Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID DRUG PRICE COMPARISONS: AVERAGE MANUFACTURER PRICE TO PUBLISHED PRICES

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EXECUTIVE SUMMARY

OBJECTIVE

To examine the differences between the published prices States use to set Medicaid reimbursement rates (i.e., average wholesale price and wholesale acquisition cost) and a statutorily defined price calculated from actual sales transactions (i.e., average manufacturer price) for drugs reimbursed by Medicaid.

BACKGROUND

Medicaid expenditures for prescription drugs continue to be a major concern to the Administration, Congress, and States; and Medicaid drug reimbursement changes are being considered. Most prescription drugs reimbursed by Medicaid are dispensed by pharmacies. The Office of Inspector General (OIG) has found evidence that Medicaid drug reimbursements exceed pharmacies' actual acquisition costs.

In general, States reimburse pharmacies for drugs at the lower of estimated acquisition cost (EAC) plus a dispensing fee or the pharmacy's usual and customary charge to the public. The EAC is the State's best estimate of the price generally and currently paid by providers for the drug.

States often lack access to drug pricing data based on actual sales and instead estimate pharmacy acquisition costs using published prices, namely, average wholesale price (AWP) and wholesale acquisition cost (WAC). Neither AWP nor WAC are necessarily based on actual sales transactions. The AWP is not defined in statute or regulations, and until recently, the same was true for WAC. OIG has recommended that Medicaid should base reimbursement on pricing data that more accurately reflects actual acquisition costs.

The Average manufacturer price (AMP) is the average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts. The AMP is statutorily defined and its calculation is based on actual sales transactions. Drug manufacturers must report AMP data for all Medicaid-covered drugs to the Centers for Medicare & Medicaid Services (CMS) quarterly as a requirement of the Medicaid drug rebate program. Most State Medicaid agencies do not have access to AMP data, which is proprietary.

To explore the potential impact of moving to a sales-based price to estimate pharmacy acquisition cost, this inspection compares AMP to

AWP and WAC for national drug codes (NDC) reimbursed by Medicaid. We compared AMP to AWP for 24,101 NDCs and AMP to WAC for 19,475 of those NDCs (4,626 NDCs had an AWP but no WAC value). We compared the per unit prices in place on January 1, 2005. We calculated median comparisons for all of the NDCs, as well as for each drug category: single source ("single source brands"), innovator multisource ("multisource brands"), and non-innovator multisource ("generics"). This analysis focuses on the comparison of a sales-based price to the published prices associated with the drug itself (i.e., the "ingredient cost") and does not address the professional costs associated with dispensing the drug or the dispensing fees.

A companion report, "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price" (OEI-03-05-00200), examines the differences between average sales price (a statutorily defined price based on actual sales and used for Medicare Part B drug reimbursement) and AWP. That analysis includes approximately 2,100 NDCs that are covered by both Medicaid and Medicare Part B.

FINDINGS

Average manufacturer price is substantially lower than both average wholesale price and wholesale acquisition cost. At the median, AMP is 59 percent lower than AWP. Forty-nine States use AWP to estimate pharmacy acquisition costs. The median State EAC formula is AWP minus 12 percent. For 98 percent of Medicaid-reimbursed NDCs, this median State EAC formula would reimburse at a price higher than AMP.

At the median, AMP is 25 percent lower than WAC. Among the eight States that use WAC in their EAC, the median State EAC formula is WAC plus 8.5 percent. For 96 percent of NDCs, this median EAC would reimburse at a price higher than AMP.

Generic drugs exhibit the largest differences between average manufacturer price and the published prices. For generic drugs, AMP is 70 percent lower than AWP at the median. In comparison, AMP is 23 percent lower than AWP at the median for single source brands and 28 percent lower for multisource brands.

State estimates of pharmacy acquisition cost exceed AMP even among States with additional discounts for generics. Seven States use EAC formulas that specify a greater discount off AWP for generic drugs than brand name drugs. However, these formulas range from AWP minus

20 percent to AWP minus 50 percent, resulting in estimates of pharmacy acquisition cost that are higher than the median AMP for generics, which is equal to AWP minus 70 percent.

For generic drugs, AMP is 40 percent lower than WAC at the median. In comparison, AMP is 4 percent lower than WAC for single source brands and 8 percent lower than WAC for multisource brands at the median.

No States use a WAC-based EAC formula with additional discounts taken for generics. State EAC formulas that use WAC range from WAC plus 5 percent to WAC plus 12 percent. The median AMP is lower than these formulas in all drug categories, but the largest difference is for generics where AMP is 40 percent lower than WAC.

CONCLUSION

The Administration and Congress have expressed interest in aligning Medicaid drug reimbursement more closely with pharmacy acquisition cost by using prices based on actual sales rather than published prices. OIG has also recommended that Medicaid should base reimbursement on pricing data that more accurately reflects actual acquisition costs.

This inspection provides additional evidence that published prices used as a basis for reimbursement are higher than prices based on actual sales. AMP, which is calculated based on statute and actual sales transactions, is substantially lower than either of the published prices (i.e., AWP and WAC). As a result, States' estimates of pharmacy acquisition costs, which are based on AWP and/or WAC, are also substantially higher than AMP. These differences are greatest for generic drugs.

Comparing a statutorily defined, sales-based price to published prices provides valuable information to those considering the implications of changing Medicaid's drug reimbursement methodology. The substantial disparities between AMP and the published prices currently being used indicate that changing the basis of Medicaid reimbursement could have a significant impact on Medicaid expenditures.

Agency Comments

CMS commented that these companion reports make clear that current Medicaid payment rules result in overpayments for drugs and emphasize the need for reform. CMS stated that Congress should enact legislation similar to the reform of Medicare Part B (i.e., switch to ASP

as the basis of reimbursement) to ensure that Medicaid payment for drugs is related to actual prices paid by pharmacies.

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INTRODUCTION

OBJECTIVE

To examine the differences between the published prices States use to set Medicaid reimbursement rates (i.e., average wholesale price and wholesale acquisition cost) and a statutorily defined price based on actual sales transactions (i.e., average manufacturer price) for drugs reimbursed by Medicaid.

BACKGROUND

All State Medicaid programs include outpatient prescription drug coverage, an optional benefit. Nationally, Medicaid spent over $34 billion on prescription drugs in 2003.[1] Over 41 million beneficiaries were enrolled in Medicaid in 2003.[2]

Approximately 6 million of these beneficiaries are dually eligible for Medicaid and Medicare (dual eligibles).[3] Currently, Medicaid provides drug coverage for these dual eligibles, but in 2006, coverage for these beneficiaries will be transferred from Medicaid to Medicare.[4]

Concerns about Medicaid Drug Reimbursement

Medicaid expenditures for prescription drugs continue to be a major concern to the Administration, Congress, and States. The President's 2006 budget proposes restructuring Medicaid pharmacy reimbursement to save an estimated $542 million in fiscal year (FY) 2006 and $15.1 billion over 10 years.[5] The House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing in December 2004 on "Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much" and explored potential reforms.[6] Congress has established a Medicaid commission to provide recommendations to achieve $10 billion in overall Medicaid savings over the next 5 years and to consider longer-term performance goals and recommendations.[7] The National Governors Association and National Conference of State Legislatures are also working on proposals to reduce Medicaid spending, including spending on prescription drugs.[8]

The Office of Inspector General (OIG) has found evidence that because States lack accurate drug pricing data, Medicaid drug reimbursements exceed pharmacies' actual acquisition costs. OIG has also found that Medicaid drug reimbursements exceed the prices paid by other Federal programs. OIG has recommended that Medicaid should base reimbursement on pricing data that more accurately reflects actual acquisition costs.[9]

Medicaid Drug Reimbursement

Drug Cost Reimbursement.

Most prescription drugs reimbursed by Medicaid are dispensed by pharmacies. Within Federal parameters intended to ensure that Medicaid acts as a prudent buyer, each State determines its own pharmacy reimbursement formula(s).[10] In general, States reimburse pharmacies for drug costs at the lower of estimated acquisition cost (EAC) plus a dispensing fee or the pharmacy's usual and customary charge to the public. Some multiple source drugs (i.e., drugs with equivalent generic versions) have a Federal upper limit (FUL) or a State maximum allowable cost (MAC).

The EAC is the State Medicaid agency's "best estimate" of the price generally and currently paid by providers for the drug.[11] The Centers for Medicare & Medicaid Services (CMS) does not prescribe a method for calculating EAC; instead, each State establishes and specifies its own EAC formula in its Medicaid State plan.

Estimating pharmacy acquisition cost presents a challenge for States because States lack access to drug pricing information calculated from actual drug sales. Instead, States rely on the published prices available in drug pricing compendia, despite the previously identified flaws of these published prices.

Forty-nine States (including the District of Columbia) use average wholesale price (AWP) minus a discount percentage in their EAC formulas. Eight States use wholesale acquisition cost (WAC) plus a markup percentage in their EAC formulas. Six of these eight States use both AWP and WAC, e.g., "the lesser of AWP minus 12 percent or WAC plus 8 percent." Some States use more complex EAC formulas. For example, seven States specify different formulas for brand name drugs versus generic drugs. Other States vary their formulas based on the pharmacy's characteristics (e.g., chain versus non-chain pharmacies).

For certain multiple source drugs that meet specified criteria, CMS sets specific Federal upper limit amounts based on the published prices. The FUL amount equals 150 percent of the lowest published price of any therapeutically equivalent version of the drug published in the national pricing compendia.[12] Additionally, some States establish MAC reimbursement levels at a rate below an established FUL or for drugs for which CMS has not set an FUL amount. Thirty-nine States had MAC programs as of January 1, 2005.[13]

Dispensing Fees.

In addition to reimbursing pharmacies for the cost of the drug (also known as the ingredient cost), States are required to determine "reasonable" dispensing fees.[14] This fee represents the charge for the professional services provided by a pharmacist when dispensing a prescription. States' dispensing fees to retail pharmacies range from $2.00 to $12.50.[15]

Drug Pricing Data

Currently, three types of drug pricing data are readily available and relevant to the Medicaid program: AWP, WAC, and AMP. A fourth price, average sales price (ASP), is used by the Medicare program to calculate reimbursement amounts for the subset of drugs that are covered by Medicare Part B. See Appendix A for a list of key drug pricing terms and acronyms and a chart depicting an example of a Medicaid drug distribution chain.

Published prices: AWP and WAC.

Average wholesale price and wholesale acquisition cost are prices that are published in commercial drug pricing compendia by private companies, such as First Databank and Medi-Span, based on pricing information reported by manufacturers.[16] Neither AWP nor WAC are necessarily based on actual sales transactions. The AWP is not defined in statute or regulations, and until recently, the same was true for WAC. The AWP is often considered a price for wholesalers to charge retailers. As currently defined in statute, WAC is:

> . . . the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.[17]

As mentioned earlier, State Medicaid agencies generally use AWP and/or WAC to estimate pharmacy acquisition costs for drug reimbursement. However, studies, investigations, and audits by OIG, the Department of Justice, and others have found that these published prices, particularly AWP, substantially overstate the actual prices pharmacies pay for drugs.

Recognizing the flaws of AWP, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, changed the basis of Medicare Part B drug reimbursement from AWP to

ASP, a statutorily defined price calculated from actual sales transactions. The Administration has proposed similar reforms for Medicaid.[18]

Prices based on actual sales: AMP and ASP.

Average manufacturer price is the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade minus customary prompt pay discounts. Its calculation is statutorily defined and based on actual sales transactions.[19] Because AMP is calculated from sales that have already occurred, it is a retrospective price.

Drug manufacturers are required to report AMP data for all Medicaid-covered drugs to CMS quarterly as a requirement of the Medicaid drug rebate program.[20] State Medicaid agencies do not currently have access to AMP data, which is proprietary.

While AMP is statutorily defined, there are some weaknesses associated with it. CMS has not issued final regulations regarding AMP calculation. The Government Accountability Office (GAO) recently released a report on the Medicaid rebate program that found inadequate oversight of manufacturers' AMP calculations and variation across manufacturers in how AMP was calculated.[21]

Average sales price is also statutorily defined and is based on actual sales transactions. It is defined as the manufacturer's unit sales to all purchasers (with certain exceptions) in a calendar quarter divided by the total number of units sold by the manufacturer during that same quarter, net any price concessions (such as volume, prompt pay, and cash discounts), free goods contingent on purchase requirements, chargebacks, and rebates (other than Medicaid rebates).[22] The ASP must be calculated and reported to CMS quarterly for drugs covered by Medicare Part B. Most drugs reimbursed by Medicaid are not covered by Medicare Part B and do not have an ASP value reported to CMS.

Companion Report: Average Sales Price to Average Wholesale Price

OIG is issuing a companion report entitled, "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price" (OEI-03-05-00200), concurrent with this report. This companion report shares a similar objective, i.e., to compare statutorily defined drug prices based on actual sales to published prices. The primary difference is scope. The companion report analyzes drugs that are covered by both Medicaid and Medicare Part B (approximately 2,100 national drug codes [NDC]) and focuses on comparing ASP to AWP. In contrast, this

report includes Medicaid-reimbursed drugs (approximately 24,000 NDCs) and compares AMP to the published prices (AWP and WAC). The AMP is the only statutorily defined, sales-based price reported to CMS for all drugs in the Medicaid program.

METHODOLOGY

National Drug Codes Reviewed

We focused our analysis on pricing data for Medicaid-reimbursed drugs, i.e., the population of NDCs reimbursed by Medicaid during the first two quarters of calendar year 2004 (January 1 through June 30, 2004), the most recent reimbursement data available. This population includes all drugs with an AMP value and at least one other price (AWP and/or WAC) in place on January 1, 2005. We used the 11-digit NDCs that Medicaid uses to identify unique formulations of each drug, including the manufacturer, strength, and package size. This population includes 25,560 NDCs.

In addition, we analyzed pricing data for Medicaid-covered drugs with an AMP value and at least one other price (AWP and/or WAC) in place January 1, 2005. This population includes additional drugs that Medicaid covers but that had no reimbursement from January 1 through June 30, 2004. This analysis is presented in Appendix B and includes 28,557 NDCs.

Excluded NDCs.

From our total population of Medicaid-reimbursed NDCs, we excluded 3 percent of NDCs at both ends of the distribution of AMP to AWP ratios. As explained below, this provides a conservative estimate of the differences between these prices. Our population for analysis of Medicaid-reimbursed drugs includes 24,101 NDCs for the AMP to AWP comparisons. Only 19,475 of these NDCs had WAC values and are therefore included in the AMP to WAC comparisons.

At the low end, we excluded all NDCs for which the AWP values were less than the AMP values. Approximately 3 percent of Medicaid-reimbursed NDCs had AWP values below AMP. In principle, it seems unlikely for AWP to be below AMP because AWP is used to represent a transaction further down the distribution chain than AMP (see Appendix A for an example of the distribution chain). The AMP is an average of actual sales from manufacturers to wholesalers. The AWP is a published price that is generally used to represent a price for wholesalers to charge retailers. While there are known incentives for a

manufacturer to increase an AWP relative to actual sales prices, there are no similar known incentives for a manufacturer to decrease an AWP below actual sales prices. It is likely that where AWP is lower than AMP, it is the result of a technical error such as a unit definition inconsistency, a data timing issue, or a reporting error.

We also excluded the NDCs at the high end where AWP values exceeded AMP by the greatest percentages. Unlike the NDCs where AWP is less than AMP, there is no apparent reason to assume that an extremely high AWP (relative to AMP) is incorrect and therefore the result of a unit definition inconsistency, a data timing issue, or a reporting error. However, it is plausible that errors occur with the same frequency at the high end of the distribution as at the low end. Therefore, we used a 3 percent threshold to parallel the exclusion of 3 percent of NDCs at the low end. We did this by drug category; i.e., single source ("single source brands"), innovator multisource ("multisource brands"), and non-innovator multisource ("generics"); because the distribution of AMP to AWP ratios differed substantially by category. CMS designates each NDC as single source, innovator multisource, or non-innovator multisource in the Medicaid Drug Rebate Initiative files.

As a result, our calculations may underestimate the extent to which AWP exceeds AMP by excluding these NDCs at the high end.

Data Sources

AMP.

We used the AMP per unit values that were reported by manufacturers to CMS and were in place on January 1, 2005. We obtained this data from the Medicaid Drug Rebate Initiative files that CMS uses to administer the Medicaid drug rebate program. The AMP values that are in place on January 1, 2005, are based on sales from July 1 through September 30, 2004, which are reported to CMS by manufacturers by October 30, 2004.

AWP and WAC.

We used the AWP per unit and the WAC per unit values that were in effect on January 1, 2005, as publisheded in First Databank's National Drug Data File. First Databank is the source from which State Medicaid agencies typically obtain AWP and WAC data for pharmacy reimbursement.[23]

State EAC Formulas.

We obtained the State EAC formulas that were in effect on January 1, 2005, from the CMS Web site. CMS compiles this information from approved State plans.

Medicaid Reimbursement Data.

Overall, we used the Medicaid reimbursement data available on the CMS Web site from the State Drug Utilization Files. At the time of our analysis, this data had been last updated in February 2005. The most recent national data included reimbursement by NDC for the first two quarters of calendar year 2004 (i.e., January 1 through June 30, 2004). We used this data to define our population of Medicaid-reimbursed drugs, to calculate weighted averages, and to identify the top 200 drugs based on Medicaid expenditures. We recognize that CMS's State Drug Utilization Files may not contain complete drug reimbursement data, but we believe that they are sufficient for purposes of this analysis.

In addition, we used data from the Medicaid Statistical Information System (MSIS) to identify drug reimbursement amounts for Medicaid beneficiaries who are not eligible for Medicare (non-dual eligibles). While total reimbursement amounts were available through June 2004, the most recent MSIS eligibility data to identify non-dual eligibles was from FY 2003 for 38 States with MSIS data. We used this data to calculate weighted averages based on reimbursement for the non-dual eligible population to determine whether the weighted averages would differ when limited to this beneficiary subpopulation compared to the entire Medicaid beneficiary population.

Analysis

For our population of Medicaid-reimbursed drugs, we calculated the following ratios by unit prices for all NDCs: (1) AMP to AWP, (2) AMP to WAC, and (3) WAC to AWP. For each set of price comparison ratios, we calculated the median, average, weighted average, range, and interquartile range. The weighted average "weights" each NDC according to Medicaid expenditures, i.e., the differences between prices for NDCs with higher Medicaid expenditures count more in the weighted average than NDCs with lower Medicaid expenditures. The interquartile range measures the difference between the 25th and 75th percentile of the distribution, i.e., the middle 50 percent of the distribution. Appendix C provides the ranges and interquartile ranges. We made these comparisons for the overall population of Medicaid-

reimbursed drugs as well as for each drug category, i.e., single source brands, multisource brands, and generic drugs.

We also conducted this analysis for a subset of drugs with the highest Medicaid expenditures. Specifically, we analyzed pricing data for the top 200 NDCs by Medicaid expenditures in 2004 for each of 3 categories.

For State EAC formulas, we calculated the median, mode, and range of percent discounts for the 49 States that use AWP in their formula. We made calculations specific to brand name drugs and generic drugs because seven States have separate formulas for each. We also calculated the median, mode, and range of percent markups of WAC for the eight States that use WAC in their formulas. These States do not distinguish brand name versus generic drugs in their WAC-based formulas.

This analysis focuses on the comparison of a sales-based price to the published prices associated with the drug itself (i.e., the "ingredient cost"). It does not address the professional costs associated with dispensing the drug nor the dispensing fees paid by State Medicaid agencies in addition to their estimates of pharmacy acquisition cost.

Limitations

We intend this inspection to provide information that is useful to those who are considering changing the basis of Medicaid reimbursement from a published price to a price based on actual sales. However, our analysis compares price points and not actual reimbursements. It is a theoretical analysis that is useful to estimate the impact of such a reimbursement change, but it does not measure the actual impact of such a change for three main reasons. First, States do not always reimburse at the amount that their EAC formulas would predict.[24] Second, our analysis does not capture the full complexity of Medicaid reimbursement, which can include tiered EAC formulas as well as other price points (i.e., usual and customary charge, FUL amounts, and State MAC amounts). Third, we are comparing published prices and State EAC formulas to AMP. However, if the basis of Medicaid reimbursement were changed to AMP, it would likely be AMP plus a markup percentage. For example, Medicare Part B moved to a sales-based price (i.e., ASP) and reimburses at ASP plus 6 percent.

Standards

This inspection was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency.

FINDINGS

Average manufacturer price is substantially lower than both average wholesale price and wholesale acquisition cost

For Medicaid-reimbursed drugs, AMP is substantially lower than either of the published prices, namely, AWP and WAC. The AMP is also lower than State estimates of pharmacy acquisition costs, which incorporate AWP and WAC.

At the median, AMP is equal to AWP minus 59 percent; in contrast, States' median estimated acquisition cost formula is AWP minus 12 percent.
At the median of over 24,000 Medicaid-reimbursed NDCs, AMP is 59 percent lower than AWP. To illustrate this 59 percent difference, for one NDC the AMP is $1.07 per pill, while the AWP is $2.61 per pill for the same drug. The median AWP-based State EAC formula is AWP minus 12 percent. This median State EAC formula would estimate pharmacy acquisition cost at $2.30 per pill for this same NDC.

Forty-nine States estimate pharmacy acquisition cost using AWP minus a discount percentage. However, even with the discount percentage, AMP is still lower than these States' estimates of pharmacy acquisition cost. The AWP minus 12 percent is the median and is also the most common EAC formula based on AWP.

For 98 percent of Medicaid-reimbursed NDCs, the median State EAC formula based on AWP results in reimbursement amounts higher than AMP. In other words, AMP is less than AWP minus 12 percent for these NDCs. Conversely, for 2 percent of NDCs, the median State EAC formula would reimburse at a price below AMP.

The relationship between AMP and AWP does not change when claims for dual eligibles are excluded. In 2006, the drug coverage for beneficiaries who are eligible for both Medicare and Medicaid (i.e., dual eligibles) will be transferred from Medicaid to Medicare Part D. Thus, we explored whether this shift would impact the relationship between AMP and AWP. We compared the average difference between AMP and AWP accounting for Medicaid reimbursement for all beneficiaries to the average difference accounting for reimbursement claims for non-dual eligibles only. Despite differences in drug utilization patterns between dual eligibles and non-dual eligibles, the relationship between AMP and AWP did not change when we excluded claims for dual eligibles.[25]

At the median, AMP is equal to WAC minus 25 percent; in contrast, States' median WAC-based EAC formula is WAC plus 8.5 percent.
At the median of over 19,000 NDCs, average manufacturer price is equal to WAC minus 25 percent.[26] To illustrate this 25 percent

difference, for one NDC, the AMP is $1.59 per pill, while the WAC is $2.11 per pill. The median State EAC formula (WAC plus 8.5 percent) would estimate pharmacy acquisition cost at $2.29 per pill for this NDC.

Eight States use WAC to estimate pharmacy acquisition cost.[27] All of these States add a percentage markup to the WAC price, ranging from 5 percent to 12 percent. WAC plus 8.5 percent is the median.

For 96 percent of Medicaid-reimbursed NDCs, the median WAC-based State EAC formula results in reimbursement amounts higher than AMP. In other words, AMP is less than WAC plus 8.5 percent for these NDCs. Conversely, for 4 percent of NDCs, the median State EAC formula based on WAC would reimburse at a price below AMP.

At the median, WAC is 22 percent lower than AWP. While AMP is considerably lower than both WAC and AWP, the comparisons make it clear that WAC is the lower of the two published prices. This is logical if WAC is meant to represent an earlier point in the distribution chain (prices paid by wholesalers) than AWP (prices paid by retailers). We compared WAC to AWP directly to determine how these published prices relate to one another. For over 99 percent of NDCs, WAC is lower than AWP. At the median, WAC is 22 percent lower than AWP.

At the median, the AWP and WAC values in the pricing compendium for January 1, 2005, had not been updated in more than 2 years. At the median, AWP values were last updated 33 months ago, and WAC values were last updated 29 months ago according to First Databank's National Drug Data File.[28] Overall, NDCs with higher Medicaid expenditures were updated more recently. When weighted by Medicaid expenditures, the average timespan since the last AWP update is 14 months; the unweighted average is 43 months.

In comparison, AMP is calculated and reported to CMS each quarter and reflects sales that occurred 6 months prior. As of January 1, 2005, only 8 percent of NDCs had AWP values that were updated within the prior 6 months. However, these 8 percent of NDCs account for almost 37 percent of expenditures because the published prices for higher expenditure NDCs tend to be updated more frequently than the published prices for lower expenditure NDCs. Ten percent of WAC values had been updated within the prior 6 months. Similarly, this 10 percent of NDCs accounted for 37 percent of expenditures.

Generic drugs exhibit the largest differences between average manufacturer price and the published prices

When we analyzed the Medicaid-reimbursed NDCs by the three drug categories (single source brands, multisource brands, and generics), we found dramatic differences across the categories. Generics demonstrated substantially larger differences between AMP and the published prices (AWP and WAC) than either of the brand name drug categories. Generic drugs comprise 76 percent of the Medicaid-reimbursed NDCs.

For generic drugs, AMP is 70 percent lower than AWP at the median. For generic drugs, AMP is 70 percent lower than AWP at the median. In comparison, AMP is 23 percent lower than AWP at the median for single source brands and 28 percent lower than AWP for multisource brands. Table 1 presents the comparisons of AMP to AWP overall and for each drug category. The values indicate the percentage by which AMP is lower than AWP.

Table 1. AMP to AWP Comparisons by Drug Category: AMP = AWP – X%

	Median	Average	Weighted Average*
Single Source Brands 3,527 NDCs	23%	25%	24%
Multisource Brands 2,356 NDCs	28%	40%	36%
Generics 18,218 NDCs	70%	65%	74%

Source: Office of Inspector General, Analysis of Medicaid drug pricing data, 2005.

*Weighted by Medicaid expenditures.

The weighted average indicates that, for generic drugs, the disparity between AMP and AWP is greater for drugs with higher Medicaid expenditures than for drugs with lower Medicaid expenditures. The weighted average is weighted by Medicaid expenditures (i.e., NDCs with higher Medicaid expenditures count more than those with lower expenditures) and thereby links the price differences with Medicaid reimbursement. Price and utilization are two important factors that may contribute to this pattern for generics. On the one hand, as the AWP of a drug increases the reimbursement price based on AWP also

increases, which could drive expenditures higher. On the other hand, high utilization of a drug can lead to both high expenditures on that drug and increased incentives to inflate AWP for that drug.

Notably, brand name drugs do not exhibit this same pattern. For brands, the weighted averages are slightly lower than the unweighted averages. This indicates that overall the disparities between AMP and AWP are not larger for brand name drugs with higher expenditures compared to brand name drugs with lower expenditures.

This is especially true for the top 200 generic drugs by Medicaid expenditures. In this subset, AMP is 78 percent lower than AWP at the median. In comparison, AMP is 23 percent less than AWP for the top 200 single source brands, and 28 percent less than AWP for the top 200 multisource brands. Table 2 displays these comparisons. The values indicate the percentage by which AMP is lower than AWP.

Table 2. AMP to AWP Comparisons for Top 200 NDCs by Medicaid Expenditures: AMP = AWP – X%

	Median
Top 200 NDCs: Single Source Brands	23%
Top 200 NDCs: Multisource Brands	28%
Top 200 NDCs: Generics	78%

Source: Office of Inspector General, Analysis of Medicaid drug pricing data, 2005.

State estimates of pharmacy acquistion cost exceed AMP even among States with additional discounts for generics. Of the 49 States that use EAC formulas based on AWP, 7 States specify a greater discount off of AWP for generic drugs than for brand name drugs. Among these seven States, the EAC formulas for generic drugs range from AWP minus 20 percent to AWP minus 50 percent. Even with these greater discounts, the median AMP (equal to AWP minus 70 percent) remains lower than States' estimated acqusition costs for generic drugs. Table 3 (on the next page) provides a summary of State EAC formulas for all 49 States that use AWP as well as the separate generic EAC formulas specified by 7 of these States.

Table 3. State Estimated Acquisition Cost Formulas Based on AWP			
State EAC Formula	**Median**	**Mode**	**Range**
All States' formulas (49 States)	AWP - 12%	AWP - 12%	AWP - 5% to AWP - 50%
Generic-specific formulas (7 States)	AWP - 27%	AWP - 20%	AWP – 20% to AWP - 50%

Source: Office of Inspector General, Analysis of State estimated acquisition cost formulas, 2005.

For generic drugs, AMP is 40 percent lower than WAC at the median. The differences between AMP and WAC are also much greater for generic drugs than either of the two brand name drug categories. For generics, AMP is equal to WAC minus 40 percent at the median. In comparison, AMP equals WAC minus 4 percent at the median for single source brands and WAC minus 8 percent for multisource brands. Table 4 presents the comparisons of AMP to WAC overall and for each drug category. The values indicate the percentage by which AMP is lower than WAC.

Table 4. AMP to WAC Comparisons by Drug Category: AMP = WAC – X%			
	Median	**Average**	**Weighted Average***
Single Source Brands 3,502 NDCs	4%	7%	6%
Multisource Brands 2,116 NDCs	8%	19%	20%
Generics 13,857 NDCs	40%	39%	59%

Source: Office of Inspector General, Analysis of Medicaid drug pricing data, 2005.

* Weighted by Medicaid expenditures.

Again, generic drugs with higher Medicaid expenditures demonstrate larger differences between AMP and WAC than generics with lower expenditures. The weighted average difference between AMP and WAC is greater than the unweighted average (59 percent compared to 39 percent) for generics. In contrast, for brand name drugs the

disparity between AMP and AWP is not larger for the drugs with higher expenditures compared to the drugs with lower expenditures.

The top 200 generic drugs by Medicaid expenditures illustrate this point, as this subset shows a greater disparity between AMP and WAC than the full population of Medicaid-reimbursed generic NDCs. For the top 200 generics, AMP is equal to WAC minus 59 percent at the median, compared to WAC minus 40 percent at the median for all Medicaid-reimbursed generics.

AMP is much lower than WAC-based State EAC formulas for generic drugs compared to brand name drugs. Eight States use WAC to estimate pharmacy acquisition cost. None specify a lower WAC-based formula for generic drugs compared to brand name drugs. These State EAC formulas all include a percentage markup of WAC, ranging from WAC plus 5 percent to WAC plus 12 percent. Table 5 summarizes these formulas.

Table 5. State Estimated Acquisition Cost Formulas Based on WAC

State EAC formula	Median	Mode	Range
All Drugs (8 States)	WAC + 8.5%	WAC + 5%	WAC + 5% to WAC + 12%

Source: Office of Inspector General, Analysis of State estimated acquisition cost formulas, 2005.

The median AMP is lower than these EAC formulas for all three drug categories. However, this difference is greatest among the generic drugs. For generics, AMP is equal to WAC minus 40 percent at the median, while State estimated acquisition costs equal WAC plus a markup of 5 to 12 percent.

CONCLUSION

The Administration and Congress have expressed interest in changing Medicaid drug reimbursement to align more closely with pharmacy acquisition cost by using prices based on actual sales rather than the published prices currently used. OIG has conducted numerous reviews of Medicaid drug reimbursement and has found that Medicaid drug reimbursements exceed pharmacies' actual acquisition costs and exceed prices paid by other Federal programs. OIG has recommended that Medicaid should base reimbursement on pricing data that more accurately reflects actual acquisition costs.

This inspection provides additional evidence that published prices are higher than prices based on actual sales transactions. We found that AMP, which is calculated based on statute and actual sales transactions, is substantially lower than either of the published prices (i.e., AWP and WAC). As a result, States' estimates of pharmacy acquisition costs, which are based on AWP and/or WAC, are also substantially higher than AMP. The differences between AMP and the published prices were especially large for generic drugs.

Our companion report, "Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price" (OEI-03-05-00200), found similar results when comparing ASP, the statutorily defined price used for Medicare reimbursement, to AWP. That analysis demonstrated that ASP is substantially lower than AWP for the drugs covered by both Medicaid and Medicare Part B.

We intend this inspection to provide useful information to those considering the implications of changing Medicaid's drug reimbursement methodology. The substantial disparities between prices based on actual sales (AMP and ASP) and the published prices currently being used indicate that changing the basis of Medicaid reimbursement could have a significant impact on Medicaid expenditures.

Agency Comments

CMS commented that these companion reports make clear that current Medicaid payment rules result in overpayments for drugs and emphasize the need for reform. Similar problems with overpayments for Medicare drugs led to passage of the MMA provisions that changed the basis of reimbursement for drugs from AWP to ASP. CMS reiterated that the President's 2006 budget proposes to solve this problem by the use of ASP so Medicaid drug prices will reflect actual

costs. CMS stated that Congress should enact legislation to ensure that Medicaid payment for drugs is related to actual prices paid by pharmacies. The full text of CMS's comments is provided in Appendix D.

END NOTES

[1] Testimony of Dennis Smith, Director of the Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, on Medicaid Prescription Drug Reimbursement before the House Energy and Commerce Subcommittee on Oversight and Investigations, December 7, 2004.

[2] Centers for Medicare & Medicaid Services. "2003 CMS Statistics." Available online at www.cms.hhs.gov/researchers/pubs/03cmsstats.pdf.

[3] Centers for Medicare & Medicaid Services. "A Strategy for Transitioning Dual Eligibles from Medicaid to Medicare Drug Coverage." May 2, 2005. Available online at http://www.cms.hhs.gov/medicarereform/strategyforduals.pdf.

[4] Ibid.

[5] United States House of Representatives Committee on the Budget. "Analysis of the President's Budget for FY 2006." Available online at http://www.house.gov/budget/analysisprez021105.pdf.

[6] Testimony transcript available online at http://www.oig.hhs.gov/testimony/docs/2004/reeb120704.pdf.

[7] Federal Register Notice. Medicaid Program; Establishment of the Medicaid Commission and Request for Nominations for Members. CMS-2214-N.

[8] Available online at www.ncsl.org and www.nga.org.

[9] Office of Inspector General reports: "Variations in State Medicaid Drug Prices," OEI-05-02-00681, issued September 2004; "Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products," A-06-02-00041, issued September 2002; "Cost Containment of Medicaid HIV/AIDS Drug Expenditures," OEI-05-99-00611, issued July 2001.

[10] Centers for Medicare & Medicaid Services State Medicaid Manual, Part 6. Available online at http://63.241.27.79/manuals/45_smm/sm_06_6000_to_6400.3.asp.

[11] Centers for Medicare & Medicaid Services State Medicaid Manual, Part 6. Available online at http://63.241.27.79/manuals/45_smm/sm_06_6000_to_6400.3.asp.

[12] 42 CFR § 447.332.

[13] Centers for Medicare & Medicaid Services. "Medicaid Prescription Reimbursement by State, Quarter Ending March 2005." Available at: http://www.cms.hhs.gov/medicaid/drugs/pre0305.pdf.

[14] Centers for Medicare & Medicaid Services State Medicaid Manual, Part 6.

[15] Centers for Medicare & Medicaid Services. "Medicaid Prescription Reimbursement by State, Quarter Ending March 2005."

[16] Three other drug price compendia are Multim, Gold Standard, and Red Book.

[17] Public Law 108-173, Section 303(c)6(B).

[18] Budget of the United State Government, Fiscal Year 2006. Available online at http://www.whitehouse.gov/omb/budget/fy2006.

[19] 42 U.S.C. § 1396r-8(k)(1).

[20] Ibid.

[21] Government Accountability Office. "Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States." GAO-05-102. February, 2005.

[22] 42 CFR § 414.804(a).

[23] Office of Inspector General. "Variation in State Medicaid Drug Prices." OEI-05-02-00681. September 2004.

[24] Ibid.

[25] We compared the weighted average price differences based on all claims to weighted averages based on claims for non-dual eligibles only and found no difference. Weighting by expenditures on non-dual eligibles only, AMP is 33 percent lower than AWP on average. Likewise, weighting by expenditures on the full Medicaid population, AMP is 33 percent lower than AWP on average.

[26] Only 19,475 of the 24,101 NDCs included in the AMP to AWP analysis had WAC values listed in the pricing compendium.

[27] Six of these States use WAC in combination with AWP, e.g., "the lesser of AWP minus 12 percent or WAC plus 8 percent."

[28] We rounded to the nearest full month increment. List prices can be updated at any time including multiple times within a month.

APPENDIX ~ A

KEY TERMS AND ACRONYMS, DRUG DISTRIBUTION CHART

Box 1: KEY TERMS AND ACRONYMS

Average manufacturer price (AMP): The average unit price paid to manufacturers by wholesalers for drugs distributed to the retail class of trade minus customary promt pay discounts. The AMP is statutorily defined and calculated from actual sales transactions. Manufacturers must report AMP to CMS quarterly for the Medicaid drug rebate program.

Average wholesale price (AWP): A price published in national drug pricing compendia issued by private companies such as First Databank and Medi-Span, based on pricing information provided by manufacturers. Its calculation is not defined in statute or regulation. It is generally considered a price for retailers.

Estimated acquisition cost (EAC): The State Medicaid agency's "best estimate" of the price generally and currently paid by providers for the drug. Within Federal parameters, each State establishes its own EAC formula in its State plan.

Multisource brand drugs: Innovator multisource drugs. Brand name drugs that have generic equivalents.

National drug code (NDC): The 11-digit code that Medicaid uses to identify unique formulations of each drug, including the manufacturer, strength, and package size.

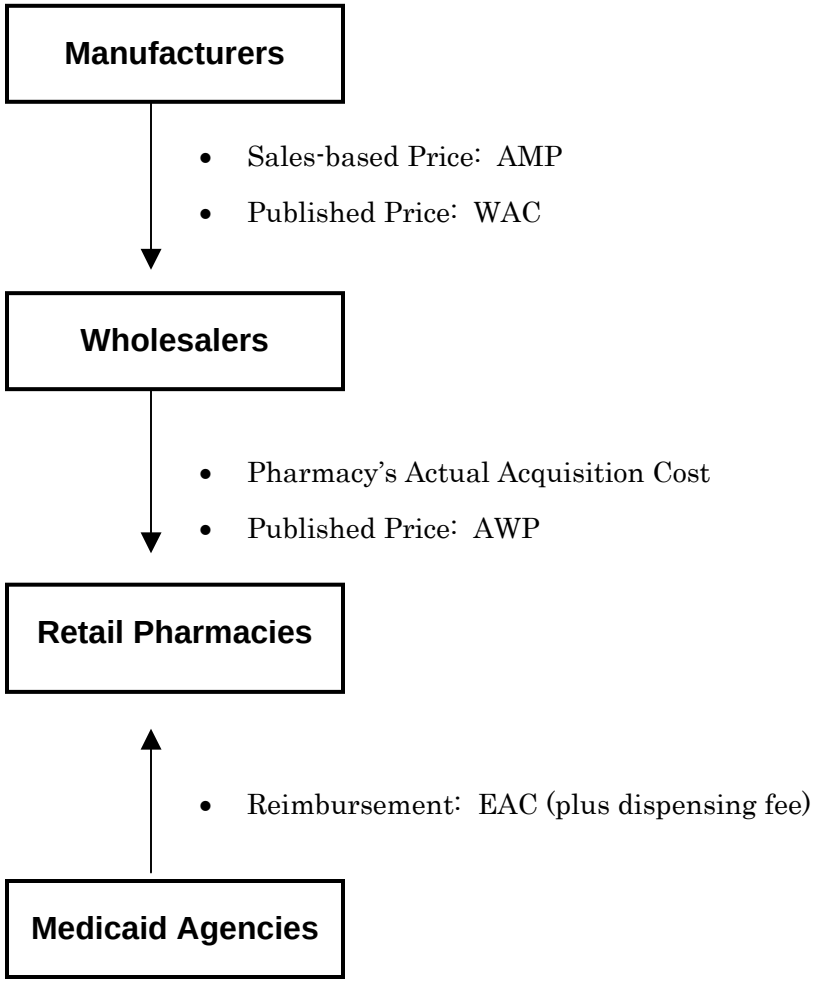
Generic drugs: Non-innovator multisource drugs.

Single source brand drugs: Single source drugs. Brand name drugs that have no generic equivalents.

Wholesale acquisition cost (WAC): A price published in national drug pricing compendia issued by private companies such as First Databank and Medi-Span. It is now statutorily defined as the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, as reported in wholesale price guides or other publications of drug pricing data.

The following chart is a simplified depiction of a typical Medicaid drug distribution chain meant to illustrate the relationships among the various drugs prices. It is not meant to capture the full complexity of the drug distribution chain.

Chart 1. Medicaid Drug Distribution Chain Example



ADDITIONAL DATA POPULATIONS: MEDICAID-COVERED DRUGS

In addition to Medicaid-reimbursed drugs, we analyzed the price comparisons for the population of Medicaid-covered drugs, including those with no reimbursement from January 1 through June 30, 2004. The population of Medicaid-covered drugs includes 28,557 NDCs, while Medicaid-reimbursed drugs includes 24,101 NDCs.

We found similar patterns of price differences between AMP and the published prices for Medicaid-covered drugs as compared to Medicaid-reimbursed drugs. For Medicaid-covered drugs, AMP is 57 percent lower than AWP at the median, compared to 59 percent for Medicaid-reimbursed drugs. The AMP is 24 percent lower than WAC for Medicaid-covered drugs and 25 percent lower than WAC for Medicaid-reimbursed drugs. Table 6 displays these results.

Table 6. Medicaid-covered drugs vs. Medicaid-reimbursed drugs

	AMP = AWP – X% Median	AMP = WAC – X% Median
Medicaid-covered Drugs	57%	24%
Medicaid-reimbursed Drugs	59%	25%

Source: Office of Inspector General, Analysis of Medicaid drug pricing data, 2005.

ADDITIONAL MEASURES: RANGES AND INTERQUARTILE RANGES

In addition to the median, average, and weighted average, we calculated the range and interquartile range for each price comparison. While the range measures the difference between the two ends of a distribution, the interquartile range measures the difference between the 25th and 75th percentile of the distribution, i.e., the middle 50 percent of the distribution. Table 7 displays these measures for the AMP to AWP comparsions, and Table 8 displays results of comparing AMP to WAC.

Table 7. AMP to AWP Comparisons: AMP = AWP – X%

	Range*	Interquartile Range
All Medicaid-reimbursed Drugs 24,101 NDCs	0% to 98%	28% to 83%
Single Source Brands 3,527 NDCs	0% to 65%	22% to 27%
Multisource Brands 2,356 NDCs	0% to 96%	22% to 56%
Generics 18,218 NDCs	0% to 98%	47% to 87%

Source: Office of Inspector General, Analysis of Medicaid drug pricing data, 2005.

* We excluded 3 percent of NDCs at the high and low ends of the distribution. See methodology for details.

Table 8. AMP to WAC Comparisons: AMP = WAC – X%

	Range*	Interquartile Range
All Medicaid-reimbursed Drugs 19,475 NDCs	(-869%) to 98%	4% to 57%
Single Source Brands 3,502 NDCs	(-28%) to 57%	2% to 9%
Multisource Brands 2,116 NDCs	(-86%) to 95%	2% to 29%
Generics 13,857 NDCs	(-869%) to 98%	14% to 64%

Source: Office of Inspector General, Analysis of Medicaid drug pricing data, 2005.

* A negative difference indicates an AMP value greater than WAC. This occurred for 9 percent of NDCs.

AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 21 2005

TO: Daniel R. Levinson
Acting Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: OIG Draft Reports: "*Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices*," (OEI-03-05-00110);

"*Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price,*" (OEI 03-05-00200); and

"*Medicaid Drug Price Comparison: Average Manufacturer Price to Average Wholesale Price*," (OEI-05-05-00240)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft reports entitled "*Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices,*" "*Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price,*" and "*Medicaid Drug Price Comparison: Average Manufacturer Price to Average Wholesale Price.*" The first OIG report addresses how prices for drugs set under the Medicaid Federal Upper Limit (FUL) program compare to reported average manufacturer prices (AMP), and estimates potential savings if FUL amounts were based on reported AMPs. The latter two reports compare how prices that most states currently use to set Medicaid reimbursement, average wholesale price (AWP), and wholesale acquisition cost (WAC), compare to statutorily defined prices based on actual sales transactions, i.e., average sales price (ASP) and AMP.

The OIG reports make clear that the current payment rules result in overpayments for drugs and emphasize the need for reform. The President's 2006 budget proposes to solve this problem by the use of average sales prices (ASP) so Medicaid drug prices will reflect actual costs.

OIG Recommendation

CMS should work with Congress to set Medicaid drug reimbursement amounts that more closely approximate pharmacy acquisition cost.

CMS Response

We concur with the OIG that the Congress needs to address drug prices paid by Medicaid to more closely relate Medicaid reimbursement to actual transaction prices.

Federal regulation (42 CFR 447.332) requires the FUL amount to be 150 percent of the published price for the least costly therapeutic equivalent using data from all available national compendia. The FUL system selects the lowest price of AWP, WAC, or direct price (DP), as reported by the national compendia to arrive at the FUL price.

States reimburse pharmacies for single source drugs at the lower of Estimated Acquisition Cost (EAC), or the pharmacy's usual and customary charge (UCC) to the general public. EAC is based on the state's reimbursement formula, generally AWP minus a percentage or WAC plus a percentage.

Neither AWP nor WAC is related to the market price of drugs. Rather, they are prices based on reports by manufacturers. Manufacturers often report inflated prices in order to increase the profit for pharmacies and, thereby, encourage pharmacies to dispense their product. State Medicaid Agencies need information on market prices in order to set appropriate payment rates. The President has proposed in the fiscal year 2006 budget to require drug manufacturers to report ASP for drugs and to cap Federal matching for drug expenditures, in the aggregate, to ASP plus 6 percent.

OIG Findings

Overall, FUL prices were five times higher than the average AMPs for generic drug products in the third quarter of 2004. If Medicaid based FUL amounts on 150 percent of the average AMP instead of the compendia prices, the program could have saved an estimated $161 million in the third quarter of 2004.

For the comparison of AMP to compendia price, AMP is substantially lower than both AWP and WAC for all National Drug Codes (NDCs) reviewed. The median price comparison for all evaluated drugs was that AMP is equal to AWP – 59 percent and AMP is equal to WAC - 25 Percent. Generic drugs exhibited the largest differences between AMP and the list prices – The median price comparison for generic drugs was AMP is equal to AWP - 70 percent and AMP is equal to WAC – 40 percent. States' median AWP based estimated acquisition cost is AWP – 12 Percent. States' median WAC based estimated acquisition cost is WAC plus 8.5 percent.

For the comparison of ASP to compendia price, ASP is substantially lower than AWP and WAC for all NDCs reviewed. For 2,077 NDCs with ASP and AWP data, ASP is equal to AWP – 49 percent. The difference between ASP and AWP was greatest for generic drugs. For 1,152 generic NDCs, ASP is equal to AWP – 68 Percent.

CMS Response/Conclusion

These reports provide additional supportive evidence that when published compendia prices are used as a basis for Medicaid drug reimbursement, Medicaid payment greatly exceeds actual acquisition cost. Legislation would be needed to define a price that manufacturers must report that can be used as a basis for state Medicaid agencies to set pharmacy payment.

In the fiscal year 2006 budget, the President proposed to require drug manufacturers to report the ASP for each drug and to cap Federal payment at an aggregate level to ASP plus 6 percent. As long as states must rely on prices that are not based on true prices paid to manufacturers, states have no means to set appropriate payment amounts. Current WACs and AWPs are greatly inflated and this inflation is encouraged by setting Medicaid payment in relation to these inflated prices. Requiring manufacturers to report true prices and to limit Medicaid payment to a reasonable amount above these prices will eliminate the opportunity for manufacturers and pharmacies to gain through the reporting of inflated prices, yield substantial state and Federal government savings, and retain flexibility for states to set prices for individual drugs as they find appropriate within the overall cap.

Prior to 2005, Medicare also used AWP as the basis for Part B drug reimbursement. However, numerous studies by the OIG and the Government Accountability Office, (GAO), indicated that Medicare's reimbursement rate was significantly higher than the prices that drug manufacturers and wholesalers actually charged physicians and suppliers who purchased these drugs. Consequently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the basis of reimbursement for prescription drugs from AWP to ASP. Congress should now enact similar legislation to ensure that Medicaid payment for drugs is related to actual prices paid by pharmacies.

ACKNOWLEDGMENTS

This report was prepared under the direction of William C. Moran, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Ann Maxwell, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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