Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

EXAMINING FLUCTUATIONS IN AVERAGE MANUFACTURER PRICES

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Inspector General

May 2007
OEI-03-06-00350

Office of Inspector General

http://oig.hhs.gov

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EXECUTIVE SUMMARY

OBJECTIVE

To determine the extent to which average manufacturer prices (AMP) fluctuated between the second quarter of 2005 and the second quarter of 2006.

BACKGROUND

Pursuant to provisions of the Deficit Reduction Act of 2005 (DRA), the Centers for Medicare & Medicaid Services (CMS) was required to make AMP data available to States as of July 1, 2006. States will have the option of using these AMP data to set drug reimbursement amounts in their Medicaid programs. As of January 1, 2007, AMPs are also to be used to establish Medicaid Federal upper limit amounts. In response to these changes, industry representatives have expressed concerns that (1) the AMP is too volatile to serve as the basis for Medicaid payment, and (2) the 2-month lag between when AMPs are reported to the States and when reimbursement amounts are established may cause pharmacies to absorb price increases in the interim.

At the time of this review, Federal law defined the AMP as the average price paid to the manufacturer for a drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts. As a result of provisions in the DRA, beginning January 1, 2007, manufacturers are no longer to include customary prompt pay discounts when reporting AMPs. Through 2006, manufacturers reported AMPs for their covered outpatient drugs to CMS by the national drug codes (NDC) each quarter. However, effective January 1, 2007, the DRA requires manufacturers to report AMPs to CMS on both a monthly and a quarterly basis. Because the monthly AMP data submitted to CMS by manufacturers will reflect sales from up to 60 days prior, there will be at least a 2-month lag between the sales period for which AMPs are reported and the effective date of the Medicaid reimbursement amounts.

For this inspection, we calculated the percentage difference among all quarterly AMPs between the second quarter of 2005 and the second quarter of 2006. These results were then broken down by drug category (single-source, innovator multiple-source, or noninnovator multiple-source) and for the top 50 NDCs ranked by total Medicaid reimbursement within each category. In general, single-source drugs are brand name products for which there are no available generics,

innovator multiple-source drugs are brand name products for which there are available generics, and noninnovator multiple-source drugs are generic products. Manufacturers provide CMS with the drug type for each of their NDCs in conjunction with AMP data.

FINDINGS

Overall, 39 percent of average manufacturer prices stayed the same between quarters, and an additional 16 percent changed by less than 2 percent. During the period under review, an average of 39 percent of AMPs did not change between quarters, and another 16 percent of AMPs changed by less than 2 percent. Twenty-four percent of AMPs fluctuated by more than 10 percent from quarter to quarter. Of this number, half increased and half decreased.

Average manufacturer prices for single-source drugs changed more frequently than those for other drug types, but most changes were relatively small. An average of 78 percent of AMPs for single-source NDCs changed from quarter to quarter during the period under review. However, of those that changed, slightly more than half fluctuated by 2 percent or less. Only 7 percent of single-source NDCs, on average, had AMPs that changed by more than 10 percent between quarters.

In comparison, the AMPs for 67 percent of innovator multiple-source and 58 percent of noninnovator multiple-source NDCs changed between quarters. However, the size of these changes tended to be larger than the changes for single-source NDCs.

Average manufacturer prices for high-expenditure drugs changed more frequently than those for other drugs, with single-source drugs being especially prone to price increases. AMPs for the top 50 NDCs by total Medicaid reimbursement in each category (single-source, innovator multiple-source, and noninnovator multiple-source) experienced more fluctuation between quarters than all AMPs as a whole. On average, AMPs for 3 percent to 5 percent of the top 50 NDCs in each category stayed the same from quarter to quarter, compared to 22 percent to 42 percent among all NDCs in each category.

AMPs for the top 50 noninnovator multiple-source NDCs showed the most variability, with more than half changing by at least 10 percent between quarters. At the same time, virtually all (99 percent) of the top 50 single-source NDCs changed by less than 10 percent between quarters. AMPs for the top 50 innovator multiple-source NDCs changed

at rates that fell between noninnovator multiple-source and single-source NDCs.

Overall, 42 percent of AMPs for the top 50 noninnovator multiple-source NDCs increased and 54 percent decreased between each quarter during the period under review. In contrast, AMPs associated with the top 50 single-source NDCs increased more than they decreased. An average of 79 percent of AMPs for the top 50 single-source NDCs increased between each quarter, with 41 percent increasing by at least 2 percent.

CONCLUSION

In this review, we found that the majority of AMPs did not fluctuate substantially from quarter to quarter and that roughly equal numbers of AMPs decreased as increased. However, when compared to AMPs for other drug types, AMPs for single-source drugs, especially those with high Medicaid expenditures, were more prone to increases between quarters. Although these increases tended to be relatively small, States may want to take the potential effects of AMP increases during the lag period into account when developing any AMP-based reimbursement formulas.

It is important to note that this analysis focused on quarterly AMP data, because CMS had yet to begin collecting AMPs on a monthly basis at the time of our review. Once AMP data are reported on a monthly basis, we expect the size and the number of fluctuations between reporting periods to be reduced.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS believes this report shows that AMPs can be used appropriately to set Medicaid payment to pharmacies. However, CMS notes that the new definition of AMP (as established by the DRA) excludes customary prompt pay discounts and includes sales of authorized generics. Therefore, CMS states that the Office of Inspector General's (OIG) findings may not be comparable to actual experience once the final regulation implementing these changes is issued and the new AMP definition takes effect.

CMS also notes that more than half of AMPs for noninnovator multiple-source drugs varied by 10 percent or more. Although this is a high percentage change, noninnovator multiple-source drugs are usually

priced far lower than the other categories of drugs, making the absolute change modest. In future work, CMS would like OIG to add an additional analysis of absolute price changes in this area of work.

OIG agrees that AMPs will likely change as a result of CMS's final rule implementing the DRA-related definitional changes. However, the analysis presented in this report can serve as the baseline for future studies that address how DRA provisions impact AMP. Finally, OIG will consider including analyses of absolute price changes in future work in this area.

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INTRODUCTION

OBJECTIVE

To determine the extent to which average manufacturer prices (AMP) fluctuated between the second quarter of 2005 and the second quarter of 2006.

BACKGROUND

Pursuant to provisions of the Deficit Reduction Act of 2005 (DRA), Public Law 109-171, the Centers for Medicare & Medicaid Services (CMS) was required to make AMP data available to States as of July 1, 2006.[1] States will have the option of using these AMP data to set drug reimbursement amounts in their Medicaid programs. In response to these changes, industry representatives have expressed concerns that (1) the AMP is too volatile to serve as the basis for Medicaid's payment methodology, and (2) the 2-month lag between when AMPs are reported to the States and when reimbursement amounts are established may cause pharmacies to absorb price increases in the interim (particularly increases in prices for brand name drugs).[2] This study assesses these concerns by examining historical changes in AMPs over time.

Medicaid Coverage of Prescription Drugs

All 50 States and the District of Columbia offer prescription drug coverage as part of their Medicaid programs. Individual States establish eligibility requirements, benefits packages, and payment rates under broad Federal standards administered by CMS. In 2005, Medicaid payments for prescription drugs totaled over $41 billion.[3]

Medicaid Drug Reimbursement Methodology

Typically, Medicaid beneficiaries obtain drugs through pharmacies. To receive reimbursement for these drugs, pharmacies submit claims to State Medicaid agencies using the national drug codes (NDC), which are 11-digit identifiers indicating the manufacturer of the drug, the product dosage form, and the package size.

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[1] Deficit Reduction Act of 2005, section 6001(b).

[2] "Medicaid Prescription Drugs: Examining Options for Payment Reform." National Association of Chain Drug Stores' statement to the House Energy and Commerce Committee, Subcommittee on Health, June 22, 2005, page 10.

[3] This amount includes both the Federal and State shares of payments. Rebates collected under the Medicaid Drug Rebate program (section 1927 of the Social Security Act) were not subtracted from this figure.

Pursuant to section 1902(a)(54) of the Social Security Act (the Act), each State is required to submit a Medicaid State plan to CMS describing its payment methodology for covered outpatient drugs. Federal regulations require, with certain exceptions, that each State's Medicaid reimbursement for a drug not exceed (in the aggregate) the lower of its estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public.[4] CMS allows States flexibility when defining estimated acquisition cost. Currently, most States base their calculations of estimated acquisition cost on a drug's average wholesale price discounted by a certain percentage. For certain multiple-source drugs, States also use the Federal upper limit and/or State maximum allowable cost programs in determining reimbursement amounts.[5]

Average Manufacturer Prices Prior to January 1, 2007

For Federal payments to be available for covered outpatient drugs provided under Medicaid, sections 1927(a)(1) and (b)(1) of the Act require drug manufacturers to enter into rebate agreements with the Secretary of the Department of Health and Human Services (the Secretary) and pay quarterly rebates to State Medicaid agencies. Under these rebate agreements, and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the AMP for each of their covered outpatient drugs by the NDC. At the time of this review, the AMP was defined by section 1927(k)(1) of the Act as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade after deducting customary prompt pay discounts.[6]

The AMP is calculated as a weighted average of prices for all the manufacturer's package sizes of a covered outpatient drug sold during a given time period and is reported for the lowest identifiable quantity of the drug (e.g., 1 milligram, 1 milliliter, 1 tablet, or 1 capsule). Through 2006, manufacturers submitted AMP data on a quarterly basis, with submissions due 30 days after the close of the quarter.

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[4] 42 CFR § 447.331(b).

[5] The Federal upper limit and State maximum allowable cost programs serve to control spending for multiple-source drugs. CMS has currently established Federal upper limit amounts for more than 500 drugs. In addition, numerous States have implemented maximum allowable cost programs to limit reimbursement amounts for certain drugs.

[6] Pursuant to section 6001(c)(1) of the DRA, as of January 1, 2007, the AMP will be determined without regard to customary prompt pay discounts extended to wholesalers.

For purposes of the Medicaid drug rebate program, drugs are classified as one of three types: single-source, innovator multiple-source, or noninnovator multiple-source. Pursuant to section 1927(k)(7)(A) of the Act, these three categories are defined as follows:

- Single-source drug: a covered outpatient drug produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA), including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.
- Innovator multiple-source drug: a multiple-source drug that was originally marketed under an original new drug application approved by the FDA.
- Noninnovator multiple-source drug: a multiple-source drug that is not an innovator multiple-source drug.

In general, single-source drugs are brand name products for which there are no available generics, innovator multiple-source drugs are brand name products for which there are available generics, and noninnovator multiple-source drugs are generic products. Manufacturers provide CMS with the drug type for each of their NDCs in conjunction with AMP data.

Medicaid Prescription Drug Reform

In an effort to reduce Medicaid prescription drug expenditures, Congress recently enacted changes that affect payments for Medicaid prescription drugs. Prior to the enactment of the DRA, section 1927(b)(3)(D) of the Act prohibited the disclosure of AMP data, except in certain narrow circumstances. During that time, AMP data were used primarily by CMS for purposes of the Medicaid drug rebate program. However, section 6001(b)(1)(B) of the DRA requires that AMPs be made available to State Medicaid programs beginning July 1, 2006. States will have the option to use these AMP data to help set reimbursement rates. In addition, as of January 1, 2007, pursuant to section 6001(a) of the DRA, Federal upper limit amounts for certain multiple-souce drugs are to be based on 250 percent of the lowest reported AMP for each drug rather than 150 percent of the lowest price published in national compendia.

Section 6001(b)(1)(A) of the DRA requires manufacturers, beginning January 1, 2007, to report AMPs to CMS on both a monthly and a quarterly basis, with monthly submissions due 30 days after the close of

the month. Because the monthly AMP data submitted to CMS by the manufacturers will reflect sales from up to 60 days prior, there would be at least a 2-month lag between the sales period for which AMPs are reported and the effective date of the Medicaid reimbursement amounts. In addition, pursuant to section 6001(c)(1) of the DRA, as of January 1, 2007, the AMP will be determined without regard to customary prompt pay discounts extended to wholesalers, and such discounts will be reported separately to CMS. In December 2006, CMS issued a proposed regulation addressing the new AMP provisions of the DRA.

Additional Office of Inpector General Work Regarding Average Manufacturer Prices

The Office of Inspector General (OIG) is currently in the process of completing two companion reports addressing DRA-related AMP provisions. "States' Use of New Drug Pricing Data in the Medicaid Program" (OEI-03-06-00490) examines the manner in which States are planning to use the newly available AMP data. "Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program" (OEI-03-06-00400) assesses the potential changes in Federal upper limit amounts under the new AMP-based calculation method.

In a June 2006 study, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005" (A-06-06-00063), we found that existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. Our discussions with industry groups confirmed the need to clarify requirements and raised additional issues related to the implementation of DRA provisions. We recommended that the Secretary direct CMS, in promulgating the AMP regulation, to: (1) clarify requirements in regard to the definition of retail class of trade and the treatment of pharmacy benefit manager rebates and Medicaid sales and (2) consider addressing issues raised by industry groups. We also recommended that the Secretary direct CMS to: (1) issue guidance in the near future that specifically addresses the implementation of the AMP-related reimbursement provisions of the DRA and (2) encourage States to analyze the relationship between the AMP and pharmacy acquisition cost before using the AMP for their reimbursement methodology.

In our June 2005 report, "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices" (OEI-03-05-00110), we found that Federal upper limit amounts were five times higher than average AMPs (a figure that we used as an estimate of pharmacy acquisition costs) in the third quarter of 2004. At that time, we recommended that CMS work with Congress to set Federal upper limit amounts that more closely resemble pharmacy acquisition costs.

METHODOLOGY

Data Sources and Scope

We obtained AMP data for the second quarter of calendar year 2005 through the second quarter of calendar year 2006 from CMS. Drug category data (single-source, innovator multiple-source, or noninnovator multiple-source) were included on the AMP files provided by CMS. A total of 51,936 unique NDCs (5,403 single-source, 4,697 innovator multiple-source, and 41,836 noninnovator multiple-source) had an AMP value in at least one of the quarters under review.

Data Analysis

For each NDC, we calculated the percentage difference between quarterly AMP values and for the 1-year span between the first and last quarters. NDCs that did not have AMP values for any particular quarter were excluded from the percentage difference calculations involving that quarter.[7]

We grouped NDCs into ranges according to the percentage that the AMP had increased or decreased for a given time period. To determine the average amount that AMPs fluctuated on a quarterly basis, we calculated the average percentage of NDCs that fell into each range over the four-quarter period. Frequency counts of AMP fluctuations based on drug categories were also performed.

Using 2005 Medicaid drug utilization data downloaded from CMS's Web site, we identified the top 50 NDCs by total Medicaid reimbursement for each of the three categories. We then examined AMP fluctuations for the top 50 NDCs among each of the three drug

[7] The number of NDCs included in each quarterly percentage difference calculation ranged from 38,123 to 45,937.

categories.[8] We repeated the analysis described above to determine variation in AMPs for the top 50 NDCs as compared to NDCs for all drugs in each category.

Limitations

AMPs used in this study reflect the customary prompt pay discounts paid by manufacturers, because this is how AMPs were reported at the time of our analysis. As a result of provisions in the DRA, beginning January 1, 2007, manufacturers are no longer to include customary prompt pay discounts when reporting AMPs. Furthermore, as of that same date, manufacturers are required to report AMPs to CMS on both a monthly and a quarterly basis.

Standards

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

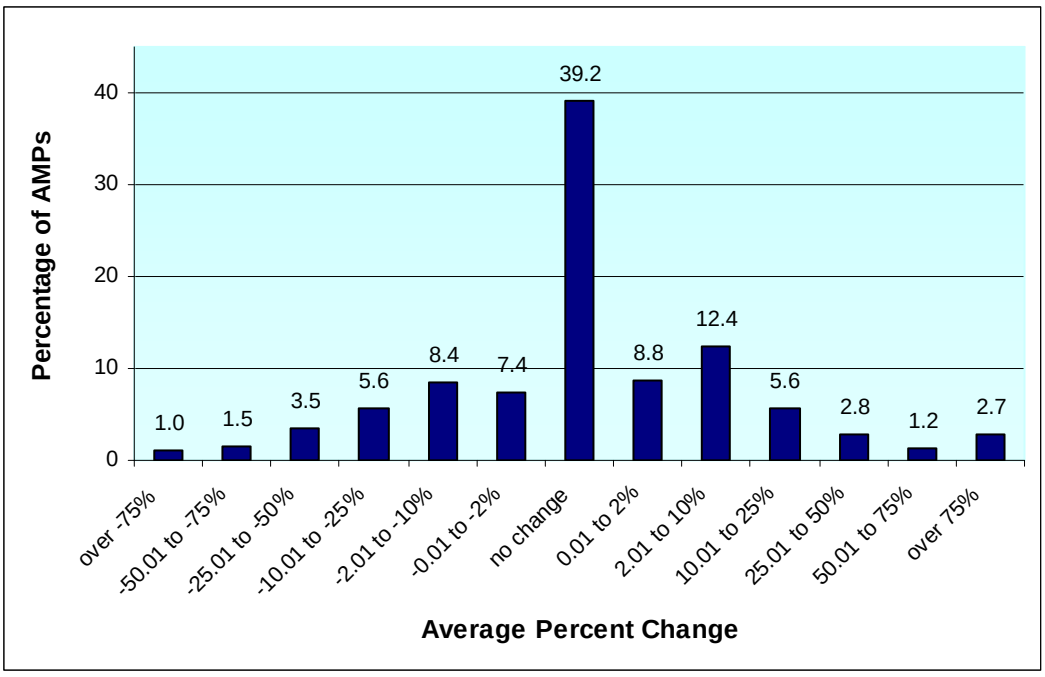
[8] Not all 50 NDCs within each category had AMP values for each quarter under review. As a result, one single-source NDC was removed in the analysis of fluctuations between the first and second quarters of 2006. In addition, one innovator multiple-source NDC and one noninnovator multiple-source NDC were removed in the analysis of fluctuations between the second and third quarters of 2005.

Overall, 39 percent of average manufacturer prices stayed the same between quarters, and an additional 16 percent changed by less than 2 percent

During the period under review, an average of 39 percent of AMPs did not change between quarters, and an additional 16 percent of AMPs changed by less than 2 percent. Twenty-four percent of AMPs fluctuated by more than 10 percent, on average, from quarter to quarter. Of this number, half increased and half decreased.

Graph 1 presents the average percentage change in AMPs between quarters from the second quarter of 2005 through the second quarter of 2006. The AMP fluctuations from quarter to quarter varied only slightly from the overall averages displayed in the graph. Fluctuations between each of the quarters under review, as well as the entire year as a whole, are presented in Appendix A.

Graph 1: Average Percent Change in AMPs Between Quarters



Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.

*Totals do not add up to 100% due to rounding.

Average manufacturer prices for single-source drugs changed more frequently than those for other drug types, but most changes were relatively small

AMPs for single-source NDCs tended to change more frequently than did AMPs for multiple-source NDCs. During the period under review, an average of 78 percent of AMPs for single-source NDCs changed from quarter to quarter. In comparison, AMPs for 67 percent of innovator multiple-source and 58 percent of noninnovator multiple-source NDCs changed in the same timeframe.

Although fewer AMPs for innovator and noninnovator multiple-source NDCs changed from quarter to quarter, any percentage changes tended to be larger than those for single-source drugs. An average of 16 percent of AMPs for innovator multiple-source drugs and 27 percent of AMPs for noninnovator multiple-source drugs increased or decreased by at least 10 percent between quarters. Among single-source drugs, the majority fluctuated by 2 percent or less. Only 7 percent of single-source NDCs had AMPs that changed by more than 10 percent between quarters.

Table 1 on the following page illustrates the average fluctuation between quarters for single-source, innovator multiple-source, and noninnovator multiple-source NDCs. Tables that track the AMP changes for NDCs in each category between each of the quarters under review are presented in Appendix B.

Table 1: Average Percent Change in AMPs Between Quarters by Category

Range of Fluctuation	Single-Source NDCs	Innovator Multiple-Source NDCs	Noninnovator Multiple-Source NDCs	All Categories
Over 75%	0.5%	1.5%	3.2%	2.7%
50.01 to 75%	0.3%	0.8%	1.4%	1.2%
25.01 to 50%	0.7%	2.0%	3.2%	2.8%
10.01 to 25%	3.4%	4.5%	6.0%	5.6%
2.01 to 10%	24.9%	18.4%	10.0%	12.4%
0.01 to 2 %	23.1%	13.3%	6.3%	8.8%
No Change	22.4%	32.9%	42.1%	39.2%
-0.01 to -2%	16.1%	11.1%	5.8%	7.4%
-2.01 to -10%	6.1%	7.9%	8.8%	8.4%
-10.01 to -25%	1.5%	3.9%	6.4%	5.6%
-25.01 to -50%	0.6%	2.3%	4.0%	3.5%
-50.01 to -75%	0.2%	0.8%	1.8%	1.5%
Over -75%	0.1%	0.6%	1.2%	1.0%

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.

*Totals do not add up to 100% due to rounding.

Average manufacturer prices for high-expenditure drugs changed more frequently than those for other drugs, with single-source drugs being especially prone to price increases

AMPs for the top 50 NDCs by total Medicaid reimbursement in each category (single-source, innovator multiple-source, and noninnovator multiple-source) experienced more fluctuation between quarters than all AMPs as a whole. On average, AMPs for 3 percent to 5 percent of the top 50 NDCs in each category stayed the same from quarter to quarter, as compared to 22 percent to 42 percent among all NDCs in each category.

AMPs for the top 50 noninnovator multiple-source NDCs showed the most variability, with more than half changing by at least 10 percent between quarters. In contrast, virtually all (99 percent) of the top 50 single-source NDCs changed by less than 10 percent between quarters. AMPs for the top 50 innovator multiple-source NDCs changed at rates that fell between those for noninnovator multiple-source and single-source NDCs.

Overall, 42 percent of AMPs for the top 50 noninnovator multiple-source NDCs increased and 54 percent decreased between each quarter during

the period under review. In contrast, AMPs associated with the top 50 single-source NDCs increased more than they decreased. An average of 79 percent of AMPs for the top 50 single-source NDCs increased between each quarter, with 41 percent increasing by at least 2 percent.

Table 2 below shows the average quarterly fluctuations among the top 50 NDCs in each category. Tables that track AMP changes for the top 50 single-source, innovator multiple-source, and noninnovator multiple-source NDCs between each of the quarters under review are presented in Appendix C.

Table 2: Average Percent Change in AMPs Between Quarters for Top 50 NDCs by Category

Range of Fluctuation	Single-Source NDCs	Innovator Multiple-Source NDCs	Noninnovator Multiple-Source NDCs
Over 75%	-	3.5%	5.5%
50.01 to 75%	-	2.0%	2.5%
25.01 to 50%	-	3.5%	5.5%
10.01 to 25%	0.5%	4.5%	8.0%
2.01 to 10%	40.2%	25.1%	15.5%
0.01 to 2 %	38.2%	27.7%	4.6%
No Change	2.5%	4.0%	4.5%
-0.01 to -2%	16.1%	13.0%	11.1%
-2.01 to -10%	2.5%	6.1%	11.1%
-10.01 to -25%	-	3.0%	13.6%
-25.01 to -50%	-	2.0%	10.6%
-50.01 to -75%	-	2.0%	5.0%
Over -75%	-	3.5%	2.5%

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.

*Totals do not add up to 100% due to rounding.

CONCLUSION

Pursuant to provisions of the DRA, CMS was required to make AMP data available to States as of July 1, 2006. States will have the option of using these AMP data to set drug reimbursement amounts in their Medicaid programs. In response to these changes, industry representatives have expressed concerns that (1) the AMP is too volatile to serve as the basis for Medicaid's payment methodology, and (2) the 2-month lag between when AMPs are reported to the States and when reimbursement amounts are established may cause pharmacies to absorb price increases in the interim.

In this review, we found that the majority of AMPs did not fluctuate substantially from quarter to quarter and that roughly equal numbers of AMPs decreased as increased. However, when compared to AMPs for other drug types, AMPs for single-source drugs, especially those with high Medicaid expenditures, were more prone to increases between quarters. Although these increases tended to be relatively small, States may want to take the potential effects of AMP increases during the lag period into account when developing any AMP-based reimbursement formulas.

Finally, it is important to note that this analysis focused on quarterly AMP data, because CMS had yet to begin collecting AMPs on a monthly basis at the time of our review. Once AMP data are reported on a monthly basis, we expect the size and the number of fluctuations between reporting periods to be reduced.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS notes that the findings of this report are based on AMPs prior to January 2007. Pursuant to provisions in the DRA, after this date, the definition of AMP excludes customary prompt pay discounts and includes sales of authorized generics. Therefore, CMS states that OIG's findings may not be comparable to actual experience once the final regulation implementing these changes is issued and the new AMP definition takes effect.

CMS also states that making AMP data available to States for reimbursement purposes will be a great improvement over the current situation, in which States base drug reimbursement on published prices in commercial compendia that have little relationship to market prices.

Because AMP changes reflect market price changes and OIG's findings indicate that the variations occur equally in both directions, CMS believes this report shows AMP's can be used appropriately to establish Medicaid payment to pharmacies.

CMS also notes that more than half of AMPs for noninnovator multiple-source drugs varied by 10 percent or more. Although this is a high percentage change, noninnovator multiple-source drugs are usually priced far lower than the other categories of drugs, making the absolute change modest. In future work, CMS would like OIG to add an additional analysis of absolute price changes in this area of work. The full text of CMS's comments is presented in Appendix D.

OIG agrees that AMPs will likely change as a result of CMS's final rule implementing the DRA-related definitional changes. However, the analysis presented in this report can serve as a baseline for future studies that address how the DRA provisions impact AMP. Finally, OIG will consider including analyses of absolute price changes in future work in this area.

APPENDIX ~ A

Table A-1: Quarterly, Yearly, and Average Percent Changes in AMPs for All NDCs

Range of Fluctuation	2nd Qtr 2005 to 3rd Qtr 2005	3rd Qtr 2005 to 4th Qtr 2005	4th Qtr 2005 to 1st Qtr 2006	1st Qtr 2006 to 2nd Qtr 2006	Average Change Between Quarters	Total Change 2nd Qtr 2005 To 2nd Qtr 2006
Over 75%	2.2%	3.1%	2.3%	3.3%	2.7%	3.5%
50.01 to 75%	0.8%	1.9%	0.9%	1.2%	1.2%	1.5%
25.01 to 50%	2.7%	2.9%	2.2%	3.5%	2.8%	5.0%
10.01 to 25%	5.4%	5.5%	4.9%	6.4%	5.6%	10.5%
2.01 to 10%	12.2%	11.0%	12.4%	13.8%	12.4%	16.1%
0.01 to 2 %	9.6%	8.7%	7.3%	9.5%	8.8%	5.5%
No Change	37.5%	40.2%	41.9%	37.1%	39.2%	27.5%
-0.01 to -2%	7.4%	8.3%	6.6%	7.1%	7.4%	4.9%
-2.01 to -10%	9.3%	8.5%	8.0%	7.9%	8.4%	8.0%
-10.01 to -25%	6.5%	4.8%	6.5%	4.8%	5.6%	7.6%
-25.01 to -50%	3.9%	2.8%	4.1%	3.3%	3.5%	5.7%
-50.01 to -75%	1.6%	1.3%	1.8%	1.5%	1.5%	2.7%
Over -75%	1.0%	1.0%	1.3%	0.8%	1.0%	1.6%

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.
*Totals do not add up to 100% due to rounding.

APPENDIX ~ B

Table B-1: Quarterly Percent Changes in AMPs for Single-Source NDCs

Range of Fluctuation	2nd Qtr 2005 to 3rd Qtr 2005	3rd Qtr 2005 to 4th Qtr 2005	4th Qtr 2005 to 1st Qtr 2006	1st Qtr 2006 to 2nd Qtr 2006	Average Change Between Quarters
Over 75%	0.4%	0.7%	0.6%	0.5%	0.5%
50.01 to 75%	0.2%	0.6%	0.2%	0.3%	0.3%
25.01 to 50%	0.8%	0.6%	0.5%	0.7%	0.7%
10.01 to 25%	3.3%	3.4%	3.5%	3.6%	3.4%
2.01 to 10%	21.3%	17.3%	34.9%	26.0%	24.9%
0.01 to 2 %	26.7%	24.9%	16.2%	24.8%	23.1%
No Change	21.5%	23.4%	22.2%	22.6%	22.4%
-0.01 to -2%	15.7%	19.9%	13.6%	15.4%	16.1%
-2.01 to -10%	7.0%	7.7%	5.7%	4.3%	6.1%
-10.01 to -25%	2.0%	1.1%	1.7%	1.2%	1.5%
-25.01 to -50%	0.9%	0.3%	0.5%	0.6%	0.6%
-50.01 to -75%	0.1%	0.1%	0.2%	0.1%	0.2%
Over -75%	0.2%	0.1%	0.1%	0.1%	0.1%

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.
*Totals do not add up to 100% due to rounding.

Table B-2: Quarterly Percent Changes in AMPs for Innovator Multiple-Source NDCs

Range of Fluctuation	2nd Qtr 2005 to 3rd Qtr 2005	3rd Qtr 2005 to 4th Qtr 2005	4th Qtr 2005 to 1st Qtr 2006	1st Qtr 2006 to 2nd Qtr 2006	Average Change Between Quarters
Over 75%	1.5%	2.1%	0.8%	1.5%	1.5%
50.01 to 75%	0.5%	1.1%	0.8%	0.9%	0.8%
25.01 to 50%	1.6%	2.2%	1.9%	2.4%	2.0%
10.01 to 25%	4.0%	4.9%	4.7%	4.3%	4.5%
2.01 to 10%	19.2%	13.1%	21.9%	19.6%	18.4%
0.01 to 2 %	15.3%	11.7%	10.3%	16.0%	13.3%
No Change	31.0%	33.5%	35.1%	31.9%	32.9%
-0.01 to -2%	9.8%	15.8%	10.4%	8.4%	11.1%
-2.01 to -10%	7.8%	9.0%	6.0%	8.6%	7.9%
-10.01 to -25%	5.1%	3.9%	3.9%	2.9%	3.9%
-25.01 to -50%	2.6%	1.9%	2.6%	2.0%	2.3%
-50.01 to -75%	0.7%	0.4%	0.9%	0.9%	0.8%
Over -75%	0.9%	0.4%	0.7%	0.4%	0.6%

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.
*Totals do not add up to 100% due to rounding.

Table B-3: Quarterly Percent Changes in AMPs for Noninnovator Multiple-Source NDCs

Range of Fluctuation	2nd Qtr 2005 to 3rd Qtr 2005	3rd Qtr 2005 to 4th Qtr 2005	4th Qtr 2005 to 1st Qtr 2006	1st Qtr 2006 to 2nd Qtr 2006	Average Change Between Quarters
Over 75%	2.5%	3.49%	2.8%	3.9%	3.2%
50.01 to 75%	1.0%	2.2%	1.0%	1.3%	1.4%
25.01 to 50%	3.0%	3.3%	2.4%	4.0%	3.2%
10.01 to 25%	5.8%	5.8%	5.1%	7.1%	6.0%
2.01 to 10%	10.3%	9.9%	8.3%	11.5%	10.0%
0.01 to 2 %	6.7%	6.2%	5.7%	6.6%	6.3%
No Change	40.4%	43.2%	45.3%	39.6%	42.1%
-0.01 to -2%	6.1%	6.0%	5.2%	5.8%	5.8%
-2.01 to -10%	9.8%	8.5%	8.5%	8.3%	8.8%
-10.01 to -25%	7.2%	5.4%	7.4%	5.5%	6.4%
-25.01 to -50%	4.4%	3.3%	4.7%	3.8%	4.0%
-50.01 to -75%	1.9%	1.5%	2.1%	1.7%	1.8%
Over -75%	1.1%	1.2%	1.5%	0.9%	1.2%

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.
*Totals do not add up to 100% due to rounding.

APPENDIX ~ C

Table C-1: Quarterly Percent Changes in AMPs for Top 50 Single-Source NDCs

Range of Fluctuation	2nd Qtr 2005 to 3rd Qtr 2005	3rd Qtr 2005 to 4th Qtr 2005	4th Qtr 2005 to 1st Qtr 2006	1st Qtr 2006 to 2nd Qtr 2006*	Average Change Between Quarters
Over 75%	-	-	-	-	-
50.01 to 75%	-	-	-	-	-
25.01 to 50%	-	-	-	-	-
10.01 to 25%	-	-	2.0%	-	0.5%
2.01 to 10%	40.0%	22.0%	54.0%	44.9%	40.2%
0.01 to 2 %	44.0%	32.0%	34.0%	42.9%	38.2%
No Change	-	4.0%	4.0%	2.0%	2.5%
-0.01 to -2%	8.0%	40.0%	6.0%	10.2%	16.1%
-2.01 to -10%	8.0%	2.0%	-	-	2.5%
-10.01 to -25%	-	-	-	-	-
-25.01 to -50%	-	-	-	-	-
-50.01 to -75%	-	-	-	-	-
Over -75%	-	-	-	-	-

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.
*There were 49 single-source NDCs between the first and second quarters of 2006.
*Totals do not add up to 100% due to rounding.

Table C-2: Quarterly Percent Changes in AMPs for Top 50 Innovator Multiple-Source NDCs

Range of Fluctuation	2nd Qtr 2005 to 3rd Qtr 2005*	3rd Qtr 2005 to 4th Qtr 2005	4th Qtr 2005 to 1st Qtr 2006	1st Qtr 2006 to 2nd Qtr 2006	Average Change Between Quarters
Over 75%	-	4.0%	-	10.0%	3.5%
50.01 to 75%	-	2.0%	4.0%	2.0%	2.0%
25.01 to 50%	2.0%	6.0%	2.0%	4.0%	3.5%
10.01 to 25%	4.1%	4.0%	6.0%	4.0%	4.5%
2.01 to 10%	24.5%	18.0%	42.0%	16.0%	25.1%
0.01 to 2 %	30.6%	26.0%	18.0%	36.0%	27.7%
No Change	6.1%	4.0%	4.0%	2.0%	4.0%
-0.01 to -2%	8.2%	28.0%	4.0%	12.0%	13.0%
-2.01 to -10%	14.3%	4.0%	-	6.0%	6.1%
-10.01 to -25%	2.0%	-	8.0%	2.0%	3.0%
-25.01 to -50%	4.1%	-	2.0%	2.0%	2.0%
-50.01 to -75%	-	4.0%	2.0%	2.0%	2.0%
Over -75%	4.1%	-	8.0%	2.0%	3.5%

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.
*There were 49 innovator multiple-source NDCs between the second and third quarters of 2005.
*Totals do not add up to 100% due to rounding.

Table C-3: Quarterly Percent Changes in AMPs for Top 50 Noninnovator Multiple-Source NDCs

Range of Fluctuation	2nd Qtr 2005 to 3rd Qtr 2005*	3rd Qtr 2005 to 4th Qtr 2005	4th Qtr 2005 to 1st Qtr 2006	1st Qtr 2006 to 2nd Qtr 2006	Average Change Between Quarters
Over 75%	6.1%	2.0%	8.0%	6.0%	5.5%
50.01 to 75%	2.0%	2.0%	4.0%	2.0%	2.5%
25.01 to 50%	4.1%	-	6.0%	12.0%	5.5%
10.01 to 25%	6.1%	6.0%	8.0%	12.0%	8.0%
2.01 to 10%	8.2%	22.0%	16.0%	16.0%	15.5%
0.01 to 2 %	10.2%	4.0%	2.0%	2.0%	4.6%
No Change	-	6.0%	2.0%	10.0%	4.5%
-0.01 to -2%	12.2%	8.0%	10.0%	14.0%	11.1%
-2.01 to -10%	16.3%	16.0%	10.0%	2.0%	11.1%
-10.01 to -25%	14.3%	12.0%	16.0%	12.0%	13.6%
-25.01 to -50%	18.4%	8.0%	8.0%	8.0%	10.6%
-50.01 to -75%	2.0%	10.0%	8.0%	-	5.0%
Over -75%	-	4.0%	2.0%	4.0%	2.5%

Source: OIG analysis of second-quarter 2005 through second-quarter 2006 AMP data, October 2006.
*There were 49 noninnovator multiple-source drugs between the second and third quarters of 2005.
*Totals do not add up to 100% due to rounding.

APPENDIX ~ D

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR 26 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: Office of Inspector General's (OIG) Draft Report: "Examining Fluctuations in Average Manufacturer Prices," (OEI-03-06-00350).

Thank you for the opportunity to review and comment on the above mentioned OIG draft report. The report addresses the extent to which average manufacturer prices (AMPs) fluctuated over a 4-quarter period, from the second quarter of 2005 to the second quarter of 2006. The passage of the Deficit Reduction Act of 2005 (DRA) affected payments for Medicaid prescription drugs. Prior to the passage of the DRA, section 1927(b)(3)(D) of the Social Security Act prohibited the disclosure of AMPs, except in certain narrow circumstances. However, pursuant to section 6001(b) of the DRA, AMPs were made available to State Medicaid programs beginning in July 2006. Effective with AMPs for January 1, 2007, and thereafter, States will have the benefit of using AMPs to evaluate/establish their estimated acquisition cost for drug reimbursement. Also, pursuant to section 6001(a) of the DRA, Federal upper limit (FUL) amounts for certain multiple-source drugs are to be based on 250 percent of the lowest reported AMP for each drug in a FUL group (computed without regard to customary prompt pay extended to wholesalers). This will replace the current methodology of 150 percent of the published price for the least costly therapeutically equivalent drug. These changes represent congressional effort to provide transparency in drug pricing, and reduce prescription drug spending in the Medicaid program.

The OIG found that 39 percent of the AMPs stayed the same between the quarters in review. An additional 16 percent of AMPs changed by less than 2 percent. Further, 24 percent of AMPs fluctuated by more than 10 percent from quarter to quarter. Of this number, half increased and half decreased. The study also evaluated AMP changes related to single-source, innovator multiple-source and noninnovator multiple-source national drug codes. The AMPs for single-source drugs changed more frequently than AMPs for other drug types (78 percent), but the majority fluctuated by 2 percent or less. Also, AMPs for high-expenditure drugs changed more frequently, with single-source high-expenditure drugs being especially prone to price increases of up to 10 percent per quarter. The OIG report notes that once AMP data are reported on a monthly basis, they expect the size and number of fluctuations between reporting periods to be reduced.

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The Centers for Medicare & Medicaid Services (CMS) appreciate the OIG's findings. However, the findings use AMPs prior to January 2007, when the definition changed to exclude customary prompt pay discounts and to include sales of authorized generics. The AMP may, in fact, change as a result of final rulemaking. Therefore, the findings of your report may not be comparable to actual experience when the final AMP definition is issued. Additionally, the availability of AMP to States to use for setting reimbursement will be a great improvement over the current situation, in which States set drug reimbursement based on price data from commercial compendia, which have little relationship to market prices. When AMP changes occur, they reflect market price changes. Also, States will need to examine AMPs closely and consider applying adjustment factors when using AMPs to set payment methodologies. CMS believes this report shows AMPs can be used appropriately to establish Medicaid payments to pharmacies. While there may be as much as a 2-month time lag in reported AMPs, the OIG finding indicates that the variations occur equally in both directions, which means that the time lag will result in shortfalls in payments for some drugs that will be balanced by excessive payments for other drugs.

We also note that AMPs of more than half of the noninnovator multiple-source drugs varied by 10 percent or more. While this is a high percentage change, these drugs are usually priced far lower than the other categories of drugs, making the absolute change modest. CMS suggests that the OIG consider adding an analysis of absolute price changes to future work in this area. Again, we appreciate the effort that went into this report and look forward to working with the OIG on this and other pertinent issues.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office include Jessica Demko, Roman Strakovsky and Stephanie Yeager. Central office staff who contributed include Sarah Craren and Gina Maree.