

**A Review of the
Office of Inspector General Report:**

***Medicaid Pharmacy—Actual Acquisition Cost of
Brand Name Prescription Drug Products***

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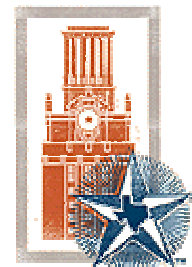
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Summary

An August 2001 report of the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) estimated that retail pharmacies were able to purchase brand name pharmaceuticals in 1999 at a rate of Average Wholesale Price (AWP) minus 21.84 percent. The report concludes that states are significantly overpaying pharmacies for these drugs, and the OIG recommends that states reduce their Medicaid reimbursement for these drugs to bring them more in line with the report's findings.

It is prudent that the allocation of resources for pharmaceutical payments, in particular, and all publicly-funded health care services, in general, be routinely reviewed for appropriateness and equity. However, a review of the OIG's study methodology by the Center for Pharmacoeconomic Studies at The University of Texas at Austin identified serious limitations with the approach used by the OIG, calling into question the accuracy of the estimated discounts and projected national savings. The lack of a detailed description of the methodology within the report leaves many unanswered questions about the appropriateness of sampling, data collection, and the external validity of calculated national savings.

State administrators should be cautious in relying on the study's findings in determining appropriate Medicaid reimbursement rates given the need to ensure that Medicaid recipients have access to pharmacy services.

Background

On August 10, 2001, the Department of Health and Human Services, Office of Inspector General (OIG) released a report entitled, "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products." The brief report outlined the results of audits of pharmacy acquisition costs for brand name drugs reimbursed under the Medicaid prescription drug program. The report was a follow-up to earlier audits conducted by the OIG during 1994. Based on the findings of the audit, the OIG developed estimates for the discount below AWP that selected pharmacies purchased brand name and generic drugs.

The main findings presented in the OIG report were as follows:

- On a nationwide basis, the invoice price for brand name drugs was estimated to be 21.84 percent below AWP for purchases during 1999.
- The estimate of the discount below AWP for brand name drugs was significantly greater than the discount designated under current reimbursement policies in most states.
- An estimated savings of up to \$1.08 billion could be realized by state Medicaid programs if states increased the discount off of AWP by 11.53 percent on the top 200 reimbursed brand name drugs.

On behalf of the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS), health services researchers at The Center for Pharmacoeconomic Studies, The University of Texas at Austin reviewed the OIG study design, methodology, and findings of the report.

Based on its review of the study, the Center has identified significant limitations to the study methodology that should be considered by health policy decision-makers when interpreting the findings and implications of the study.

Limitations

The following is a listing and description of the limitations identified by The Center for Pharmacoeconomic Studies:

Sampling of Pharmacies and Drug Prices

1. Non-Representative Sample Strata: The rationale for categorizing Medicaid provider pharmacies into one of five selected strata (Urban Chain, Urban Independent, Rural Chain, Rural Independent, Non-Traditional) based on “type of pharmacy” for sampling purposes was not stated. The sampling technique, based on equal representation of the five types of pharmacies, is not representative of pharmacy participation in state Medicaid programs and introduces a risk of both under-sampling and over-sampling different types of pharmacy providers.

A more appropriate sampling technique would have considered proportional representation based on either: (1) Medicaid prescription volume; or (2) total Medicaid reimbursements. For example, in contrast to the OIG’s methodology, other national surveys of health care services conducted by the U.S. Department of Health and Human Services are appropriately weighted for sample data to be extrapolated nationally.¹

2. No Correction for Non-Respondents: Of the 256 pharmacies that were contacted for participation in the auditing process, 40 pharmacies did not provide invoice data to the OIG. No analysis of non-responders (15.6% of the sample) was discussed in the report. The report contained no description of the characteristics of these pharmacies; therefore, it is not known to what extent response bias was present.
3. Non-Representative Pharmacy Invoice Samples: While pharmacies were sampled evenly across selected categories, a disproportionately large number of “Urban Chain” pharmacy prices (47.6%) were utilized in the final calculation of the discount off of AWP prices. On average, 111 prices were selected from each “Urban Chain” pharmacy, while 29, 43, and 38 prices were selected from “Urban Independent,” “Rural Chain,” and “Rural Independent” pharmacies, respectively.

It is difficult to understand why urban chain pharmacies would have nearly four times the number of prices listed on the invoices, compared to urban independents. Both types of pharmacies should have very similar drug inventories, except perhaps in quantity of supply per specific drug. The listing of prescription drug items by specific product should be nearly identical.

Moreover, using only the largest invoice is inappropriate since it may not represent a typical purchasing event for a pharmacy. Selecting the largest invoice introduces bias by skewing the results towards periodic discounts related to “one-time” purchases.

It is unlikely that purchases associated with smaller invoices would result in achieving similar discounts. Thus, the use of the largest invoice tends to overestimate the actual discount off of AWP realized by community pharmacies.

4. Inappropriate Extrapolation from Limited Sample to Nationwide Estimate: While the use of only 216 pharmacies to predict purchasing patterns of nearly 50,000 pharmacies nationwide is not necessarily inappropriate with respect to size of the sample, under- and over-representation of pharmacies within the sample may lead to inappropriate extrapolations, nationwide. For example, the OIG used the same number of pharmacies in each state without regard to the distribution of Medicaid pharmacies across states to make statewide and national estimates using these samples. The inappropriate sampling technique produces significant potential for estimation error in the extrapolations.

Estimation of Discounts

5. Inconsistent Categorization of Brand vs. Generic Product: The methodology by which a product is classified as a “brand name” or “generic” must be a combination of both the “innovator” status and the particular reimbursement classification of that drug by each particular state. Because of aggressive discount pricing strategies by manufacturers for selected innovator products, many states have reclassified original “brand name” products into the “generics” or “multi-source” reimbursement category. Most often, states reimburse pharmacies for these branded products based on the Maximum Allowable Cost (MAC), an indexed amount based on median generic product costs. One of the more common agents in this class, Amoxil[®], accounted for over 1.7 million Medicaid prescriptions in FY2000. Classifying these agents as “brand name” products over-estimates the discount realized by pharmacies.

Extrapolation of Estimated Discounts to National Savings

6. Discounts Not Weighted by Sales: The extrapolation of national discounts and savings for branded drugs are not weighted by volume of prescriptions or expenditures. For example, the report calculates an average of the estimated discounts on sampled invoice items, then assigns that same estimate to Medicaid’s top volume drugs without regard to differences in the product mix among invoices and the top 200 drugs. Inaccuracies in the projected savings will exist to the extent that the invoice drugs are not representative of the top 200 drugs.
7. Not All Drugs Paid for at AWP Rate: The nationwide savings extrapolation assumes that all brand name drugs were reimbursed based upon an estimated acquisition cost that is derived from the AWP discount. Nearly all states stipulate that Medicaid reimbursement for brand name drugs be based upon the LOWER OF: (1) Estimated Acquisition Cost (EAC) plus a dispensing fee, where EAC is the discounted AWP; or (2) the pharmacy’s Usual and Customary price. For example, a previous analysis of the Texas Medicaid Vendor Drug Program showed that 22.1 percent of claims were paid at submitted Usual and Customary prices.² Therefore, the assumption that all payments were made based upon discounted AWP overestimates potential savings.

8. Misleading Presentation of Estimation Variance. Whenever averages (means) are calculated and reported, it is also helpful to report how much variation in the measurement of the average actually exists. In statistics, this measurement is known as “standard deviation”. For example, if the observed discounts for all items collected from the invoices fell within a close range around the calculated average (either slightly higher or slightly lower than the average), we would have a significant degree of confidence that the mean is representative of actual discounts. Thus, in this case, the value of standard deviation would be small. However, if large deviations are observed in discounts around the calculated average, it creates uncertainty as to whether the calculated average is, in fact, an appropriate representation of actual discounts.

Unfortunately, the OIG did not report the “standard deviation” of the calculated mean discount, but instead, reported an alternative measure of variation that actually becomes very small when a large number of measurements are made—the “standard *error* of the mean” (reported by the OIG as 0.35 percent of AWP.) This reported measurement implies a high degree of precision for the estimated average mean; however, confidence in this measure and its precision should be questioned for two reasons.

First, our calculations from information contained in the report reveal that the standard deviation for the estimated mean discount off of AWP was 44.6 percent. This figure is relatively large compared to the estimated mean discount of 21.84 percent, indicating substantial variation among individual item discounts.

This variation pattern (known as a positively skewed distribution) is common in cost data. It is typically characterized by the clustering of most data points at the low end of the scale with a few data points having much higher values. In the case of these discounts, it is likely that most, perhaps a significant majority, of the products are purchased at relatively low discounts off of AWP (less than 21.84 percent) while some products are purchased at larger discounts. The relatively few large individual discounts inflate the mean discount to the point that it is not a good representation of the overall group discount; in these situations, the median (or midpoint of the data, which was not reported in the OIG report) is the preferred measure. Relying on this inflated mean discount for reimbursement would result in pharmacies being paid less than their costs for most products.

Second, is the issue of the validity of the measure. The precision of a measure is not meaningful unless the measure truly represents discounts actually observed. The issues noted above call into question whether the OIG approach achieved a valid estimate of the discounts off of AWP and the projected savings. The implication of having a highly precise measure may lead readers to place unwarranted confidence in the results.

Conclusion and Recommendation

With public and private prescription drug benefit plans experiencing double-digit growth rates in total expenditures over the last several years, administrators have investigated various cost-containment strategies. In addition to cost-sharing, formularies, and plan limitations, the appropriateness of the pharmacy reimbursement mechanism is commonly reviewed.

Compensation for Medicaid pharmacy services includes both: (1) reimbursement for a product component; and (2) payment for professional services. Reimbursement related to the product component should include the acquisition, distribution and warehousing costs related to the product. The professional services component should include a payment for fixed and variable costs related to dispensing medications and counseling Medicaid patients on the appropriate use of their drugs.

Therefore, it is important, for matters of consistency, that payments for both components be reviewed simultaneously to ensure that pharmacy providers are compensated appropriately. We encourage states to routinely conduct studies that investigate the adequacy and appropriateness of current reimbursement levels to pharmacists for the “product management” and “dispensing fees” components of professional services provided to Medicaid recipients.

We believe that the OIG’s initiatives to determine the appropriateness of Medicaid pharmacy reimbursement rates are worthy goals. However, we suggest that states exercise caution in relying on this report because of several significant issues relating to methodology and extrapolation of national estimates based on what appears to be an unrepresentative sample of pharmacies and invoices.

Given the limitations noted above, states may want to conduct their own studies of pharmacy’s acquisition costs to more accurately determine the pharmacy’s costs of purchasing, managing, and distributing an inventory of pharmaceuticals within each state. In addition, we would encourage a parallel study that investigates the appropriateness of current pharmacist “dispensing fee” payments for professional services provided to Medicaid recipients.

¹ U.S. Department of Health and Human Services, “Sample design of the 1997 medical expenditure panel survey household component: Methodology,” AHRQ Publication 01-0001, November 2000.

² Lawson KA, Hong SH, Johnsrud MT, Skrepnek G, “An assessment of cost saving options for the Medicaid Vendor Drug Program,” May 1995, The University of Texas College of Pharmacy, Austin, Texas.

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Since its establishment in 1994, The Center for Pharmacoeconomic Studies at The University of Texas at Austin has conducted economic and policy research on the impact of pharmaceutical services and products on patients' quality of life and health care outcomes in Texas and across the U.S. The Center serves as a bridge in bringing researchers together from different sectors of the health care delivery system, in addition to fostering collaborations with other academic institutions to disseminate scholarly findings. Researchers at the Center provide expertise in the areas of study design, methodology, data collection and analysis, and interpretation of economic and policy research. The Center also develops and presents educational programming to further the understanding of pharmacoeconomics and its role in the decision-making process within the health care delivery system.