

**Memorandum**

Date MAY - 4 1999  
From *Michael Mangano*  
for June Gibbs Brown  
Inspector General  
Subject Office of Inspector General's Partnership Plan--Utah Division of Health Care Financing  
To Reports on Medicaid Pharmacy Acquisition Costs of Brand Name and Generic Drugs  
(A-06-99-00035 and A-06-99-00036)

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Administrator  
Health Care Financing Administration

We are transmitting for your information and use, two reports entitled, "Medicaid Pharmacy -Acquisition Costs of Brand Name Prescription Drug Products" and "Medicaid Pharmacy - Acquisition Costs of Generic Prescription Drug Products." These reviews of Medicaid prescription drugs pharmacy acquisition costs were conducted by the Utah Division of Health Care Financing (UHCF) as part of our partnership efforts with State Medicaid agencies to expand oversight of the Medicaid program. We provided the UHCF with copies of the Office of Inspector General (OIG) audit reports on this subject as well as technical assistance during the course of the reviews.

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, the reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or an upper limit 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 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 plus a dispensing fee.

Like most States, the State of Utah reimburses pharmacies for the ingredient cost of Medicaid prescription drugs using a formula which discounts the average wholesale price (AWP). The objective of the UHCF reviews was to develop a statewide estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs. To accomplish their objective, invoices were obtained from a randomly selected sample of Medicaid pharmacy providers. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV pharmacies, etc.). The non-traditional pharmacies were excluded from the estimate as those pharmacies purchase drugs at substantially greater discounts than retail pharmacies.

Both reviews found that pharmacies pay less than AWP to acquire drugs. The results of each audit are as follows:

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### BRAND NAME DRUGS

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- The review of brand name drugs examined 2,588 invoice prices of brand name drugs. The pricing information was obtained from 55 pharmacies and each invoice price was compared to AWP. The review estimated that the actual acquisition cost that pharmacies have to pay to acquire brand name drugs is 18.4 percent below AWP. The review also disclosed a savings of \$3.4 million for the year ending June 30, 1998 if reimbursement had been based on AWP less 18.4 percent rather than Utah's current reimbursement rate of AWP less 12 percent. Total reimbursement for brand name drugs was \$49.4 million for the same time period.
  
- The results of the Utah brand name drug review were consistent with the findings of an earlier OIG review (A-06-96-00030). In that report, we estimated that the actual acquisition cost of brand name drugs was a national average of 18.3 percent below AWP.

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### GENERIC DRUGS

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- The review of generic drugs examined 1,492 invoice prices of generic drugs. The pricing information was obtained from 55 pharmacies and each invoice price was compared to AWP. The review estimated that the actual acquisition cost that pharmacies have to pay to acquire brand name drugs is 60.1 percent below AWP. The review also disclosed a savings of \$4.1 million for the year ending June 30, 1998 if reimbursement had been based on AWP less 60.1 percent rather than the Federal upper limit amount or Utah's current reimbursement rate of AWP less 12 percent for drugs without upper limits. Total reimbursement for generic drugs was \$9.1 million for that time period.
  
- The results of the Utah review showed that the discount below AWP was substantially greater than what was found by the OIG in a similar review (A-06-97-00011) that was based on 1994 data. In that report, we estimated that the actual acquisition cost of generic drugs was a national average of 42.5 percent below AWP.

The UHCF recommended that the State of Utah reimburse the ingredient portion of Medicaid drugs, brand name and generic, in a manner more consistent with the findings of their reports. We continue to believe that the ingredient portion of Medicaid drug

Page 3 - Nancy-Ann Min DeParle

reimbursement should be consistent with what pharmacies actually pay for brand name and generic drugs as the cost of Medicaid prescription drugs has grown from \$6.9 billion in Fiscal Year (FY) 1992 to \$12.4 billion in FY 1997. We are currently considering an update of our previous reviews as they were based on 1994 data.

If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits at (410) 786-7104.

For further information, contact

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Attachment

STATE OF UTAH

Department of Health

Division of Health Care Financing

**MEDICAID PHARMACY - ACQUISITION  
COST OF GENERIC  
PRESCRIPTION DRUG PRODUCTS**

FEBRUARY 1999

STATE OF UTAH

Department of Health

Division of Health Care Financing

**MEDICAID PHARMACY - ACQUISITION  
COST OF GENERIC  
PRESCRIPTION DRUG PRODUCTS**

FEBRUARY 1999

# GENERIC PRESCRIPTION DRUG SUMMARY

The State of Utah's Division of Health Care Financing, which is part of the Department of Health, conducted a statewide review of pharmacy acquisition cost for generic drugs reimbursed under the Medicaid prescription drug program. The State of Utah reimburses pharmacies for Medicaid prescriptions using a formula which discounts the average wholesale price (AWP). **The objective of our review was to develop a statewide estimate of the discount below AWP at which pharmacies purchase generic drugs.** Estimates for brand name drugs were also developed and those results are included in a separate report.

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, home IV pharmacies, etc.). We excluded the non-traditional category 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 obtained 1,492 invoice prices for generic drugs. The pricing information came from 55 pharmacies. We compared each invoice drug price to AWP and estimated that the actual acquisition cost that pharmacies have to pay to acquire generic drugs was 60.1% below AWP.

The federal Health Care Financing Administration (HCFA) provides a list of multi-source drugs with upper reimbursement limits. Medicaid reimburses the pharmacies for drugs without upper limits at 12% below AWP (which is EAC, the estimated acquisition cost). Medicaid reimburses the pharmacies for drugs with upper limits at the lower of EAC or the upper limit. We estimate that factoring in the upper limits the effective rate paid by Medicaid to Utah Pharmacies was 26.6% below AWP.

The difference between 60.1% and 26.6% which is 33.5% would be the savings percent. We estimate that for FYE 6/30/98 the ingredient portion of generic drugs paid by the State of Utah would have dropped from \$9.1 million to \$5.0 million for a difference of \$4.1 million. To accomplish this savings, the EAC should be changed from 12% below AWP to 60.1% below AWP for generic drugs.

The above estimates do not account for quantity and other discounts that pharmacies receive from distributors. Also, as well as ingredient costs and ingredient revenues the pharmacies have noningredient costs and noningredient revenues. Noningredient revenues include dispensing fees which Medicaid pays and co-pays which many Medicaid recipients pay. Noningredient costs can include but are not limited to containers, labels, staff, and overhead.

Our study closely followed a Federal study performed by the Office of Inspector General (OIG), a copy of which is included in Appendix 4. We are recommending that the State of Utah reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of our report.

# TABLE OF CONTENTS

|   | <u>PAGE</u> |
|---|-------------|
| INTRODUCTION .....                                      | 1           |
| BACKGROUND .....  | 1           |
| SCOPE .....   | 2           |
| SAMPLING PROCEDURES .....                               | 3           |
| FINDINGS .....  | 4           |
| COMPARISON TO WHOLESALE ACQUISITION COST .....          | 5           |
| CONCLUSIONS AND RECOMMENDATIONS .....                   | 5           |
| APPENDICES .....  | 6           |
| APPENDIX 1 - SAMPLE DESCRIPTION .....                   | 7           |
| APPENDIX 2 - STATEWIDE SAMPLE RESULTS .....             | 10          |
| APPENDIX 3 - JUNE 6, 1996 BARRON'S ARTICLE .....        | 13          |
| APPENDIX 4 - OFFICE OF INSPECTOR GENERAL'S REPORT ..... | 17          |

# INTRODUCTION

The State of Utah's Division of Health Care Financing, which is part of the Department of Health, conducted a statewide review of pharmacy acquisition cost for drugs reimbursed under the Medicaid prescription drug program. The objective of our review was to develop a statewide estimate of the discount below AWP at which pharmacies purchase generic drugs. Estimates for brand name drugs were also developed and those results are included in a separate report.

## BACKGROUND

Prior to 1984, most States used 100% of AWP for reimbursement of acquisition cost (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). However, the OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9% below AWP. In 1989, the OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5% 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.

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."

Medicaid reimbursement of drugs depends on if the drug has a **Federal upper limit**. If a drug has a federal upper limit then reimbursement is based on the lowest of the pharmacist's usual and customary charge to the general public, the Federal upper limit amount, or the **estimated acquisition cost (EAC)**. If a drug does not have a Federal upper limit established then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or EAC. The Federal upper limit amounts are established by the Health Care Financing Administration (HCFA). The upper limit amounts are based on 150% of the average of the lowest of three products in the multi-source class. The EAC for Utah is calculated by using AWP for a drug less a percentage of 12% ( $AWP \times (1.0 - .12) = EAC$ ).



## SCOPE

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; (3) the cost of dispensing which includes costs for computers, multipart labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead; (4) and identifying or reviewing any internal control systems.

Medicaid in the State of Utah pays **dispensing fees** per claim paid of \$3.90 for pharmacies in urban areas and \$4.40 for pharmacies in rural areas (\$1.00 is also paid for certain over the counter products). A survey done in July 1998 indicated that the Health Maintenance Organizations (HMOs) in Utah pay \$2.00 to \$2.75 as a dispensing fee.

Effective July 1, 1997, most Medicaid recipients are required to pay a \$1.00 **co-payment** for each prescription filled. Recipients exempt from the co-pay requirement include children under age 18, pregnant women, residents of a nursing home who are entitled to keep only \$45 personal needs money, most enrollees in an HMO that includes prescription drug coverage, and recipients whose monthly household income is less than the payment amount in the Family Employment Program. This co-payment pays the pharmacies in addition to what Medicaid in the State of Utah pays the pharmacies. Each recipient has a maximum co-payment of \$5.00 per month.

In addition to comparing an estimate of the difference between the invoice price and AWP, **we also compared invoice price and AWP to WAC** (Wholesale Acquisition Cost). Some states reimburse using WAC instead of or in addition to using AWP. WAC is maintained by the same company, First DataBank, that maintains AWP. WAC is the price the wholesalers tell First DataBank they paid to the manufacturers. AWP represents the most common wholesale price charged to the retailer or hospital.

We tried to gather data regarding the **discounts** that pharmacies receive. The federal study did not gather this information. It appears that WAC does not take into effect the quantity discounts since our data shows that the invoice price is lower than WAC (see findings and recommendations). The invoices that we gathered do not reflect quantity discounts or free goods. Our response to gather information regarding information on discounts has been spotty. One provider indicated that they receive a 3.0% gross rebate for quantity discounts. Another provider showed information that they were getting a rebate of about 0.2%. Some providers indicated that they were too small to get any quantity discounts. No quantity discounts are reflected in our data. It seems that in order to be fair, discounts should be taken into consideration, however it is anticipated that there would be significant resistance from providers in gathering the information. Another discount is the cash discount which is typically 2/10 net 30, which means that a 2% discount is given if paid in 10 days.

## SAMPLING PROCEDURES

To accomplish our objective, we designed a sampling procedure (a detailed description of our sample design is included as **Appendix 1** to this report). Medicaid pharmacy providers were designated as the primary units. We obtained a listing of all Medicaid pharmacy providers as of June 6, 1998. We classified each pharmacy as chain, independent, or nontraditional. 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. Urban was defined as those pharmacies in Davis, Salt Lake, Utah, and Weber counties. All other counties were defined as Rural. We selected a stratified random sample of 60 pharmacies with 12 pharmacies selected from each of five strata urban-chain, rural-chain, urban-independent, rural-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV pharmacies, etc.). All strata had a universe of at least 12. 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 between June 1997 and May 1998. We identified the sources of supply as wholesalers, chain warehouse distributors, generic distributors, and direct manufacturers. Three of the nontraditional pharmacies that we selected were home IV pharmacies that did not have purchases from the sources that we requested. Their purchases were small enough that they purchased from nearby retail pharmacies. We did not include these retail pharmacy purchases, but counted these home IV pharmacies as pharmacies with no purchases from the requested sources.

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. We used the State of Utah's MMIS (Medicaid Management Information System) as the primary source for verifying National Drug Codes (NDCs) and identifying items as over-the-counter, brand name or generic. We used the **Red Book**, a nationally recognized reference for drug product and pricing information as a comparison to the MMIS system. We also used MMIS for the purpose of obtaining AWP for each drug. Since we used MMIS, we were able to determine the AWP for the same date as the invoice. 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.

We used statistical software to generate all random numbers. We obtained the total number of pharmacies from a June 6, 1998 State of Utah Department of Health pharmacy provider listing. There were 460 pharmacies on the list of which we excluded the 66 out-of-state pharmacies, leaving a total population of 394 pharmacies.

## FINDINGS

We estimated that the invoice price for generic drugs is 60.1% below AWP excluding the non-traditional pharmacies. We gathered 1,492 invoice prices received from 55 pharmacies. The standard error for the 1,492 invoices for this estimate was .13.

When we say that the invoice price is 60.1% below AWP we mean that AWP has to decrease 60.1% to equal the invoice price  $((AWP-Invoice)/AWP)$ . A second method would be to increase the invoice by a different percentage to equal AWP  $((AWP-Invoice)/Invoice)$ . The Federal report in **Appendix 4** used the first method. And, the Estimated Acquisition Cost (EAC) which in Utah's case is 12% below AWP is computed using the first method,  $((AWP-EAC)/AWP)=12\%$ . And so on this report we will use the formula  $((AWP-Invoice)/AWP)$  rather than the formula  $((AWP-Invoice)/Invoice)$  so that our percentage will be comparable with EAC and the report in **Appendix 4**.

The estimates of the differences between AWP less Invoice  $((AWP-Invoice)/AWP)$  for generic drugs, are summarized in the following table:

| Category                           | AWP-Invoice |
|------------------------------------|-------------|
| <b>Rural-Chain</b>                 | 56.6%       |
| <b>Rural-Independent</b>           | 60.7%       |
| <b>Urban-Chain</b>                 | 60.5%       |
| <b>Urban-Independent</b>           | 60.6%       |
| <b>Non-Traditional</b>             | 60.9%       |
| <b>Total (Excluding Non-Trad.)</b> | 60.1%       |
| <b>Total (Including Non-Trad.)</b> | 60.2%       |

The following table shows the number of pharmacies sampled and the number of prices reviewed by individual category for generic drugs.

| Category                           | Number of Sample Pharmacies<br>Responding | Prices From Sample Pharmacies |
|------------------------------------|---|-------------------------------|
| <b>Rural-Chain</b>                 | 9   | 436                           |
| <b>Rural-Independent</b>           | 12  | 182                           |
| <b>Urban-Chain</b>                 | 10  | 525                           |
| <b>Urban-Independent</b>           | 12  | 233                           |
| <b>Non-Traditional</b>             | 12  | 116                           |
| <b>Total (Including Non-Trad.)</b> | 55  | 1,492                         |

Five pharmacies refused to participate in our study. They were three Rite Aid (Payless) pharmacies, one Target pharmacy, and one Fred Meyer pharmacy.

We calculated a savings amount of as much as \$4.1 million for the ingredient portion of generic drugs for FYE 6/30/98. The combined ingredient and dispensing fees paid for 966,589 generic prescriptions for FYE 6/30/98 was \$12,972,999. Using a weighted average of a \$4 dispensing fee per prescription the dispensing fees are \$3,866,356 leaving \$9.1 million for ingredients. Since the effective reimbursement including the upper limit is 73.4% of AWP the estimated AWP is \$12.4 million. A reimbursement of AWP less a discount of 60.1% would have \$5.0 million in expenditures. Thus, the estimated savings is \$9.1 million less \$5.0 million or \$4.1 million.

## COMPARISON TO WHOLESALE ACQUISITION COST

When we compared WAC to AWP and to invoice we found that 336 of the 1,492 prices were not included in the WAC data (The WAC database does not include as many drugs as does the AWP database). Also, the WAC data came from price information as of August 11, 1998. Each price came with an effective date, or the date that particular price went into effect. And so we also eliminated those prices where the invoice date is before the effective date thus further reducing the number of prices down to 833. The comparisons, for only those prices where the invoice date and the AWP date falls within the effective time period for the WAC date, are as follows (Note that the AWP-Invoice comparison below is different then the comparison above because the analysis below includes fewer prices):

| Category                          | AWP-Invoice  | AWP-WAC      | WAC-Invoice  |
|-----------------------------------|--------------|--------------|--------------|
| Rural-Chain                       | 58.1%        | 20.9%        | 37.2%        |
| Rural-Independent                 | 58.2%        | 33.4%        | 24.8%        |
| Urban-Chain                       | 59.5%        | 19.7%        | 39.8%        |
| Urban-Independent                 | 60.5%        | 35.0%        | 25.5%        |
| Non-Traditional                   | 60.1%        | 14.6%        | 45.5%        |
| <b>Total (Excluding Non-Trad)</b> | <b>59.4%</b> | <b>26.0%</b> | <b>33.4%</b> |
| <b>Total (Including Non-Trad)</b> | <b>59.5%</b> | <b>24.5%</b> | <b>35.0%</b> |

WAC and AWP are data bases maintained by the same company, First DataBank. Theoretically WAC is supposed to take into consideration discounts. However, our study shows that the invoice cost is lower then WAC, and so WAC does not appear to be the invoice cost less all discounts.

## CONCLUSIONS AND RECOMMENDATIONS

Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost and AWP. 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.

# APPENDICES

APPENDIX 1

## SAMPLE DESCRIPTION

### Sample Objectives:

Develop a statewide estimate of the extent of the discount below average wholesale prices (AWP) of actual invoice prices to Medicaid pharmacies for generic drugs.

### Population:

The primary sampling population was all Pharmacies listed as Medicaid providers with the State of Utah Department of Health as of June 6, 1998.

### Sample Design:

A sample was designed with Medicaid pharmacy providers as the sample units. A stratified random sample of pharmacies was selected. A sample of 12 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 June 1997 to May 1998 for which to provide invoices. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distributors, generic manufacturers and direct manufacturers. All invoice prices were compared to AWP.

### Sample Size:

Twelve pharmacies were selected from each stratum of our sample frame. Sixty pharmacies were selected.

### The source of Random Numbers:

Microsoft Excel 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 discounts 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 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 use 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 difference.

Other Evidence:

We used MMIS to obtain AWP. MMIS obtained AWP from First Data Bank.



## APPENDIX 2

STATEWIDE SAMPLE RESULTS  
GENERIC DRUGS

|                          | Sample Universe | Participating Pharmacies<br>Sample Size | Prices Checked | Point Estimate | Standard Error | Confidence Lower Limit | Confidence Upper Limit | Standard Deviation |
|--------------------------|-----------------|---|----------------|----------------|----------------|------------------------|------------------------|--------------------|
| RURAL-CHAIN              | 41              | 9                                       | 436            | 47.7           | 1.87           | 45.01                  | 50.44                  | 5.61               |
| RURAL-INDEPENDENT        | 55              | 12                                      | 182            | 48.8           | 1.69           | 46.34                  | 51.26                  | 5.87               |
| URBAN-CHAIN              | 159             | 10                                      | 525            | 50.6           | 1.13           | 48.84                  | 52.44                  | 3.58               |
| URBAN-INDEPENDENT        | 89              | 12                                      | 233            | 49.0           | 1.86           | 46.18                  | 51.87                  | 6.44               |
| NON-TRADITIONAL          | 50              | 12                                      | 116            | 56.4           | 6.12           | 47.22                  | 65.66                  | 17.30              |
| TOTAL INCLUDING NON-TRAD | 394             | 55                                      | 1,492          | 50.5           | .13            | 48.87                  | 52.03                  | .96                |
| TOTAL EXCLUDING NON-TRAD | 344             | 43                                      | 1,376          | 49.6           | .11            | 48.36                  | 50.80                  | .74                |

The Pharmacies not participating are: Target Stores (1), Rite Aid (Payless) Corp. (3), and Fred Mayer (1).

# State Of Utah

## Comparison Of State Pharmacy Acquisition Cost Review To Federal Review

### Generic Drugs

| Pharmacy Type<br>Data                        | State Review<br>6/97-5/98 | Federal Review<br>CY 1994 |
|--|---------------------------|---------------------------|
| Rural-Chain<br>AWP-Invoice/AWP               | 56.6%                     | 47.5%                     |
| Prices From Sample                           | 436                       |                           |
| Rural-Independent<br>AWP-Invoice/AWP         | 60.7%                     | 47.4%                     |
| Prices From Sample                           | 182                       |                           |
| Urban-Chain<br>AWP-Invoice/AWP               | 60.5%                     | 37.6%                     |
| Prices From Sample                           | 525                       |                           |
| Urban-Independent<br>AWP-Invoice/AWP         | 60.6%                     | 46.7%                     |
| Prices From Sample                           | 233                       |                           |
| Non-Traditional<br>AWP-Invoice/AWP           | 60.1%                     | na                        |
| Prices From Sample                           | 116                       |                           |
| Total Including Non-Trad.<br>AWP-Invoice/AWP | 60.2%                     | na                        |
| Prices From Sample                           | 1,492                     |                           |
| Total Excluding Non-Trad.<br>AWP-Invoice/AWP | 60.1%                     | 42.5%                     |
| Prices From Sample                           | 1,376                     |                           |

# Hooked on Drugs

Why do insurers pay such outrageous prices for pharmaceuticals?

BY BILL ALPERT • Jim Fanning saw the plaque in a doctor's splendid home: "This is the house that leucovorin built." Leucovorin is one of the cancer drugs that typifies a basic drug-industry pricing convention that, in Fanning's view, is a multibillion-dollar fraud. Fanning, the pharmacy director of Fort Worth-based ChemoLab, isn't alone in criticizing the published

wholesale prices that most insurers, public and private, use in determining how much to pay for pharmaceuticals. For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60%-90% below the so-called average wholesale price, or AWP, used in reimbursement claims.

But Medicare, one of the largest insurers that still reimburses at AWP, is about to demand a change. The huge federal health-insurance program, trying to forestall insolvency, soon will propose regulations aimed at cutting the amount it lays out for the nearly \$2 billion in annual drug claims it covers outside of hospitals. The move — especially if it is followed by others now paying near AWP for drugs — will attack from a new direction the pricing practices of a drug industry already beset by antitrust suits from retail drugstores. It also could upset a large segment of the health-care industry, which has thrived on the huge spread between the published wholesale prices used in insurance claims and the far lower wholesale prices actually paid.

That segment includes oncology practices, respiratory therapy firms and home-infusion companies. It also includes the drug makers themselves, whose allegedly inflated price lists and the opportunity for profiteering that they afford to middlemen, gain them market share and encourage overuse of their products. Among the publicly traded companies that could be affected: Apria Healthcare Group, Lincare Holdings, RoTech Medical, OmniCare, Abbott Laboratories and Baxter International.

Most people don't even know that Medicare pays for pharmaceuticals and related products, but through piecemeal congressional authorizations, the program now covers certain drugs for emphysema, cancer, kidney dialysis and organ transplantation, often requiring injection. While still barely 1% of its nearly \$184 billion in 1995 spending, Medicare's outpatient drug-bill (not including co-payments) was \$1.8 billion last year, double 1992's level.

Under its current regulations, Medicare provides reimbursement for those drugs at the lesser of either its estimate of what the drugs cost the doctors or the Average Wholesale Price.

But Medicare's attempts to survey

doctors for their costs have been stymied by federal paperwork rules, so it reimburses at the AWP.

Like most drug buyers focused on average wholesale price, Medicare looks to compendia such as the *Red Book*, put out monthly by Medical Economics, of Montvale, N.J., or the rival *Blue Book* published by First DataBank, a Hearst subsidiary in San Bruno, Calif. Only after Medicare's drug bill started to rocket did policy makers at the Department of Health and Human Services start closely scrutinizing their AWP payments.

They've asked the department's inspector general's office to examine how Medicare suppliers' true acquisition costs square with the program's reimbursement levels.

Claims for nebulizer drugs, the inhalants used by many asthma and emphysema sufferers, were the first studied by the auditors. From under \$80 million in 1992, Medicare's annual bill for inhalation drugs grew to \$250 million last year, most of it for a steroid called albuterol

sulfate.

In a report released Thursday, the inspector general's office stated that the medical-equipment firms that Medicare reimburses at an average wholesale price-derived 40-43 cents per milliliter actually paid less than half that, on average: just 19 cents.

The report asserted that Medicare could have saved about \$94 million if its reimbursements had been based on actual wholesale prices over the 14 months covered by the study.

Another report by the inspector general produced a similar finding for feeding-tube liquids, like the market-leading Ensure products of Abbott Labs. These, the IG found, cost nursing homes 42% less than the price that Medicare bases its reimbursements on. Such products cost Medicare and its beneficiaries several hundred million dollars a year.

The inspector general currently is looking at prices for big-ticket drugs, and intravenous liquids, too. Barron's has done the same, in an examination of

the top 20 Medicare drugs (which account for about 75% of the program's drug spending), as well as for various intravenous solutions. Our study shows that for many drugs coming off-patent, the average wholesale prices in no way represents the true wholesale price.

For about 300 dose forms of the drugs, Barron's got the AWP's from the *Red Book* and the *Blue Book*. Then, we collected current quotes or price lists from several leading wholesaler specializing in sales to doctors, home health firms, nursing homes and hospitals.

These wholesalers included: The Oncology Therapeutics Network, a South San Francisco-based joint venture of Bristol-Myers Squibb and Axion; Florida Infusion Services of Palm Harbor, Fla.; National Specialty Services, of Nashville; and UltraCare, of Overland Park, Kan. Prices also came in from the Boulder, Colo., hospital buying group Vista Purchasing Partners.

This sampling showed that for single-source drugs still enjoying patent protection, such as Bristol-Myers Squibb's Taxol or Platinol, true wholesale prices are generally 10%-20% below published AWP's.

But for generic drugs, nearly every manufacturer's price was 60%-85% below the published average wholesale price. Some of the generics account for significant spending by Medicare, claiming half of the top 20 slots. Two of them, albuterol and leucovorin, are in the No. 2 and No. 5 slots, respectively.

Pricing is even more unreal worse for intravenous nutritional and solutions, a category dominated by Abbott Laboratories and Baxter International. Catalog wholesale prices for these items are, on average, 80%-93% below those companies' AWP's.

The prices from the different wholesalers were closely bunched. "There are really no special deals out there," contends Fanning, who buys plenty of drugs at wholesale himself.

If most health-care providers can get these prices, is it any wonder an industry wag says that AWP really means "Ain't What's Paid"?

The high prices on generic drugs have led investigators to seek the source of the published AWP's. Back in 1992, major drug manufacturers told the inspector general's office that the *Red Book*, not the manufacturers, determined the AWP. But *Red Book* officials blamed the manufacturers.

The answers are the same today. Phil Southern, associate product manager of the *Red Book*, says it publishes prices that are "fixed right from

## AWP: AIN'T WHAT'S PAID

► A sample of drugs whose published Average Wholesale Price is wildly above the wholesale price available to almost any buyer. Some of these AWP's actually have risen, while real wholesale prices have plummeted. Publishers say drug makers dictate AWP's.

| Drug   | Use             | Maker      | '95 AWP | Wholesale Price | % Under AWP |
|--|-----------------|------------|---------|-----------------|-------------|
| Doxorubicin HCL powder, 10 mg injectable           | Chemotherapy    | Adna Labs* | \$46.00 | \$13.00         | 72%         |
| Etoposide 100 mg in 5 ml for injection             | Chemotherapy    | Gensia     | 141.97  | 34.00           | 76          |
| Gentamicin Sulfate, 100 mg in 10 ml injection      | Antibiotic      | Abbott     | 6.18    | 1.26            | 80          |
| Intravenous Immune Globulin, 10 mg                 | Chemotherapy    | Baxter     | 640.71  | 266.00          | 58          |
| Leucovorin Calcium, 350 mg injection               | Chemotherapy    | ImmuneX    | 137.94  | 22.50           | 84          |
| Methotrexate 250 mg injection                      | Chemotherapy    | Chiron     | 26.88   | 6.40            | 76          |
| Vancomycin HCL 5 gm in 100 ml injection            | Antibiotic      | Abbott     | 135.99  | 36.00           | 74          |
| Vincristine Sulfate 1 mg injection                 | Chemotherapy    | EE Lilly   | 34.62   | 6.72            | 81          |
| 8.5% Amino Acid sol., 1000 ml for parenteral nutr. | TPN             | Abbott     | 152.65  | 10.81           | 93          |
| 50% Dextrose Sol., 500 ml in glass                 | Intravenous Sol | Baxter     | 27.03   | 2.56            | 91          |
| Lactated Ringer's Injection, 500 ml                | Intravenous Sol | Baxter     | 11.16   | 1.61            | 86          |
| Normasol 500 ml                                    | Intravenous Sol | Abbott     | 16.86   | 2.04            | 88          |
| Potassium Phosphate, 15 ml vial                    | Intravenous Sol | Abbott     | 5.55    | 0.48            | 91          |

\* Unit of Pharmacia-Upjohn

Source: 1995 Red Book, Medical Economics, Montvale, N.J.

the manufacturers. "They're not our prices," he insists.

Ed Edelstein, *Blue Book* editor, says that, while some brand-name firms don't give him prices, generic firms do. "The AWP is the manufacturer's suggested wholesale price," he says. "It's our editorial policy to go along with that."

But Immunex, with a thriving generic cancer-drug business, says its average wholesale prices aren't its own. "The drug manufacturers have no control over the AWP's published . . ." says spokeswoman Valerie Dowell.

A maker of generic inhalants gives a different answer, but off the record: "The AWP's typically originate with the manufacturer."

More puzzling is the way generic AWP's stay at their lofty perches, or even rise, as competition forces a drug's true wholesale price into the abyss. "The reason this is happening," suggests Michael Neff, pharmacy program administrator of Medi-Cal-California's Medicaid agency, "is that most folks in a position to pay - even state Medicaid programs and HMOs - generally use AWP as a benchmark for reimbursement."

In 1993, the Bristol-Myers Squibb cancer drug Vepesid came off-patent, opening the market for a generic form called etoposide. A 100-milligram dose of Vepesid had an AWP of about \$136. The first generic etoposide was Gensia Pharmaceutical's, with a market price of about \$75, but the AWP of \$142.

The second generic to market, from Pharmacia, pushed the market price to \$60, but Pharmacia set an AWP around

### FALSE CLAIMS?

Some of these firms make drugs, or bill insurers for drugs, that cost far less than the published Average Wholesale Price that Medicare and other insurers pay on claims. Says one wholesaler: "It may be legal, but it's certainly not ethical."

| Company                       | Symbol | Exchange | Recent Price | Medicare Reimbursement Change Might Affect   |
|-------------------------------|--------|----------|--------------|--|
| Abbott Labs                   | ABT    | NYSE     | 43 1/2       | Medicare buys \$500 million of Lipron, also \$100s-of-millions of nutritional                  |
| American Home Prods           | AHOM   | NNM      | 45 1/2       | Medicare/Medicaid pay for 60% of firm's respiratory and infusion services revenues             |
| American Oncology Resources   | AORI   | NNM      | 44 1/4       | One-third of revenues from Medicare/Medicaid; chemo drugs a big profit center                  |
| Amgen                         | AMGN   | NNM      | 60 1/2       | \$75 million in Medicare payments for Neupogen = 10% of drug's U.S. sales                      |
| Baxter International          | BAX    | NYSE     | 46 1/2       | Government demands rationale for its published prices on intravenous products                  |
| Bristol-Myers Squibb          | BMY    | NYSE     | 88 1/2       | Cancer drugs a mainstay; Medicare bought about 25% of U.S. sales of Taxol                      |
| Chiron                        | CHIR   | NNM      | 97           | Cancer drugs approx 5% of sales  |
| Coram                         | CRH    | NYSE     | 4 1/2        | One-third of revenues from nutritional therapy; 27% of payments from Medicare/Medicaid         |
| Gensia                        | GNSA   | NNM      | 5 1/2        | Largest product is generic etoposide, just got approval for generic doxorubicin                |
| Immunex                       | IMNX   | NNM      | 15 1/2       | Cancer collaboration with American Home Products; leucovorin a \$20 million product            |
| Lincare Holdings              | LINC   | NNM      | 41 1/4       | 80% of revenues from Medicare/Medicaid, who are after firm's 85% gross margins                 |
| Omnicare                      | OCR    | NYSE     | 56           | Nursing home pharmacy gets 50% of sales from Medicaid/Medicare; expanding in infusion business |
| Pharmacia-Upjohn              | PNU    | NYSE     | 42 3/4       | Cancer drugs approx. 9% of drug sales  |
| Physician Practice Management | PHYM   | NNM      | 49 1/4       | 45% of revenues from Medicare/Medicaid; chemo drugs a big profit center                        |
| RoTach                        | ROTC   | NNM      | 19 1/4       | 50% of revenues Medicare/Medicaid; 6% from chemo and nutrition therapy                         |

\$140. Today, the market price for 100 milligrams of etoposide is around \$35, but Gensia acidly raised its AWP last year by about 10%.

When some drug salespeople visit a doctor, says another Medicaid administrator, the salesperson lets the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm.

If manufacturers deliberately maintain lofty AWP's on their generic drugs, it directly profits their customers, not them. Of course, the drug makers might then gain market share and higher sales from their customers' over-utilization.

Indeed, for makers of generics, unreal average wholesale prices pose a classic social dilemma. If some, but not all, rectify their AWP's, the honest makers cut their own throats. "Manufacturers have told me that if they act on their own they'll dry up their own business," says Medi-Cal's Neff. "If I'm a buyer and one drug gives me 20% higher reimbursement, who am I going to go with?"

Some insurers, including Medicare, decree maximum prices for each generic drug, to avoid the alleged manipulation of AWP's. But it takes a year or so to establish a maximum price for new generics, and insurers haven't gotten around to setting prices for many doses.

There definitely is over-utilization of these products, acknowledges a maker of inhalation drugs. "Because HCFA [the Health Care Financing Administration, the federal Medicare-Medicaid agency] is paying a somewhat arbitrary price, this has been discussed for almost three years."

It's not rocket science; what's taken them so long?"

Some of the inspector general's investigators believe they've been played for fools. "We trusted the industry and the providers," says one investigator, off the record. "We didn't know how pervasive the discounting was. We thought it was available to just select providers."

Now, the Justice Department is serving "civil investigative demands" — a kind of subpoena in antitrust investigations — on manufacturers, asking them how those inaccurate AWP's wind up in the *Red Book and Blue Book*.

Baxter has received one, according to investigators, for its intravenous solutions,

*If most health-care providers can get much lower prices for pharmaceuticals than insurers do, is it any wonder that an industry wag says that "average wholesale price" really stands for "ain't what's paid"?*

whose true wholesale prices — like those of rival Abbott — seem to be 90% below the average wholesale price. Baxter wouldn't comment to *Barron's*.

The drug makers created false statements so that the doctors could make hundreds of millions of dollars, maintains an angry investigator. "If OIG doesn't get

them, the Justice Department will."

Some investigators view the spreads guaranteed by extreme average wholesale prices as a kind of kickback to doctors, in violation of federal laws.

One group of infusion-industry veterans is reportedly considering attacking the problem by filing a private suit under the False Claims Act. This is the whistleblower law that allows citizens with knowledge of fraud against the government to sue on behalf of the government and share in the recovery.

Meanwhile, the cooler-headed policymakers at the inspector general's office and in HCFA are reconsidering Medicare's drug reimbursement rules. They plan to suggest their changes in the Federal Register soon.

"Medicare's been paying too much for our drugs," says deputy inspector general George Grob. "We're paying the window-sticker price when everybody else wants a discount and is getting it."

Tom Alt, of HCFA's Bureau of Policy Development, notes that any savings for Medicare will mean savings for beneficiaries, who are kicking in 20% co-payments at current Medicare prices.

Any reduction in reimbursement levels probably would have some effect on the firms that enjoy the spreads between everyday low wholesale prices and the average wholesale prices at which Uncle Sam reimburses them.

That includes oncology practice-management firms like American Oncology Resources and Physician Reliance Network, which earn significant profits on the chemotherapy drugs they administer to cancer patients. Likewise, respiratory therapy and infusion firms like American HomePatient, Apria Healthcare, Coram Healthcare, Lincare Holdings and Ro-Tech Medical, which owe their sensational profit margins, to various degrees, to their drug spreads.

Then, there are the drug makers themselves, including Abbott, Baxter, Chiron, Genzia and Immunex — all with wide AWP spreads on their generic offerings.

Dr. H. Merrick Reese, the CEO of Physician Reliance, says he doubts that HCFA plans to cut reimbursement rates for cancer drugs, which he says his firm marks up only modestly.

More likely, Medicare will go after the inhalation drugs like albuterol, says Dr. Joseph Bailes, who chairs the clinical practice committee of the American Society of Clinical Oncology.

Chemo Labs is doing what it can to ensure that the AWP tricksters start running out of fools. Located near Fort Worth Airport, Fanning's firm will supply chemotherapy drugs for insurers, shipping doses to oncologists as needed, and for a fraction of the average wholesale price.

And the most aggressive public insurers, including Medicaid programs in six states, are turning their backs on AWP.

They now base their drug payments on WAC — the Wholesale Acquisition Cost actually paid by medical-care providers.

*Blue Book* editor Edelstein warns, however, that this won't end the game. "Then the manufacturers will just start fooling around with that price," he warns.

For now, says Fanning, the Chemo Lab pharmacist, the bonanza drug is etoposide. Someday, he expects to see a plaque saying: "This is the house that etoposide built."

## APPENDIX 4

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICAID PHARMACY - ACTUAL  
ACQUISITION COST OF GENERIC  
PRESCRIPTION DRUG PRODUCTS**



**JUNE GIBBS BROWN  
Inspector General**

**AUGUST 1997  
A-06-97-00011**



## 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 generic 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 a nationwide estimate of the discount below AWP at which pharmacies purchase generic drugs. Estimates for brand name drugs were also developed and those results were reported in a separate report.

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. We obtained pricing information from 314 pharmacies. Specifically, we obtained 9,075 invoice prices for generic drugs.

We estimated that, on average, actual acquisition cost of generic drugs was 42.5 percent below AWP. Unlike brand name drugs, where reimbursement is predominantly based on a discounted AWP, reimbursement of generic drugs can be limited by Federal upper limit amounts that are established by HCFA. Taking the upper limits into consideration, we calculated a savings of as much as \$145.5 million in Calendar Years (CY) 1994 and 1995 for 200 generic drugs with the greatest amount of Medicaid reimbursement in each year, if reimbursement had been based on the findings of this report.

For the 11 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 excluded the non-traditional category 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 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 July 7, 1997. The HCFA concurred with the findings and recommendations of this report. The HCFA hoped that this report would provide the necessary impetus for States to restructure their payment methodology for outpatient drugs. The full text of HCFA's comments is included in Appendix 3.

# TABLE OF CONTENTS

|  | <u>PAGE</u> |
|--|-------------|
| INTRODUCTION                           | 1           |
| BACKGROUND                             | 1           |
| SCOPE                                  | 2           |
| FINDINGS AND RECOMMENDATIONS           | 4           |
| CONCLUSIONS AND RECOMMENDATIONS        | 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 cost for drugs reimbursed under the Medicaid prescription drug program. The objective of our review was to develop a nationwide estimate of the difference between actual acquisition cost of drugs by the retail pharmacy and AWP for generic 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 a Federal 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 costs (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 cost. However, the OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, the 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".

## SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop a nationwide estimate of the difference between the actual invoice prices of generic 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 such as therapeutic interventions, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multipart 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 line item.

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 generic 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 generic drug. We also obtained from HCFA a listing of the top 200 generic drugs in terms of the amount reimbursed by Medicaid for CY 1994 and for CY 1995. 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 the staff of the OAS Field Office in Little Rock, Arkansas with assistance from staff in 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 pharmacies pay an average of 42.5 percent less than AWP for drugs sold to Medicaid beneficiaries. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison of AWP for 9,075 invoice prices received from 314 pharmacies in the 11 State sample. The standard error for this estimate was .90 percent.

The estimates by individual categories for generic drugs are summarized in the following table:

| Category                 | Point Estimate | Standard Error | Sample Pharmacies | Prices Compared |
|--------------------------|----------------|----------------|-------------------|-----------------|
| Rural-Chain              | 47.5           | 1.63           | 73                | 2,963           |
| Rural-Independent        | 47.4           | .93            | 78                | 1,798           |
| Urban-Chain              | 37.6           | 2.82           | 72                | 2,634           |
| Urban-Independent        | 46.7           | 2.44           | 91                | 1,680           |
| Non-Traditional          | 57.7           | 1.98           | 59                | 1,262           |
| Overall (Exc. Non-Trad.) | 42.5           | .90            | 314               | 9,075           |

While the estimate of the discount below AWP of invoice price for generic drugs is significant, this difference is mitigated by Federal upper limit amounts for generic drugs. Reimbursement for the ingredient cost, or EAC, of generic drugs is limited to the upper limit amounts established by HCFA. The upper limit amounts are based on 150 percent of AWP for the lowest priced generic equivalent. However, every generic drug does not have an upper limit established and in those cases, reimbursement of EAC is the same as reimbursement of EAC for brand name drugs. The EAC for brand name drugs is predominantly based on a discounted AWP, with 10 percent being the most common discount. Therefore, reimbursement of generic drugs which do not have upper limits is greatly in excess of the actual cost of the drug.

In order to assess the significance of the difference between what pharmacists pay for generic drugs and what Medicaid reimburses for those drugs, we calculated the difference for the 200 generic drugs with the most Medicaid reimbursement in CY 1994 and for the 200 with the most Medicaid reimbursement in CY 1995. For 187 drugs with upper limit amounts, we multiplied Medicaid utilization by the difference between the upper limit (what Medicaid pays for EAC)

and AWP discounted by 42.5 percent (pharmacy cost per our review). For 213 drugs without upper limits, we multiplied Medicaid utilization by AWP discounted by the difference between 42.5 percent and the most commonly used discount of 10 percent. We used the AWP for each drug that was in effect January 1, 1994 and January 1, 1995, respectively. We also used the upper limit amount that was in effect January 1, 1994 or January 1, 1995.

The difference between what Medicaid reimburses for ingredient cost and our estimate of what pharmacies actually pay was \$145.5 million for the 2-year period. The majority, \$132.7 million, of the difference was attributable to the 213 drugs without upper limits established.

Reimbursement for 112 of the 187 drugs with upper limits was \$37.3 million more than the estimated cost and reimbursement for the remaining 75 drugs was \$24.5 million less than estimated cost. The following table details the results of our calculations:

|   | 1994 | 1995 | 1994<br>&<br>1995 | Difference between<br>Reimbursement and<br>Acq. Cost * | Total<br>Reimbursement<br>by Medicaid |
|---|------|------|-------------------|--|---------------------------------------|
| Drugs without upper limits                | 116  | 97   | 213               | \$132,656  | \$414,408                             |
| Drugs with upper limits greater than cost | 54   | 58   | 112               | \$37,304   | \$153,725                             |
| Drugs with upper limits less than cost    | 30   | 45   | 75                | \$(24,495)   | \$90,977                              |
| Totals                                    | 200  | 200  | 400               | \$145,465  | \$659,110                             |

\* - Amounts in thousands

## 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 \$145.5 million in CY 1994 and CY 1995 for the 200 most reimbursed drugs in each year. 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 July 7, 1997. The HCFA concurred with the findings and recommendations of this report. The HCFA hoped that this report would provide the necessary impetus for States to restructure their payment methodology for outpatient drugs. The full text of HCFA's comments is included in Appendix 3.

## APPENDICES

## SAMPLE DESCRIPTION

### Sample Objectives:

Develop a nationwide estimate of the extent of the discount below average wholesale prices (AWP) of actual invoice prices to Medicaid pharmacies for generic 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. A maximum of 60 pharmacies was selected from each State. Some States did not have 12 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.

**NATIONWIDE SAMPLE RESULTS  
GENERIC NAME DRUGS**

|                                 | NATIONWIDE               | SAMPLE<br>UNIVERSE | SAMPLE<br>SIZE | DRUG<br>PRICES<br>REVIEWED | POINT<br>ESTIMATE | STANDARD<br>ERROR | 90 PERCENT<br>CONFIDENCE LEVEL |                |
|---------------------------------|--------------------------|--------------------|----------------|----------------------------|-------------------|-------------------|--------------------------------|----------------|
|                                 |                          |                    |                |                            |                   |                   | LOWER<br>LIMIT                 | UPPER<br>LIMIT |
| G<br>E<br>N<br>E<br>R<br>I<br>C | RURAL-CHAIN              | 1,095              | 73             | 2,963                      | 47.51             | 1.63              | 44.82                          | 50.20          |
|                                 | RURAL-INDEPENDENT        | 1,499              | 78             | 1,798                      | 47.38             | 0.93              | 45.85                          | 48.92          |
|                                 | URBAN-CHAIN              | 8,194              | 72             | 2,634                      | 37.61             | 2.82              | 32.97                          | 42.26          |
|                                 | URBAN-INDEPENDENT        | 6,242              | 91             | 1,680                      | 46.72             | 2.44              | 42.70                          | 50.73          |
|                                 | NON-TRADITIONAL          | 2,026              | 59             | 1,262                      | 57.70             | 1.98              | 54.43                          | 60.96          |
|                                 | OVERALL (EXCL. NON-TRAD) | 17,030             | 314            | 9,075                      | 42.45             | 0.90              | 40.97                          | 43.93          |



DEPARTMENT OF HEALTH & HUMAN SERVICES

- APPENDIX 3  
(PAGE 1 OF 2)

Health Care Financing Administra:

The Administrator  
Washington, D.C. 20201

JUL 7 1997

DATE:

TO: June Gibbs Brown  
Inspector General

FROM: Bruce C. Vladeck  
Administrator

A handwritten signature in cursive script, appearing to read "Bruce C. Vladeck", written over the printed name of the sender.

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicaid Pharmacy--  
Actual Acquisition Cost of Generic Prescription Drug Products."  
(A-06-97-00011)

We reviewed the above-referenced report concerning the pharmacy acquisition cost for generic drugs reimbursed under the Medicaid prescription drug program.

Our detailed comments are attached for your consideration. Thank you for the opportunity to review and comment on this report.

Attachment

Health Care Financing Administration (HCFA) Comments on  
Office of Inspector General (OIG) Draft Report Entitled:  
"Medicaid Pharmacy--Actual Acquisition Cost of Generic Prescription Drug Products,"  
(A-06-97-00011)

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. Additionally, HCFA should study any of the other factors it believes could significantly impact pharmacy reimbursement.

HCFA Response

We concur. The findings shown in the report confirm the belief shared by many states that the pharmacy's actual generic drug acquisition costs are much less than the prices paid by many states to the pharmacies. An increasing number of state outpatient drug programs are changing the basis for reimbursing ingredient costs from the average wholesale price to the lower of the wholesaler acquisition cost, the usual and customary charge, or the estimated acquisition cost, in order to be closer to the actual price paid by the pharmacy to acquire the drug. This report provides a monetary incentive for states to reassess their drug reimbursement methodology as they look for ways to stretch their operating budgets.

The report also recommends that HCFA study other factors that affect drug costs such as dispensing fees. Regional office personnel who function as drug rebate coordinators polled the states in their regions in both 1995 and 1996 to ascertain whether states are considering lowering the dispensing fee. Their findings indicate that states are beginning to consider reducing their dispensing fees only when the need for additional savings becomes critical. However, based on the number of states that are changing to capitated reimbursement arrangements, we believe the lowering of state dispensing fees is becoming less important.

We believe the findings in this report are significant and warrant the attention of all state Medicaid agencies. We intend to share this report with all state Medicaid agencies and hope this report will provide the necessary impetus for states to restructure their payment methodology for outpatient drugs.

STATE OF UTAH

Department of Health

Division of Health Care Financing

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

FEBRUARY 1999



STATE OF UTAH

Department of Health

Division of Health Care Financing

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

FEBRUARY 1999

## BRAND NAME PRESCRIPTION DRUG SUMMARY

The State of Utah's Division of Health Care Financing, which is part of the Department of Health, conducted a statewide review of pharmacy acquisition cost for brand name drugs reimbursed under the Medicaid prescription drug program. The State of Utah reimburses pharmacies for Medicaid prescriptions using a formula which discounts the average wholesale price (AWP). **The objective of our review was to develop a statewide estimate of the discount below AWP at which pharmacies purchase brand name drugs.** Estimates for generic drugs were also developed and those results are included in a separate report.

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 (nursing home pharmacies, hospital pharmacies, home IV pharmacies, etc.). We excluded the non-traditional category 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 obtained 2,588 invoice prices for brand name drugs. The pricing information came from 55 pharmacies. We compared each invoice drug price to AWP and estimated that the actual acquisition cost that pharmacies have to pay to acquire brand name drugs was 18.4% below AWP.

Utah pharmacies are reimbursed by Medicaid for brand name drugs at 12% below AWP. A brand name drug avoids the federal upper limits which apply to multi-source drugs when physicians specify that the drug is medically necessary.

We estimate that if the estimated acquisition cost (EAC) reimbursement rate paid by the State were changed from 12% below AWP to 18.4% below AWP that the amount paid by the State during FYE 6/30/98 for the ingredient portion of name brand drugs would have dropped from \$46.2 million to \$42.8 million for a difference of \$3.4 million.

The above estimates do not account for quantity and other discounts that pharmacies receive from distributors. Also, as well as ingredient cost and ingredient revenues, the pharmacies have noningredient costs and noningredient revenues. Noningredient revenues include dispensing fees which Medicaid pays, and co-pays which many Medicaid recipients pay. Noningredient costs can include but are not limited to containers, labels, staff, and overhead.

Our study closely followed a Federal study performed by the Office of Inspector General (OIG), a copy of which is included in Appendix 4. We are recommending that the State of Utah reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of our report.

# TABLE OF CONTENTS

|   | <u>PAGE</u> |
|---|-------------|
| INTRODUCTION .....                                    | 1           |
| BACKGROUND .....                                      | 1           |
| SCOPE .....   | 2           |
| SAMPLING PROCEDURES .....                             | 3           |
| FINDINGS .....  | 4           |
| COMPARISON TO WHOLESALE ACQUISITION COST .....        | 5           |
| CONCLUSIONS AND RECOMMENDATIONS .....                 | 5           |
| APPENDICES .....                                      | 6           |
| APPENDIX 1 - SAMPLE DESCRIPTION .....                 | 7           |
| APPENDIX 2 - STATEWIDE SAMPLE RESULTS .....           | 10          |
| APPENDIX 3 - JUNE 6, 1996 BARRON'S ARTICLE .....      | 13          |
| APPENDIX 4- OFFICE OF INSPECTOR GENERAL'S REPORT .... | 17          |

# INTRODUCTION

The State of Utah's Division of Health Care Financing, which is part of the Department of Health, conducted a statewide review of pharmacy acquisition cost for drugs reimbursed under the Medicaid prescription drug program. The objective of our review was to develop a statewide estimate of the discount below AWP at which pharmacies purchase brand name drugs. Estimates for generic drugs were also developed and those results are included in a separate report. We plan to evaluate the adequacy of the Federal upper limit amounts of generic drug reimbursements in that report.

## BACKGROUND

Prior to 1984, most States used 100% of AWP for reimbursement of acquisition cost (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). However, the OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9% below AWP. In 1989, the OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5% 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.

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."

Medicaid reimbursement of drugs depends on if the drug has a **Federal upper limit**. If a drug has a federal upper limit then reimbursement is based on the lowest of the pharmacist's usual and customary charge to the general public, the Federal upper limit amount, or the **estimated acquisition cost** (EAC). If a drug does not have a Federal upper limit established then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or EAC. The Federal upper limit amounts are established by the Health Care Financing Administration (HCFA). The upper limit amounts are based on 150% of the average of the lowest three products in the multi-source class. The EAC for Utah is calculated by using AWP less a discount percentage of 12% ( $AWP \times (1.0 - .12) = EAC$ ). Brand name drugs avoid the upper-limits when physicians specify that they are medically necessary.

## SCOPE

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; (3) the cost of dispensing which includes costs for computers, multipart labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead; (4) and identifying or reviewing any internal control systems.

Medicaid in the State of Utah pays a **dispensing fee** per claim paid of \$3.90 for pharmacies in urban areas and \$4.40 for pharmacies in rural areas (\$1.00 is also paid for certain over the counter products). A survey done in July 1998 indicated that the Health Maintenance Organizations (HMOs) in Utah pay \$2.00 to \$2.75 as a dispensing fee.

Effective July 1, 1997, most Medicaid recipients are required to pay a \$1.00 **co-payment** for each prescription filled. Recipients exempt from the co-pay requirement include children under age 18, pregnant women, residents of a nursing home who are entitled to keep only \$45 personal needs money, most enrollees in an HMO that includes prescription drug coverage, and recipients whose monthly household income is less than the payment amount in the Family Employment Program. This co-payment pays the pharmacies in addition to what Medicaid in the State of Utah pays the pharmacies. Each recipient has a maximum co-payment of \$5.00 per month.

In addition to comparing an estimate of the difference between the invoice price and AWP, **we also compared invoice price and AWP to WAC** (Wholesale Acquisition Cost). Some states reimburse using WAC instead of or in addition to using AWP. WAC is maintained by the same company, First DataBank, that maintains AWP. WAC is the price the wholesalers tell First DataBank they paid to the manufacturers. AWP represents the most common wholesale price charged to the retailer or hospital.

We tried to gather data regarding the **discounts** that pharmacies receive. The federal study did not gather this information. It appears that WAC does not take into effect the quantity discounts since our data shows that the invoice price is lower than WAC (see findings and recommendations). The invoices that we gathered do not reflect quantity discounts or free goods. The results of our efforts to gather information regarding information on discounts has been spotty. One provider indicated that they receive a 3.0% gross rebate for quantity discounts. Another provider showed information that they were getting a quantity rebate of about 0.2%. Some providers indicated that they were too small to get any quantity discounts. No quantity discounts are reflected in our data. It seems that in order to be fair, discounts should be taken into consideration, however it is anticipated that there would be significant resistance from the providers in gathering the information. Another discount is the cash discount which is typically 2/10 net 30, which means that a 2% discount is given if paid in 10 days.

## SAMPLING PROCEDURES

To accomplish our objective, we designed a sampling procedure (a detailed description of our sample design is included as **Appendix 1** to this report). Medicaid pharmacy providers were designated as the primary units. We obtained a listing of all Medicaid pharmacy providers as of June 6, 1998. We have classified each pharmacy as a chain, independent or nontraditional. 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. Urban was defined as those pharmacies in Davis, Salt Lake, Utah, and Weber counties. All other pharmacies were defined as Rural. We selected a stratified random sample of 60 pharmacies with 12 pharmacies selected from each of five strata urban-chain, rural-chain, urban-independent, rural-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV pharmacies, etc.). All strata had a universe of at less 12. 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 between June 1997 and May 1998. We identified the sources of supply as wholesalers, chain warehouse distributors, generic distributors, and direct manufacturers. Three of the nontraditional pharmacies that we selected were home IV pharmacies that did not have purchases from the sources that we requested. Their purchases were small enough that they purchased from nearby retail pharmacies. We did not include these retail pharmacy purchases, but counted these home IV pharmacies as pharmacies with no purchases from the requested sources.

We reviewed every line item on the invoices supplied by the sampled pharmacies to ensure that invoices contained the information necessary for our review. We eliminated over-the-counter items. We used the State of Utah's MMIS (Medicaid Management Information System) as the primary source for verifying National Drug Codes (NDCs) or identify items as over-the-counter, brand name or generic. We used the **Red Book**, a nationally recognized reference for drug product and pricing information as a comparison to the MMIS system. We also used MMIS for the purpose of obtaining AWP for each drug. Since we used MMIS, we were able to determine the AWP for the same date as the invoice. 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.

We used statistical software to generate all random numbers. We obtained the total number of pharmacies from a June 6, 1998 State of Utah Department of Health pharmacy provider listing. There were 460 pharmacies on the list of which we excluded 66 out-of-state pharmacies, leaving a total population of 394 pharmacies.

## FINDINGS

We estimated that the invoice price for brand names is 18.4% below AWP excluding the non-traditional pharmacies. We gathered 2,588 brand name invoice prices received from 55 pharmacies. The standard error for the 2,588 invoices for this estimate was .07.

When we say that the invoice price is 18.4% below AWP we mean that AWP has to decrease 18.4% to equal the invoice price  $((\text{AWP}-\text{Invoice})/\text{AWP})$ . A second method would be to increase the invoice by a different percentage to equal AWP  $((\text{AWP}-\text{Invoice})/\text{Invoice})$ . The Federal report in **Appendix 4** used the first method. And, the Estimated Acquisition Cost (EAC) which in Utah's case is 12% below AWP is computed using the first method,  $((\text{AWP}-\text{EAC})/\text{AWP})=12\%$ . And so on this report we will use the formula  $((\text{AWP}-\text{Invoice})/\text{AWP})$  rather than the formula  $((\text{AWP}-\text{Invoice})/\text{Invoice})$  so that our percentage will be comparable with EAC and the report in **Appendix 4**.

The estimates of the differences between AWP and Invoice  $((\text{AWP}-\text{Invoice})/\text{AWP})$  for brand name drugs, are summarized in the following table:

| Category                    | AWP - Invoice |
|-----------------------------|---------------|
| Rural-Chain                 | 17.4 %        |
| Rural-Independent           | 17.6 %        |
| Urban-Chain                 | 19.2 %        |
| Urban-Independent           | 18.1 %        |
| Non-Traditional             | 25.7 %        |
| Total (Excluding Non-Trad.) | 18.4 %        |
| Total (Including Non-Trad.) | 19.4%         |

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

| Category                    | Number of Sample Pharmacies<br>Responding | Prices From Sample Pharmacies |
|-----------------------------|---|-------------------------------|
| Rural-Chain                 | 9   | 719                           |
| Rural-Independent           | 12  | 371                           |
| Urban-Chain                 | 10  | 868                           |
| Urban-Independent           | 12  | 488                           |
| Non-Traditional             | 12  | 142                           |
| Total (Including Non-Trad.) | 55  | 2,588                         |

Five Pharmacies refused to participate in our study. They were three Rite Aid (Payless) pharmacies, one Target pharmacy, and one Fred Meyer pharmacy.

We calculated a savings amount of as much as \$3.4 million for the ingredient portion of name brand drugs for FYE 6/30/98. The combined ingredient and dispensing fees paid for 828,975 name brand prescriptions for FYE 6/30/98 was \$49,494,390. Using a weighted average of a \$4 dispensing fee per prescription the dispensing fees are \$3,315,900 leaving \$46.2 million for ingredients. Since the reimbursement is 88% of AWP the estimated AWP is \$52.5 million. A reimbursement of AWP less a discount of 18.4% would have \$42.8 million in expenditures. Thus, the estimated savings is \$46.2 million less \$42.8 million or \$3.4 million.

## COMPARISON TO WHOLESALE ACQUISITION COST

When we compared WAC to AWP and to invoice we found that 109 of the 2,588 prices were not included in the WAC data (The WAC database does not include as many drugs as does the AWP database). Also, the WAC data came from price information as of August 11, 1998. Each price came with an effective date, or the date that particular price went into effect. And so we also eliminated those prices where the invoice date is before the effective date thus further reducing the number of prices down to 808. The comparisons, for only those prices where the invoice date and the AWP date falls within the effective time period for the WAC date, are as follows (Note that the AWP-Invoice comparison below is different then the comparison above because the analysis below includes fewer prices):

| Category                   | AWP-Invoice | AWP-WAC | WAC-Invoice |
|----------------------------|-------------|---------|-------------|
| Rural-Chain                | 19.3%       | 18.2%   | 1.0%        |
| Rural-Independent          | 17.6%       | 17.7%   | 0.0%        |
| Urban-Chain                | 20.7%       | 18.5%   | 2.3%        |
| Urban-Independent          | 18.9%       | 18.7%   | 0.2%        |
| Non-Traditional            | 33.1%       | 20.7%   | 12.5%       |
| Total (Excluding Non-Trad) | 19.6%       | 18.4%   | 1.2%        |
| Total (Including Non-Trad) | 21.3%       | 18.7%   | 2.7%        |

WAC and AWP are data bases maintained by the same company, First DataBank. Theoretically WAC is supposed to take into consideration discounts. However, our study shows that the invoice cost is lower then WAC and so WAC is not the invoice cost less a discount.

## CONCLUSIONS AND RECOMMENDATIONS

Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost and AWP. 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.



# APPENDICES

# APPENDIX 1

## SAMPLE DESCRIPTION

### Sample Objectives:

Develop a statewide estimate of the extent of the discount below average wholesale prices (AWP) of actual invoice prices to Medicaid pharmacies for brand name drugs.

### Population:

The primary sampling population was all Pharmacies listed as Medicaid providers with the State of Utah Department of Health as of June 6, 1998.

### Sample Design:

A sample was designed with Medicaid pharmacy providers as the sample units. A stratified random sample of pharmacies was selected. A sample of 12 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 June 1997 to May 1998 for which to provide invoices. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distributors, generic manufacturers, and direct manufacturers. All invoice prices were compared to AWP.

### Sample Size:

Twelve pharmacies were selected from each stratum of our sample frame. Sixty pharmacies were selected.

### The source of Random Numbers:

Microsoft Excel 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 discounts 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 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 difference.

Other Evidence:

We used MMIS to get the AWP. MMIS obtained AWP from First DataBank.

## APPENDIX 2

STATEWIDE SAMPLE RESULTS  
BRAND NAME DRUGS

|                          | Sample Universe | Participating          | Prices Checked | Point Estimate | Standard Error | Confidence  |             | Standard Deviation |
|--------------------------|-----------------|------------------------|----------------|----------------|----------------|-------------|-------------|--------------------|
|                          |                 | Pharmacies Sample Size |                |                |                | Lower Limit | Upper Limit |                    |
| RURAL-CHAIN              | 41              | 9                      | 719            | 17.4           | .77            | 16.26       | 18.51       | 2.32               |
| RURAL-INDEPENDENT        | 55              | 12                     | 371            | 17.6           | .48            | 16.94       | 18.33       | 1.65               |
| URBAN-CHAIN              | 159             | 10                     | 868            | 19.2           | .91            | 17.69       | 20.61       | 2.89               |
| URBAN-INDEPENDENT        | 89              | 12                     | 488            | 18.1           | .34            | 17.60       | 18.65       | 1.19               |
| NON-TRADITIONAL          | 50              | 12                     | 142            | 25.7           | 5.51           | 17.46       | 33.87       | 16.52              |
| TOTAL INCLUDING NON-TRAD | 394             | 55                     | 2,588          | 19.4           | .10            | 18.14       | 20.56       | .74                |
| TOTAL EXCLUDING NON-TRAD | 344             | 43                     | 2,446          | 18.4           | .07            | 17.72       | 19.14       | .43                |

The Pharmacies not participating are: Target Stores (1), Rite Aide (Payless) Corp. (3), and Fred Meyer (1).

# State Of Utah

## Comparison Of State Pharmacy Acquisition Cost Review To Federal Review

### Brand Name Drugs

| Pharmacy Type<br>Data                        | State Review<br>6/97-5/98 | Federal Review<br>CY 1994 |
|--|---------------------------|---------------------------|
| Rural-Chain<br>AWP-Invoice/AWP               | 17.4%                     | 17.4%                     |
| Prices From Sample                           | 719                       |                           |
| Rural-Independent<br>AWP-Invoice/AWP         | 17.6%                     | 16.4%                     |
| Prices From Sample                           | 371                       |                           |
| Urban-Chain<br>AWP-Invoice/AWP               | 19.2%                     | 18.5%                     |
| Prices From Sample                           | 868                       |                           |
| Urban-Independent<br>AWP-Invoice/AWP         | 18.1%                     | 18.7%                     |
| Prices From Sample                           | 488                       |                           |
| Non-Traditional<br>AWP-Invoice/AWP           | 25.7%                     | na                        |
| Prices From Sample                           | 142                       |                           |
| Total Including Non-Trad.<br>AWP-Invoice/AWP | 19.4%                     | na                        |
| Prices From Sample                           | 2,588                     |                           |
| Total Excluding Non-Trad.<br>AWP-Invoice/AWP | 18.4%                     | 18.3%                     |
| Prices From Sample                           | 2,446                     |                           |

APPENDIX 3



# Hooked on Drugs

*Why do insurers pay such outrageous prices for pharmaceuticals?*

BY BILL ALPERT • Jim Fanning saw the plaque in a doctor's splendid home: "This is the house that leucovorin built." Leucovorin is one of the cancer drugs that typifies a basic drug-industry pricing convention that, in Fanning's view, is a multibillion-dollar fraud. Fanning, the pharmacy director of Fort Worth-based Chemolab, isn't alone in criticizing the published

wholesale prices that most insurers, public and private, use in determining how much to pay for pharmaceuticals. For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60%-90% below the so-called average wholesale price, or AWP, used in reimbursement claims.

But Medicare, one of the largest insurers that still reimburses at AWP, is about to demand a change. The huge federal health-insurance program, trying to forestall insolvency, soon will propose regulations aimed at cutting the amount it lays out for the nearly \$2 billion in annual drug claims it covers outside of hospitals. The move — especially if it is followed by others now paying near AWP for drugs — will attack from a new direction the pricing practices of a drug industry already beset by antitrust suits from retail drugstores. It also could upset a large segment of the health-care industry, which has thrived on the huge spread between the published wholesale prices used in insurance claims and the far lower wholesale prices actually paid.

That segment includes oncology practices, respiratory therapy firms and home-infusion companies. It also includes the drug makers themselves, whose allegedly inflated price lists and the opportunity for profiteering that they afford to middlemen, gain them market share and encourage overuse of their products. Among the publicly traded companies that could be affected: Apria Healthcare Group, Lincare Holdings, RoTech Medical, OmniCare, Abbott Laboratories and Baxter International.

Most people don't even know that Medicare pays for pharmaceuticals and related products, but through piecemeal congressional authorizations, the program now covers certain drugs for emphysema, cancer, kidney dialysis and organ transplantation, often requiring injection. While still barely 1% of its nearly \$184 billion in 1995 spending, Medicare's outpatient drug bill (not including co-payments) was \$1.8 billion last year, double 1992's level.

Under its current regulations, Medicare provides reimbursement for those drugs at the lesser of either its estimate of what the drugs cost the doctors or the Average Wholesale Price.

But Medicare's attempts to survey

doctors for their costs have been stymied by federal paperwork rules, so it reimburses at the AWP.

Like most drug buyers focused on average wholesale price, Medicare looks to compendia such as the *Red Book*, put out monthly by Medical Economics, of Montvale, N.J., or the rival *Blue Book* published by First DataBank, a Hearst subsidiary in San Bruno, Calif. Only after Medicare's drug bill started to rocket did policy makers at the Department of Health and Human Services start closely scrutinizing their AWP payments.

They've asked the department's inspector general's office to examine how Medicare suppliers' true acquisition costs square with the program's reimbursement levels.

Claims for nebulizer drugs, the inhalants used by many asthma and emphysema sufferers, were the first studied by the auditors. From under \$80 million in 1992, Medicare's annual bill for inhalation drugs grew to \$250 million last year, most of it for a steroid called albuterol

sulfate.

In a report released Thursday, the inspector general's office stated that the medical-equipment firms that Medicare reimburses at an average wholesale price-derived 40-43 cents per milliliter actually paid less than half that, on average: just 19 cents.

The report asserted that Medicare could have saved about \$94 million if its reimbursements had been based on actual wholesale prices over the 14 months covered by the study.

Another report by the inspector general produced a similar finding for feeding-tube liquids, like the market-leading Ensure products of Abbott Labs. These, the IG found, cost nursing homes 42% less than the price that Medicare bases its reimbursements on. Such products cost Medicare and its beneficiaries several hundred million dollars a year.

The inspector general currently is looking at prices for big-ticket drugs, and intravenous liquids, too. Barron's has done the same, in an examination of

the top 20 Medicare drugs (which account for about 75% of the program's drug spending), as well as for various intravenous solutions. Our study shows that for many drugs coming off-patent, the average wholesale prices in no way represents the true wholesale price.

For about 200 dose forms of the drugs, Barron's got the AWP's from the *Red Book* and the *Blue Book*. Then, we collected current quotes or price lists from several leading wholesaler specializing in sales to doctors, home health firms, nursing homes and hospitals.

These wholesalers included: The Oncology Therapeutics Network, a South San Francisco-based joint venture of Bristol-Myers Squibb and Axion; Florida Infusion Services of Palm Harbor, Fla.; National Specialty Services, of Nashville; and UltraCare, of Overland Park, Kan. Prices also came in from the Boulder, Colo., hospital buying group Vista Purchasing Partners.

This sampling showed that for single-source drugs still enjoying patent protection, such as Bristol-Myers Squibb's Taxol or Platinol, true wholesale prices are generally 10%-20% below published AWP's.

But for generic drugs, nearly every manufacturer's price was 60%-85% below the published average wholesale price. Some of the generics account for significant spending by Medicare, claiming half of the top 20 slots. Two of them, albuterol and leucovorin, are in the No. 2 and No. 6 slots, respectively.

Pricing is even more unreal worse for intravenous nutritional and solutions, a category dominated by Abbott Laboratories and Baxter International. Catalog wholesale prices for these items are, on average, 80%-93% below those companies' AWP's.

The prices from the different wholesalers were closely bunched. "There are really no special deals out there," contends Fanning, who buys plenty of drugs at wholesale himself.

If most health-care providers can get these prices, is it any wonder an industry wag says that AWP really means "Ain't What's Paid"?

The high prices on generic drugs have led investigators to seek the source of the published AWP's. Back in 1992, major drug manufacturers told the inspector general's office that the *Red Book*, not the manufacturers, determined the AWP. But *Red Book* officials blamed the manufacturers.

The answers are the same today. Phil Southerd, associate product manager of the *Red Book*, says it publishes prices that are fixed right from

## AWP: AIN'T WHAT'S PAID

► A sample of drugs whose published Average Wholesale Price is wildly above the wholesale price available to almost any buyer. Some of these AWP's actually have risen, while real wholesale prices have plummeted. Publishers say drug makers dictate AWP's.

| Drug   | Use             | Maker      | '95 AWP | Wholesale Price | % Under AWP |
|--|-----------------|------------|---------|-----------------|-------------|
| Doxorubicin HCL powder, 10 mg injectable           | Chemotherapy    | Adna Labs* | \$46.00 | \$13.00         | 72%         |
| Etoposide 100 mg in 5 ml for injection             | Chemotherapy    | Gensa      | 141.97  | 34.00           | 76          |
| Gentamicin Sulfate, 100 mg in 10 ml injection      | Antibiotic      | Abbott     | 6.18    | 1.26            | 80          |
| Intravenous Immune Globulin, 10 mg                 | Chemotherapy    | Baxter     | 640.71  | 266.00          | 58          |
| Leucovorin Calcium, 350 mg injection               | Chemotherapy    | Immunex    | 137.94  | 22.50           | 84          |
| Methotrexate 250 mg injection                      | Chemotherapy    | Chron      | 26.88   | 6.40            | 76          |
| Vancomycin HCL 5 gm in 100 ml injection            | Antibiotic      | Abbott     | 135.99  | 36.00           | 74          |
| Vincristine Sulfate 1 mg injection                 | Chemotherapy    | Eli Lilly  | 34.62   | 6.72            | 81          |
| 8.5% Amino Acid sol., 1000 ml for parenteral nutr. | TPN             | Abbott     | 152.65  | 40.81           | 93          |
| 50% Dextrose Sol., 500 ml in glass                 | Intravenous Sol | Baxter     | 27.03   | 2.56            | 91          |
| Lactated Ringer's Injection, 500 ml                | Intravenous Sol | Baxter     | 11.16   | 1.57            | 86          |
| Normosal 500 ml                                    | Intravenous Sol | Abbott     | 16.86   | 2.04            | 88          |
| Potassium Phosphate, 15 ml vial                    | Intravenous Sol | Abbott     | 5.55    | 0.48            | 91          |

\* Not of Pharmaceutical Origin

Source: 1995 Red Book, Trade Press, Barron's

the manufacturers. "They're not our prices," he insists.

Ed Edelstein, *Blue Book* editor, says that, while some brand-name firms don't give him prices, generic firms do. "The AWP is the manufacturer's suggested wholesale price," he says. "It's our editorial policy to go along with that."

But Immunex, with a thriving generic cancer-drug business, says its average wholesale prices aren't its own. "The drug manufacturers have no control over the AWP's published . . ." says spokeswoman Valene Dowell.

A maker of generic inhalants gives a different answer, but off the record: "The AWP's typically originate with the manufacturer."

More puzzling is the way generic AWP's stay at their lofty perches, or even rise, as competition forces a drug's true wholesale price into the abyss. "The reason this is happening," suggests Michael Neff, pharmacy program administrator of Medi-Cal, California's Medicaid agency, "is that most folks in a position to pay — even state Medicaid programs and HMOs — generally use AWP as a benchmark for reimbursement."

In 1993, the Bristol-Myers Squibb cancer drug Vepesid came off-patent, opening the market for a generic form called etoposide. A 100-milligram dose of Vepesid had an AWP of about \$136. The first generic etoposide was Gensia Pharmaceutical's, with a market price of about \$75, but the AWP of \$142.

The second generic to market, from Pharmacia, pushed the market price to \$60, but Pharmacia set an AWP around

### FALSE CLAIMS?

► Some of these firms make drugs, or bill insurers for drugs, that cost far less than the published Average Wholesale Price that Medicare and other insurers pay on claims. Says one wholesaler: "It may be legal, but it's certainly not ethical."

| Company                       | Symbol | Exchange | Recent Price | Medicare Reimbursement Change Might Affect   |
|-------------------------------|--------|----------|--------------|--|
| Abbott Labs                   | ABT    | NYSE     | 43 3/8       | Medicare buys \$500 million of Lipron; also \$100s-of-millions of nutritional                  |
| American Home Prods           | AHOM   | NNM      | 45 1/2       | Medicare/Medicaid pay for 60% of firm's respiratory and infusion services revenues             |
| American Oncology Resources   | AORI   | NNM      | 44 1/4       | One-third of revenues from Medicare/Medicaid; chemo drugs a big profit center                  |
| Amgen                         | AMGN   | NNM      | 60 1/2       | \$75 million in Medicare payments for Neupogen = 10% of drug's U.S. sales                      |
| Baxter International          | BAX    | NYSE     | 46 3/4       | Government demands rationale for its published prices on intravenous products                  |
| Bristol-Myers Squibb          | BMJ    | NYSE     | 88 3/4       | Cancer drugs a mainstay; Medicare bought about 25% of U.S. sales of Taxol                      |
| Chiron                        | CHIR   | NNM      | 97           | Cancer drugs approx 5% of sales  |
| Coram                         | CRH    | NYSE     | 4 1/2        | One-third of revenues from nutritional therapy; 27% of payments from Medicare/Medicaid         |
| Gensia                        | GNSA   | NNM      | 5 1/2        | Largest product is generic etoposide; just got approval for generic doxorubicin                |
| Immunex                       | IMNX   | NNM      | 15 1/2       | Cancer collaboration with American Home Products; leucovonn a \$20 million product             |
| Lincare Holdings              | LINC   | NNM      | 41 1/4       | 50% of revenues from Medicare/Medicaid, who are after firm's 85% gross margins                 |
| Omnicare                      | OCR    | NYSE     | 56           | Nursing home/pharmacy gets 50% of sales from Medicaid/Medicare; expanding in infusion business |
| Pharmacia-Upjohn              | PNU    | NYSE     | 42 1/4       | Cancer drugs approx 9% of drug sales   |
| Physician Practice Management | PHYN   | NNM      | 49 1/4       | 45% of revenues from Medicare/Medicaid; chemo drugs a big profit center                        |
| RoTech                        | ROTC   | NNM      | 19 1/4       | 50% of revenues Medicare/Medicaid; 6% from chemo and nutrition therapy                         |

Source: Company reports

\$140. Today, the market price for 100 milligrams of etoposide is around \$35 but Gensia actually raised its AWP last year by about 10%.

When some drug salespeople visit a doctor, says another Medicaid administrator, the salesperson lets the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm.

If manufacturers deliberately maintain lofty AWP's on their generic drugs, it directly profits their customers, not them. Of course, the drug makers might then gain market share and higher sales from their customers' over-utilization.

Indeed, for makers of generics, unreal average wholesale prices pose a classic social dilemma. If some, but not all, rectify their AWP's, the honest makers cut their own throats. "Manufacturers have told me that if they act on their own they'll dry up their own business," says Medi-Cal's Neff. "If I'm a buyer and one drug gives me 20% higher reimbursement, who am I going to go with?"

Some insurers, including Medicare, decree maximum prices for each generic drug, to avoid the alleged manipulation of AWP's. But it takes a year or so to establish a maximum price for new generics, and insurers haven't gotten around to setting prices for many doses.

There definitely is over-utilization of these products, acknowledges a maker of inhalation drugs. "Because HCFA [the Health Care Financing Administration, the federal Medicare-Medicaid agency] is paying a somewhat arbitrary price, this has been discussed for almost three years."

It's not rocket science; what's taken them so long?"

Some of the inspector general's investigators believe they've been played for fools. "We trusted the industry and the providers," says one investigator, off the record. "We didn't know how pervasive the discounting was. We thought it was available to just select providers."

Now, the Justice Department is serving "civil investigative demands" — a kind of subpoena in antitrust investigations — on manufacturers, asking them how those inaccurate AWP's wind up in the *Red Book* and *Blue Book*.

Baxter has received one, according to investigators, for its intravenous solutions,

*If most health-care providers can get much lower prices for pharmaceuticals than insurers do, is it any wonder that an industry wag says that "average wholesale price" really stands for "ain't what's paid"?*

whose true wholesale prices — like those of rival Abbott — seem to be 90% below the average wholesale price. Baxter wouldn't comment to *Barron's*.

"The drug makers created false statements so that the doctors could make hundreds of millions of dollars," maintains an angry investigator. "If OIG doesn't get

them, the Justice Department will."

Some investigators view the spreads guaranteed by extreme average wholesale prices as a kind of kickback to doctors, in violation of federal laws.

One group of infusion-industry veterans is reportedly considering attacking the problem by filing a private suit under the False Claims Act. This is the whistleblower law that allows citizens with knowledge of fraud against the government to sue on behalf of the government and share in the recovery.

Meanwhile, the cooler-headed policymakers at the inspector general's office and in HCFA are reconsidering Medicare's drug reimbursement rules. They plan to propose their changes in the Federal Register soon.

"Medicare's been paying too much for our drugs," says deputy inspector general George Grob. "We're paying the window-sticker price when everybody else wants a discount and is getting it."

Tom Alt, of HCFA's Bureau of Policy Development, notes that any savings for Medicare will mean savings for beneficiaries, who are kicking in 20% co-payments at current Medicare prices.

Any reduction in reimbursement levels probably would have some effect on the firms that enjoy the spreads between everyday low wholesale prices and the average wholesale prices at which Uncle Sam reimburses them.

That includes oncology practice-management firms like American Oncology Resources and Physician Reliance Network, which earn significant profits on the chemotherapy drugs they administer to cancer patients. Likewise, respiratory therapy and infusion firms like American HomePatient, Apria Healthcare, Coram Healthcare, Lincare Holdings and Ro-Tech Medical, which owe their sensational profit margins, to various degrees, to their drug spreads.

Then, there are the drug makers themselves, including Abbott, Baxter, Chiron, Genia and Immunex — all with wide AWP spreads on their generic offerings.

Dr. H. Merrick Reese, the CEO of Physician Reliance, says he doubts that HCFA plans to cut reimbursement rates for cancer drugs, which he says his firm marks up only modestly.

More likely, Medicare will go after the inhalation drugs like albuterol, says Dr. Joseph Bailes, who chairs the clinical practice committee of the American Society of Clinical Oncology.

ChemoLabs is doing what it can to ensure that the AWP tricksters start running out of fools. Located near Fort Worth Airport, Fanning's firm will supply chemotherapy drugs for insurers, shipping doses to oncologists as needed, and for a fraction of the average wholesale price.

And the most aggressive public insurers, including Medicaid programs in six states, are turning their backs on AWP.

They now base their drug payments on WAC — the Wholesale Acquisition Cost actually paid by medical-care providers.

*Blue Book* editor Edelstein warns, however, that this won't end the game. "Then the manufacturers will just start fooling around with that price," he warns.

For now, says Fanning, the ChemoLab pharmacist, the bonanza drug is etoposide. Someday, he expects to see a plaque saying: "This is the house that etoposide built."

APPENDIX 4

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 I** 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.

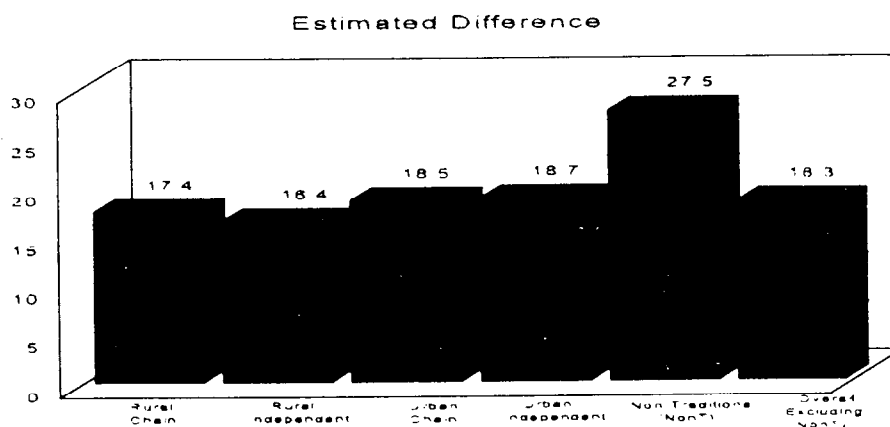
We involved State agency officials in planning the methodology for this review. A meeting was held in Richmond, Virginia, with HCFA officials and Medicaid pharmacy representatives from the sample States to collaboratively design our approach. A second meeting was also held in Richmond, Virginia, involving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

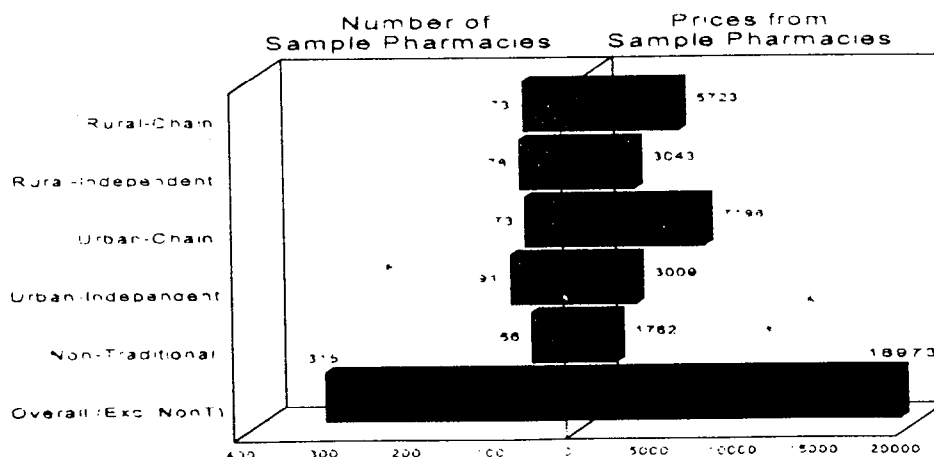
## FINDINGS AND RECOMMENDATIONS

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

| NATIONWIDE               | SAMPLE UNIVERSE | SAMPLE SIZE | DAILY PRICES REVIEWED | POINT ESTIMATE | STANDARD ERROR | 95% CONFIDENCE LEVEL |             |
|--------------------------|-----------------|-------------|-----------------------|----------------|----------------|----------------------|-------------|
|                          |                 |             |                       |                |                | LOWER LIMIT          | UPPER LIMIT |
| 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  
17 MAR 19 P 3:50  
OFFICE OF INSPECTOR GENERAL

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