Memorandum

Date AUG 10 2001

From Michael F. Mangano
Principal Deputy Inspector General

Subject Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products (A-06-00-00023)

To Thomas Scully
Administrator
Centers for Medicare and Medicaid Services

Attached is the Department of Health and Human Services, Office of Inspector General's final report entitled, "Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products." This report provides the results of our review of pharmacy acquisition costs for brand name drugs reimbursed under the Medicaid prescription drug program. Most States use average wholesale price (AWP) minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for drug prescriptions. Although this discount averaged 10.31 percent nationally in 1999, we believe that it is not a sufficient discount to ensure that a reasonable price is paid for drugs.

We believe that there is a critical need for States to better control the costs of their Medicaid drug program because expenditures are rising at a dramatic rate. Medicaid drug expenditures increased by slightly over 90 percent since our previous review in 1994. In Calendar Year (CY) 1994, expenditures for Medicaid drugs totaled $9.4 billion and these expenditures rose to $17.9 billion by CY 1999. Such increases have adversely affected States' budgets as well as significantly impacted the Federal Government. In our opinion, States could better control costs if they would develop reimbursement methodologies that were more in line with actual drug costs. Therefore, the objective of this 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 are being summarized in a separate report.

As part of our review, we obtained pricing information from 216 pharmacies in 8 States and obtained 16,204 invoice prices for brand name drug products. We estimated that nationally, pharmacy actual acquisition cost was an average of 21.84 percent below AWP. Our previous estimate, based on CY 1994 pricing data, showed a discount of 18.30 percent below AWP for brand name drugs. Therefore, this review showed that from 1994 to 1999 there was an increase of 19.3 percent in the average discount below AWP for brand name drugs.

This current 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. We estimated that the Medicaid program could

have saved as much as $1.08 billion if reimbursement had been based on a 21.84 percent average discount below AWP. This projection was based on the 200 brand name drugs with the greatest amount of Medicaid reimbursement for CY 1999.

Per Federal Medicaid regulations, States are required to reimburse brand name drugs based on "estimated acquisition cost." Accordingly, we recommend that the Centers for Medicare and Medicaid Services (CMS) require the States to bring pharmacy reimbursement more in line with the actual acquisition cost of brand name drugs being realized by pharmacies in their States. We will be issuing additional reports, one for each State in our review, for use by CMS and the respective States for their consideration in revising Medicaid drug reimbursement methodologies.

The CMS Acting Deputy Administrator responded to our draft report in a memorandum dated July 13, 2001. The CMS agreed that an accurate acquisition cost should be used to determine drug reimbursement and stated that CMS would encourage States to review their estimates of acquisition costs in light of our findings.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please contact me or George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

Please refer to Common Identification Number A-06-00-00023 in all correspondence relating to this report.

Attachments

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

AUGUST 2001
A-06-00-00023

EXECUTIVE SUMMARY

As a follow-up to our previous work, the Office of Inspector General conducted a nationwide review of pharmacy acquisition costs for brand name drugs reimbursed under the Medicaid prescription drug program. Since most States use average wholesale price (AWP) minus a percentage discount, which varies by State, as a basis for reimbursing pharmacies for drug prescriptions, the objective of this review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name drugs. We also developed estimates for the discount below AWP at which pharmacies purchase generic drugs and those results are being summarized in a separate report.

To accomplish our objective, we selected a stratified random sample of 8 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. Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. Of the 8 States, 2 States (Montana and Florida) were selected from the universe of 10 States and the District of Columbia that were included in our previous review. The other 6 States (Colorado, Indiana, Texas, Washington, West Virginia, and Wisconsin) were selected from the remaining 38 States.

In addition, a random sample of Medicaid provider pharmacies from each State was selected. The pharmacies were selected from each of five categories -- urban-chain, rural-chain, urban-independent, rural-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). We sampled the non-traditional category so that they could be excluded from our estimates. We believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and those discounts would inflate our estimate.

We obtained pricing information from 216 pharmacies in 8 States which resulted in an analysis of 16,204 invoice prices for brand name drug products. 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. These differences were then projected to the universe of pharmacies in each category for each State and to an overall estimate for each State. Additionally, the results from each State were projected to estimate the nationwide difference between invoice price and AWP for each category.

We estimated that the actual acquisition cost for brand name drugs was a national average of 21.84 percent below AWP. Our previous estimate, based on Calendar Year (CY) 1994 pricing data, showed a discount estimate of 18.30 percent below AWP for brand name drugs. As a result, this review showed that from 1994 to 1999 there was an increase of 19.3 percent in the average discount below AWP for brand name drugs.

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 these results, we calculated that as much as $1.08 billion could have been saved for the 200 brand name drugs with the greatest amount of Medicaid reimbursements in CY 1999, if reimbursement had been based on discounted percentages below AWP as identified in this report.

Federal Medicaid regulations require States to reimburse pharmacies' ingredient drug cost based on estimated acquisition cost. Therefore, we recommend that the Centers for Medicare and Medicaid Services (CMS) require the States to bring pharmacy reimbursement for brand name drugs more in line with the actual acquisition cost which we identified as being 21.84 percent below AWP.

The CMS Acting Deputy Administrator responded to our draft report in a memorandum dated July 13, 2001. The CMS agreed that an accurate acquisition cost should be used to determine drug reimbursement and stated that CMS would encourage States to review their estimates of acquisition costs in light of our findings. The full text of CMS' comments is included in **APPENDIX 3.**

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INTRODUCTION

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 the Centers for Medicare and Medicaid Services (CMS). 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 the average wholesale price (AWP) for a drug less a percentage discount. The AWP is the price assigned to the drug by its manufacturer and is compiled by commercial organizations - **Red Book, First DataBank**, and **Medi-Span** for use by the pharmaceutical community. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, the Office of Inspector General (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 that found 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, CMS 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 1997, OIG issued separate reports on the actual acquisition cost of brand name and generic drugs. The 1997 reports were based on comparisons of 18,973 invoice prices for brand name products and 9,075 invoice prices for generic products. The reports showed average discounts of 18.30 percent below AWP and 42.45 percent below AWP, respectively. Drug expenditures in Calendar Year (CY) 1994 totaled about $9.4 billion. In CY 1999, drug expenditures increased to about $17.9 billion.

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. Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription for instances such as therapeutic intervention, patient education, and physician consultation; and 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 stratified random sample of 8 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 was a demonstration project using prepaid capitation financing. Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. Of the 8 States, 2 States (Montana and Florida) were selected from a universe of 10 States and the District of Columbia that were included in our previous review. The other 6 States (Colorado, Indiana, Texas, Washington, West Virginia, and Wisconsin) were selected from the remaining 38 States.

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 1999 listing of the metropolitan statistical areas and their components. We selected a stratified random sample of 40 pharmacies from each State with 8 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.). We sampled the non-traditional category separately so they could be excluded from our estimates. We excluded the non-traditional category because we believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and those discounts 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 1999. Supply sources included wholesalers, chain warehouse distribution centers, generic distributors, and manufacturers. Each pharmacy was initially assigned a month from January 1999 through December 1999 in order to provide a cross-section

of this 12-month time period. However, we permitted some pharmacies to provide invoices from other months in 1999, if invoices were not available for the requested 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 were needed to obtain AWP for the drug. We used the **2000 Red Book**, a nationally recognized reference for drug product and pricing information, to obtain NDCs or identify over-the-counter items. Two prominent wholesalers, as well as four chain stores, whose invoices contained the wholesaler item numbers rather than NDCs, provided us with a listing that converted their item numbers to NDCs.

To verify the drug name, we utilized the drug product file on the CMS web site. In addition to verifying the drug name, we were also able to determine the drug-type indicator from this file. The drug-type indicator showed whether the drug was a brand name or generic drug. We also obtained from CMS a listing of the top 200 brand name drugs in terms of the amount reimbursed by Medicaid for CY 1999.

In order to identify the NDC for each drug, we obtained a pricing file supplied by **First Data Bank** through the State of Florida. 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.

Since some States also use wholesalers acquisition cost (WAC) in their reimbursement methodology, we also compared the invoice drug price to WAC for each drug for which WAC was available on the pricing file. We calculated the percentage, if any, by which WAC must be increased to equate to the invoice price. The results of the WAC comparisons are reported separately in **APPENDIX 2**.

We used Office of Audit Services (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 from the National Council for Prescription Drug Programs. We did not independently verify any information obtained from third party sources. Additionally, we did not attempt to identify any special discounts, rebates, or other types of special incentives not reflected on the invoices. Our review was conducted by our Little Rock, Arkansas OAS field office, with assistance from our Office of Council to the Inspector General, from July 2000 to March 2001.

FINDINGS

We estimated that nationally, the invoice price for brand name drugs was an average of 21.84 percent below AWP. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison to AWP of 16,204 invoice prices

received from 216 pharmacies in the 8-State sample. The standard error for this estimate was 0.35 percent.[1]

The estimates that invoice prices for brand name drugs were discounted below AWP are summarized in the following chart. This chart also shows the number of pharmacies sampled and the number of prices reviewed by individual categories of brand name drugs.

Category	Percent Below AWP (Point Estimate)	Sample Pharmacies	Prices Compared
Rural-Chain	20.68	52	3,533
Rural-Independent	20.86	55	2,628
Urban-Chain	22.19	56	7,719
Urban-Independent	22.00	53	2,324
Non-Traditional	31.18	61	1,528
Overall (Exc. Non-Trad.)	21.84	216	16,204

The estimate of the discount below AWP for brand name drugs was significantly greater than the discount allowed under current reimbursement policies in most States. While ingredient cost, or EAC, was not based on AWP in every State or in every situation, EAC was predominantly based on a discounted AWP. The average discount below AWP for reimbursement of EAC was 10.31 percent in 1999. Therefore, changes in the States' reimbursement policies, consistent with the findings in this report, would produce significant savings.

We calculated a savings amount of as much as $1.08 billion for the 200 brand name drugs with the greatest amount of Medicaid reimbursements for CY 1999. The savings amount was determined by multiplying the nationwide utilization for each drug by 11.53 percent of AWP, which represents the difference between the findings of this report, AWP minus 21.84 percent, and our previous findings of AWP minus 10.31 percent. We used the AWP for each drug that was in effect January 1, 1999. Therefore, using a reduction in AWP of 21.84 percent rather than 10.31 percent would result in a savings of as much as $1.08 billion. The total amount Medicaid reimbursed for the 200 drugs in this calculation was $8.47 billion in CY 1999.

[1] The lower limit and upper limit at the 90 percent confidence level were 21.26 and 22.42, respectively.

The following chart provides a comparison of the results of this review and the results of the prior review, which was based on 1994 pricing data. The results of the 1994 review showed that the discount below AWP was 18.30 percent while the results of this review show that the discount below AWP had increased to 21.84 percent. This shows that the discount below AWP had increased by over 19 percent since the last review.

	Percent Below AWP		
Category	**(Point Estimate) 1999**	**(Point Estimate) 1994**	**Percentage Difference**
Rural-Chain	20.68	17.40	18.85%
Rural-Independent	20.86	16.39	27.27%
Urban-Chain	22.19	18.45	20.27%
Urban-Independent	22.00	18.71	17.58%
Non-Traditional	31.18	27.52	13.30%
Overall (Exc. Non-Trad.)	21.84	18.30	19.34%

In addition to our comparison of AWP to acquisition cost, we also compared WAC to invoice price. This was done because some States use WAC plus a percentage in their pharmacy reimbursement methodology. We estimated that the invoice price for brand name drugs was a national average of 1.81 percent below WAC. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison to AWP of 12,132 invoice prices received from 216 pharmacies in the 8-State sample. The standard error for this estimate was 0.15 percent. The detailed results of the WAC comparisons are shown in **APPENDIX 2**.

CONCLUSIONS AND RECOMMENDATIONS

Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost for brand name drugs and AWP. We have also estimated that changing reimbursement policy consistent with the findings of our report could have resulted in savings of as much as $1.08 billion for the 200 most reimbursed brand name drugs in CY 1999. 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. However, we also believe that the results of this report are significant enough to warrant a review of pharmacy reimbursement policy. Per Federal Medicaid regulations, States are required to reimburse pharmacies' ingredient drug portion of the reimbursement based on EAC. Therefore,

we recommend that CMS require the States to bring pharmacy reimbursement for brand name drugs more in line with the actual acquisition cost that we identified as being 21.84 percent below AWP.

CMS' COMMENTS

The CMS Acting Deputy Administrator responded to our draft report in a memorandum dated July 13, 2001. The CMS agreed that an accurate acquisition cost should be used to determine drug reimbursement and stated that CMS would encourage States to review their estimates of acquisition costs in light of our findings. The full text of CMS' comments is included in **APPENDIX 3**.

SAMPLE DESCRIPTION

Sample Objectives:

Develop a nationwide estimate of the extent of the discount below AWP of actual invoice prices paid 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 stratified multistage sample was designed with States as the primary sample units and Medicaid pharmacy providers within those States as the secondary sample units. A stratified 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 eight pharmacies was selected from each of five strata. The five 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 1999 for which to provide invoices. All pharmacies were initially assigned a month from January 1999 to December 1999 in a method designed to provide a cross-section of the 12-month period. However, some pharmacies were permitted to submit invoices from other months in 1999, 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, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Eight States were selected for review from our primary sampling frame. Eight pharmacies were selected from each stratum of our secondary sample frame. Therefore, a maximum of 40 pharmacies was selected from each State. Of the 8 States, 2 States were selected from the universe of 10 sampled States plus the District of Columbia in our previous review. The remaining 6 States were selected from the remaining universe of 38 States.

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 refused to provide the requested information. If a stratum had eight or fewer pharmacies, we reviewed all pharmacies in that stratum. Spares were substituted for pharmacies that were not providers during the review period and for misclassified pharmacies. 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 supplier type during the assigned month.

Estimation Methodology:

We used OAS statistical software for stratified 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 a pricing file received from the State of Florida.

NATIONWIDE SAMPLE RESULTS
BRAND NAME DRUGS

AWP Statistics

	Category	Sample Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP (Point Estimate)
AWP	Rural-Chain	1,008	52	3,533	20.68
	Rural-Independent	1,243	55	2,628	20.86
	Urban-Chain	5,745	56	7,719	22.19
	Urban-Independent	2,398	53	2,324	22.00
	Non-Traditional	1,123	61	1,528	31.18
	Overall (Excl. Non-Trad.)	10,394	216	16,204	21.84

WAC Statistics

	Category	Sample Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below WAC (Point Estimate)
WAC	Rural-Chain	1,008	52	2,249	-1.93
	Rural-Independent	1,243	55	2,101	-2.59
	Urban-Chain	5,745	56	6,239	-1.13
	Urban-Independent	2,398	53	1,543	-2.98
	Non-Traditional	1,123	58	1,168	-14.99
	Overall (Excl. Non-Trad.)	10,394	216	12,132	-1.81

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: JUL 13 20

TO: Michael F. Mangano
Acting Inspector General
Office of Inspector General

FROM: Michael McMullan
Acting Deputy Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Medicaid Pharmacy--Actual Acquisition Cost of Prescription Drug Products*, (A-06-00-00023)

Thank you for the opportunity to review and comment on the above-referenced draft report. The objective of this review was to develop an estimate of the discount below average wholesale price (AWP) at which pharmacies purchase brand name drugs.

Federal regulations provide for the reimbursement of drugs under the Medicaid program 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 reimbursement amount, established by the Centers for Medicare & Medicaid Services (CMS), plus a dispensing fee. If a drug is a single source (brand) drug, or a generic for which an upper limit has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The EAC, which is established at the state level, is typically calculated by using the AWP for a drug less a percentage discount.

In a previous study, based on calendar year (CY) 1994 pricing data, the OIG identified a discount estimate of 18.30 percent below AWP. In comparison, this latest review estimated that actual acquisition cost had increased to a national average of 21.84 percent below AWP. As a result, as much as $1.08 billion could have been saved for the 200 most frequently reimbursed drugs in CY 1999, if reimbursement had been based on a greater percentage discount off of AWP.

The following are CMS's comments to the recommendation.

*The Health Care Financing Administration (HCFA) was renamed to the **Centers for Medicare & Medicaid Services** (CMS). We are exercising fiscal restraint by exhausting our stock of stationery.*

OIG Recommendation

CMS should require that the States to bring pharmacy reimbursement for brand name drugs more in line with the actual acquisition cost which OIG identified as a 21.84 percent discount below AWP.

CMS Response

We concur that an accurate acquisition cost should be used to determine drug reimbursement. Once this report is finalized, we plan to share it with the states and encourage them to review their estimates of acquisition costs in light of the OIG findings. We also note the shortcomings of using AWP as a basis for reimbursement, and will continue to look for an alternate basis for reimbursement.