. However, some pharmacies were permitted to submit invoices from October, November, or December as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Eleven States were selected for review from our primary sampling frame. Twelve pharmacies were selected from each stratum of our secondary sample frame. Therefore, a maximum of sixty pharmacies was selected from each State. Some States did not have twelve pharmacies in all strata or have every strata.

Source of Random Numbers:

OAS statistical sampling software was used to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices we calculated the percentage of the discount below AWP of actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that did not respond to our request or did not provide usable information. If a pharmacy stratum had 12 or fewer pharmacies, we reviewed all of the pharmacies in that stratum. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that type of supplier during the month assigned to the pharmacy.

Estimation Methodology:

We used OAS Statistical Software for multistage variable sampling to project the percentage difference between actual invoice prices and AWP for each stratum, as well as an overall percent difference.

Other Evidence:

We obtained AWP from First DataBank.

APPENDIX 2

**NATIONWIDE SAMPLE RESULTS
BRAND NAME DRUGS**

[Redacted Header]							
RURAL-CHAIN	1,095	73	5,723	17.40	1.05	15.67	19.13
RURAL-INDEPENDENT	1,499	78	3,043	16.39	1.07	14.63	18.15
URBAN-CHAIN	8,194	73	7,198	18.45	0.52	17.60	19.31
URBAN-INDEPENDENT	6,242	91	3,009	18.71	0.90	17.22	20.19
NON-TRADITIONAL	2,026	66	1,762	27.52	2.28	23.76	31.27
OVERALL (EXCL. NON-TRAD)	17,030	315	18,973	18.30	0.66	17.21	19.38



The Administrator
Washington, D.C. 20201

MAR 18 1997

FROM: Bruce C. Vladeck *Bruce Vladeck*
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicaid Pharmacy-
Actual Acquisition Cost of Prescription Drug Products" (A-06-96-00030)

TO: June Gibbs Brown
Inspector General

We reviewed the above-referenced report concerning pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program. The report develops an estimate of the discount below Average Wholesale Price at which pharmacies purchase brand name drugs and the potential savings that could be realized if Medicaid reimbursed based on the actual acquisition cost.

Our detailed comments are attached for your consideration. We would like to extend our appreciation for, and acknowledgment of, OIG's extensive efforts in performing this review. It is particularly gratifying inasmuch as OIG invited Health Care Financing Administration staff to participate in their discussions with state pharmaceutical representatives in the preliminary design, review, and evaluation of this report.

Attachment

RECEIVED
1997 MAR 19 P 3:50
OFFICE OF INSPECTOR
GENERAL

IG	_____
EAIG	_____
SAIG	_____
PDIG	_____
DIG-AS	_____ /
DIG-EC	_____
DIG-EI	_____
DIG-OI	_____
DIG-MP	_____
AIG-LC	_____
OGC/IG	_____ /
ExecSec	_____ /
Date Sent	3-19

The Health Care Financing Administration (HCFA) Comments on
Office of Inspector General (OIG) Draft Report:
Medicaid Pharmacy -Actual Acquisition Cost of Prescription Drug Products
(A-06-96-00030)

OIG Recommendation

HCFA should work to ensure that states reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report.

HCFA Response

We concur. HCFA will find this report beneficial in determining the appropriateness of the reimbursement levels throughout HCFA's review of state plan amendments (SPAs) containing proposed changes to pharmacy reimbursement while considering all other factors involved.

OIG Recommendation

HCFA should study any of the other factors (for example, dispensing fees) it believes could significantly impact pharmacy reimbursement.

HCFA Response

We concur. In addition to considering influencing pharmacy reimbursement, we will consider other factors such as reimbursement for cognitive services, and the level of reimbursement for other significant third party payers in our determination on the appropriateness of any submitted changes to states' Medicaid pharmacy reimbursement levels.

Additional Comments

We consistently recognized that a disparity existed between pharmacy acquisition costs and the Average Wholesale Price (AWP), and expected the draft report to confirm this. We historically provided guidance to the states that the AWP is not an accurate estimate of acquisition costs without a discount off AWP being applied. We therefore expect that states will consider the results of this report as one of the factors in contemplating proposed changes to policy reimbursement.

Taken alone, we agree with OIG's estimate of potential savings. However, as OIG acknowledges, estimated acquisition cost is only one factor in pharmacy reimbursement. Other factors to consider are the AWP, dispensing fees, acquisition costs, and the statutory prohibition on reducing pharmacy reimbursement under Medicaid through 1994. If these remained constant, we would agree with OIG's estimate.