DEC 23 2008

TO: Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Daniel R. Levinson /S/
Inspector General

SUBJECT: Memorandum Report: "Comparison of First-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2008," OEI-03-08-00530

This congressionally mandated review compares average sales prices (ASP) to average manufacturer prices (AMP) for Medicare Part B prescription drugs and identifies drugs with ASPs that exceeded AMPs by at least 5 percent during the first quarter of 2008. It also determines the impact of lowering reimbursement amounts for drugs that meet the 5-percent threshold.

Since the advent of the ASP reimbursement methodology in 2005, the Office of Inspector General (OIG) has issued eight reports comparing ASPs to AMPs. Unlike those previous reports, this current pricing comparison examined drugs that met the 5-percent threshold based on either complete or partial AMP data.[1] Of the 312 drugs with complete AMP data in the first quarter of 2008, 16 met the 5-percent threshold under the revised ASP payment methodology recently mandated by statute. Eight of these 16 drugs were previously eligible for price adjustment under the revised payment methodology, with 3 drugs meeting the 5-percent threshold in each of the past five quarters. If reimbursement amounts for all 16 drugs had been based on 103 percent of the AMPs, we estimate that Medicare expenditures would have been reduced by $5.1 million during the third quarter of 2008 alone. Of the 129 drugs with only partial AMP data, 25 had ASPs that exceeded the AMPs by at least 5 percent in the first quarter of 2008. We estimate that Medicare expenditures would have been reduced by $2.6 million during the third quarter of 2008 if reimbursement amounts for these 25 drugs had been based on 103 percent of the AMPs. We could not perform pricing comparisons for an additional 76 drugs because none of the drug products used to establish Medicare reimbursement had corresponding AMP data. Manufacturers for more

[1] In previous reports, OIG performed pricing comparisons only for those drugs with AMP data for every drug product used by the Centers for Medicare & Medicaid Services (CMS) to calculate Medicare reimbursement amounts. To ensure that a broader range of drugs is subject to OIG's pricing comparisons, this report additionally examined drugs with only partial AMP data (i.e., drugs with AMP data for some, but not all, of the products used to establish Medicare reimbursement).

than one-fifth of these products had a Medicaid drug rebate agreement and were therefore generally required to submit AMPs. OIG is working with CMS to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data.

BACKGROUND

Section 1847A(d)(2)(B) of the Social Security Act (the Act) mandates that OIG compare ASPs to AMPs. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), section 1847A(d)(3)(A) of the Act states that the Secretary of the Department of Health and Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement amounts. Section 1847A(d)(3)(C) of the Act goes on to state that ". . . the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment . . . the lesser of (i) the widely available market price . . . (if any); or (ii) 103 percent of the average manufacturer price . . . ."

Medicare Part B Coverage of Prescription Drugs

Medicare Part B covers only a limited number of outpatient prescription drugs. Covered drugs include injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

Medicare Part B Payments for Prescription Drugs

CMS contracts with private companies, known as Medicare Administrative Contractors (MAC), to process and pay Medicare Part B claims, including those for prescription drugs. To obtain reimbursement for covered outpatient prescription drugs, physicians and suppliers submit claims to their MACs using procedure codes. CMS established the Healthcare Common Procedure Coding System (HCPCS) to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. In the case of prescription drugs, each HCPCS code defines the drug name and dosage size but does not specify manufacturer or package size information.

Medicare and its beneficiaries spent approximately $11 billion for Part B drugs in 2007.[2] Although Medicare paid for more than 675 outpatient prescription drug HCPCS codes that year, the majority of spending for Part B drugs was concentrated on a relatively small subset of those codes. In 2007, 52 codes accounted for 90 percent of the expenditures for Part B drugs, with only 11 of these drugs representing half of the total Part B drug expenditures.

[2] Medicare expenditures for Part B drugs were calculated using 2007 data in CMS's Part B Extract and Summary System (BESS), which were 98 percent complete at the time of extraction.

Reimbursement Methodology for Part B Drugs and Biologicals

Since January 2005, Medicare Part B has been paying for most covered drugs using a reimbursement methodology based on ASPs.[3] Section 1847A(c) of the Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, defines an ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program.[4] Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.[5] [6]

Manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer, product dosage form, and package size of the drug. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of each quarter.[7]

Because Medicare Part B reimbursement for outpatient drugs is based on HCPCS codes rather than NDCs and more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk file to calculate volume-weighted ASPs for covered HCPCS codes.

Calculation of Volume-Weighted Average Sales Prices

To calculate volume-weighted ASPs, CMS uses an equation that involves the following variables: the ASP for the 11-digit NDC as reported by the manufacturer, the volume of sales for the NDC as reported by the manufacturer, and the number of billing units in the NDC as determined by CMS. The amount of the drug contained in an NDC may differ from the amount of the drug specified by the HCPCS code that providers use to bill Medicare. Therefore, the number of billing units in an NDC describes the number of HCPCS code units that are in that NDC. For instance, an NDC may contain a total of 10 milliliters of Drug A, but the corresponding HCPCS code may be defined as only 5 milliliters of Drug A. In this case, there are two billing units in the NDC. CMS calculates the number of billing units in each NDC when developing its crosswalk files.

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[3] In 2004, the reimbursement amount for most covered drugs was based on 85 percent of the average wholesale price as published in national pricing compendia, such as the "Red Book." Before 2004, Medicare Part B reimbursed for covered drugs based on the lower of either the billed amount or 95 percent of the average wholesale price.

[4] Section 1847A(c)(3) of the Act.

[5] Pursuant to section 1927(c)(1)(C)(i) of the Act, "best price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.

[6] Section 1847A(c)(2) of the Act.

[7] Section 1927(b)(3) of the Act.

Before April 2008, CMS calculated volume-weighted ASPs using the equation presented in Appendix A. However, section 112(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007, P.L. No. 110-173, changed section 1847A(b) of the Act to require that CMS compute volume-weighted ASPs using a revised methodology, effective April 2008. This revised methodology was initially proposed by OIG in a February 2006 report entitled "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310). The revised equation for calculating volume-weighted ASPs is also provided in Appendix A.

Third-quarter 2008 Medicare allowances for most covered drug codes were based on first-quarter 2008 ASP submissions from manufacturers, which were volume-weighted using the revised methodology. Under the ASP pricing methodology, the Medicare allowance for most Part B drugs is equal to 106 percent of the volume-weighted ASP for the HCPCS code. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

The Medicaid Drug Rebate Program and Average Manufacturer Prices

For Federal payment to be available for covered outpatient drugs provided under Medicaid, sections 1927(a)(1) and (b)(1) of the Act mandate that drug manufacturers enter into rebate agreements with 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 NDCs on a quarterly basis, with submissions due 30 days after the close of each quarter.[8]

As generally defined in section 1927(k)(1) of the Act, the AMP is 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. Before the passage of the DRA, manufacturers were required to deduct customary prompt pay discounts when calculating AMPs. However, section 6001(c)(1) of the DRA amended section 1927(k)(1) of the Act such that AMPs must be determined without regard to customary prompt pay discounts, effective January 2007. In December 2006, CMS instructed manufacturers to exclude customary prompt pay discounts from their AMP calculations as of January 2007.[9] In July 2007, CMS published a final rule at 72 Fed. Reg. 39142 (July 17, 2007) that, among other things, implements section 6001(c)(1) of the DRA and clarifies the way in which the AMP must be calculated. Specifically, 42 CFR § 447.504 of the final regulation clarifies the manner in which the AMP is to be determined.[10]

[8] Section 6001(b)(1)(A) of the Deficit Reduction Act of 2005 (DRA), P.L. No. 109-171, changed section 1927(b) of the Act to require that manufacturers also report AMPs on a monthly basis, effective January 2007. Drug manufacturers will continue to report quarterly AMP data in addition to their monthly submissions.

[9] CMS, Medicaid Drug Rebate Program, "Bulletin for Participating Drug Manufacturers," Release No. 76, December 15, 2006.

[10] In December 2007, the United States District Court for the District of Columbia preliminarily enjoined the implementation of the regulation for certain purposes not relevant to this report. Section 203 of the Medicare Improvements for Patients and Providers Act of 2008 also delayed the implementation of certain aspects of the regulation and the DRA requirements. Again, those aspects are not relevant for the purposes of this report.

The AMP is generally calculated as a weighted average of prices for all of a manufacturer's package sizes of a drug sold during a given quarter and is reported for the lowest identifiable quantity of the drug (e.g., 1 milliliter, 1 tablet, 1 capsule).

If a manufacturer fails to provide AMP data in a timely manner, civil monetary penalties may be imposed.[11] In addition, pursuant to section 1927(b)(4)(B) of the Act, the Secretary may terminate a rebate agreement "for violation of the requirements of the agreement or other good cause shown." CMS has terminated a number of manufacturers for failure to report drug pricing data as required by section 1927 of the Act. CMS has also provided OIG with information about manufacturers that failed to submit drug-pricing data for the purposes of evaluating potential civil monetary penalty actions.

Office of Inspector General's Monitoring of Average Sales Prices and Average Manufacturer Prices

Since the ASP reimbursement methodology for Part B prescription drugs was implemented in January 2005, OIG has issued seven quarterly reports comparing ASPs and AMPs. In addition, OIG recently completed an annual overview of ASPs and AMPs, which examined data across all four quarters of 2007 using the revised ASP payment methodology recently implemented by CMS. A list of all eight reports is provided in Appendix B.

Although CMS has acknowledged the Secretary's authority to adjust ASP payment limits based on the findings of OIG's pricing comparisons, CMS has yet to make any changes to Part B drug reimbursement as a result of these studies. Rather, CMS has emphasized both the complexity of substituting payment amounts and the importance of proceeding cautiously to avoid unintended consequences.[12] In commenting on OIG's reports, CMS has expressed a desire to both better understand fluctuating differences between ASPs and AMPs and engage stakeholders, with the intent of developing a process for making price substitutions.[13] However, CMS has not specified what, if any, steps it will take to adjust Medicare reimbursement amounts for drugs that meet the 5-percent threshold specified in section 1847A(d)(3) of the Act.

OIG will continue to meet its congressional mandate by issuing reports based on quarterly pricing comparisons, along with annual overviews to summarize findings across each calendar year.

METHODOLOGY

We obtained from CMS NDC-level ASP data from the first quarter of 2008, which were used to establish Part B drug reimbursement amounts for the third quarter of 2008. In addition, we obtained the file that CMS used to crosswalk NDCs to their corresponding HCPCS codes.

[11] Pursuant to section 1927(b)(3)(C) of the Act.
[12] OEI-03-08-00450, December 2008.
[13] OEI-03-07-00140, July 2007 and OEI-03-08-00450, December 2008.

Both the ASP data and the crosswalk file were current as of June 10, 2008. We also obtained AMP data from CMS for the first quarter of 2008, which were current as of May 13, 2008.

Analysis of Average Sales Price Data From the First Quarter of 2008
As mentioned previously, Medicare does not base reimbursement for covered drugs on NDCs; instead, it uses HCPCS codes. Therefore, CMS uses ASP information submitted by manufacturers for each NDC to calculate a volume-weighted ASP for each covered HCPCS code. When calculating these volume-weighted ASPs, CMS includes only NDCs with ASP submissions that are deemed valid. We did not examine NDCs that CMS opted to exclude from its calculation, nor did we verify the accuracy of CMS's crosswalk files.

As of June 2008, CMS had established prices for 527 HCPCS codes based on the revised ASP reimbursement methodology mandated by section 112(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007.[14] Reimbursement amounts for the 527 HCPCS codes were based on ASP data for 3,384 NDCs.

Analysis of Average Manufacturer Price Data From the First Quarter of 2008
In previous quarters, OIG performed pricing comparisons for only those drug codes with AMP data for every drug product used by CMS to calculate the Medicare reimbursement amount. As a result of that conservative approach, at least 17 percent of HCPCS codes were excluded from our analysis in any given quarter. To ensure that a broader range of drug codes is subject to OIG's pricing comparisons, this report additionally examined drug codes with only partial AMP data (i.e., drug codes with AMP data for some, but not all, of the products used to establish Medicare reimbursement). For the purposes of this report, we divided HCPCS codes into the following three groups:

(1) HCPCS codes with AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs,

(2) HCPCS codes with AMP data for only some of the NDCs that CMS used in its calculation of volume-weighted ASPs, and

(3) HCPCS codes with no AMP data for any of the NDCs that CMS used in its calculation of volume-weighted ASPs.

As previously noted, the AMP for each NDC is reported for the lowest identifiable quantity of the drug contained in that NDC (e.g., 1 milliliter, 1 tablet, 1 capsule). In contrast, the ASP is reported for the entire amount of the drug contained in the NDC (e.g., for 50 milliliters, for 100 tablets). To ensure that the AMP would be comparable to the ASP, it was necessary to convert the AMP for each NDC so that the AMP represented the total amount of the drug contained in that NDC.

[14] Several Part B drugs, including certain vaccines and blood products, are not paid under the ASP methodology.

To calculate "converted AMPs" for NDCs in the first and second groups, we multiplied the AMP by the total amount of the drug contained in each NDC, as identified by sources such as the CMS crosswalk file, manufacturer Web sites, the "Red Book," and the Food and Drug Administration's NDC directory. For certain NDCs, we were unable to successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP.

Using NDCs with successful AMP conversions, we then calculated a volume-weighted AMP for each of the corresponding HCPCS codes, consistent with the revised methodology for calculating volume-weighted ASPs. Appendix C provides a more detailed description of the methods we used both to convert AMPs and calculate volume-weighted AMPs. Table 1 provides the final number of HCPCS codes and NDCs included in our analysis after we removed NDCs with either no AMP data or unsuccessful AMP conversions.

Table 1: Number of Drug Codes and NDCs Included in OIG's Pricing Comparison

Availability of AMP Data for HCPCS Code	Number of HCPCS Codes	Number of NDCs
Complete AMP Data	312	1,283
Partial AMP Data	129	1,129
No AMP Data	76	436

Source: OIG analysis of first-quarter 2008 ASP and AMP data, 2008.

Comparing Volume-Weighted ASPs to Volume-Weighted AMPs for the First Quarter of 2008 Using the Revised ASP Payment Methodology

For each of the HCPCS codes included in our study, we compared the volume-weighted ASPs and AMPs and identified codes with an ASP that exceeded the AMP by at least 5 percent.

For those HCPCS codes that met or exceeded the 5-percent threshold, we reviewed the associated NDCs to verify the accuracy of the billing unit information. According to our review, NDCs for eight codes had billing unit information in CMS's crosswalk file that may not have accurately reflected the number of billing units actually contained in the NDC. Because volume-weighted ASPs and AMPs are calculated using this billing unit information, we could not be certain that the results for these codes were correct. Therefore, we did not consider these eight HCPCS codes as having met the 5-percent threshold.

For the remaining HCPCS codes, we then estimated the monetary impact of lowering reimbursement to 103 percent of the AMP.[15] For each of the HCPCS codes that met the

[15] Section 1847A(d)(3)(C) of the Act directs the Secretary to replace payment amounts for drugs that meet the 5-percent threshold with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP. For the purposes of this study, we used 103 percent of the AMP to estimate the impact of lowering reimbursement amounts. If widely available market prices had been available for these drugs and lower than 103 percent of the AMP, the savings estimate presented in this report would have been greater.

5-percent threshold, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the third-quarter 2008 reimbursement amount for the HCPCS code, which is equal to 106 percent of the volume-weighted ASP. To estimate the financial effect for the third quarter of 2008, we then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2007, as reported in BESS.[16] This estimate assumes that the number of services that were allowed by Medicare in 2007 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2007 and 2008.

Identifying Codes That Would Also Have Met the 5-Percent Threshold in 2007 if the Revised ASP Payment Methodology Had Been In Effect

CMS was not required to implement the revised ASP payment methodology until the fourth quarter of 2007.[17] However, to establish a more useful and consistent benchmark for comparisons of ASPs and AMPs over time, OIG recently completed a report examining ASPs and AMPs for all four quarters of 2007 using the revised methodology (i.e., we recalculated volume-weighted ASPs and AMPs using the revised methodology for the first three quarters of 2007).[18] In this current report, we used these recalculated ASPs and AMPs to determine whether codes meeting the 5-percent threshold in the first quarter of 2008 would have also met the 5-percent threshold in any quarter of 2007 if the revised ASP payment had been in effect throughout the year. We performed this analysis only on codes with complete AMP data, as codes with partial data had not been included in our prior pricing comparisons.

Limitations

We did not verify the accuracy of manufacturer-reported ASP and AMP data, nor did we verify the underlying methodology used by manufacturers to calculate ASPs and AMPs.

Manufacturers are required to submit their quarterly ASP and AMP data to CMS 30 days after the close of the quarter. Our analyses were performed on ASP and AMP data compiled by CMS soon after that deadline. We did not verify whether manufacturers later provided revised or missing data to CMS.

Furthermore, the definition of AMP changed effective January 2007, such that AMPs must now be determined without regard to customary prompt pay discounts.[19] Because manufacturers are still required to include customary prompt pay discounts in their ASP

[16] At the time of extraction, 2007 BESS data were 98 percent complete.

[17] There is a two-quarter lag between the sales period for which ASPs are reported and the effective date of reimbursement amounts based on those ASPs. Therefore, the methodological changes that went into effect in April 2008 were applied by CMS to ASP data from two quarters prior (i.e., the fourth quarter of 2007).

[18] "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007" (OEI-03-08-00450). The 2007 overview report used only the revised ASP payment methodology; therefore, the results presented in that report may differ from the results presented in each of the separate quarterly reports previously published by OIG.

[19] Section 1927(k)(1) of the Act (as amended by section 6001(c)(1) of the DRA) and CMS, Medicaid Drug Rebate Program, "Bulletin for Participating Drug Manufacturers," Release No. 76, December 15, 2006.

calculations, the dynamic between ASPs and AMPs may be different in this report as compared to that in OIG reports using prices submitted before 2007.

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

RESULTS

Of the 312 Drug Codes With Complete AMP Data, Volume-Weighted ASPs for 16 Exceeded the Volume-Weighted AMPs by at Least 5 Percent

Consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs to AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by a threshold of 5 percent. Under the revised ASP payment methodology recently mandated by statute, 16 of the 312 HCPCS codes with complete AMP data (5 percent) met this 5-percent threshold in the first quarter of 2008. A list of the 16 HCPCS codes, including their descriptions and HCPCS dosage amounts, is presented in Appendix D.

Table 2 describes the extent to which ASPs exceeded AMPs for the 16 HCPCS codes.[20] For over 60 percent of the codes (10 of 16), volume-weighted ASPs exceeded volume-weighted AMPs by 20 percent or more. The ASPs for two of these codes were more than double the AMPs.

Table 2: Extent to Which ASPs Exceeded AMPs for 16 HCPCS Codes With Complete AMP Data

Percentage by Which ASP Exceeded AMP	Number of HCPCS Codes
5.00%–9.99%	3
10.00%–19.99%	3
20.00%–29.99%	3
30.00%–39.99%	3
40.00%–49.99%	0
50.00%–59.99%	0
60.00%–69.99%	2
70.00%–79.99%	0
80.00%–89.99%	0
90.00%–99.99%	0
100% and above	2
Total	**16**

Source: OIG analysis of first-quarter 2008 ASP and AMP data, 2008.

[20] Because of the confidential nature of ASP data, the information in the table is presented in ranges.

Half of the 16 HCPCS codes were previously identified by OIG as having ASPs that exceeded the AMPs by at least 5 percent.[21] Under the revised ASP payment methodology, three HCPCS codes (J1364, J2690, and Q0169) would have met the 5-percent threshold in each of the past five quarters, dating back to the first quarter of 2007. An additional three HCPCS codes would have met the 5-percent threshold in three of the past five quarters if the revised methodology had been used since the beginning of 2007. Table 3 presents a breakdown of the eight HCPCS codes that previously met the threshold for price adjustments.

Table 3: Eight HCPCS Codes That Met the 5-Percent Threshold in the First Quarter of 2008 and Previous Quarters (According to CMS's Revised Payment Methodology)

HCPCS Code	OIG Comparisons of ASPs to AMPs				
	First Quarter 2008	Fourth Quarter 2007	Third Quarter 2007	Second Quarter 2007	First Quarter 2007
J1364	X	X	X	X	X
J2690	X	X	X	X	X
Q0169	X	X	X	X	X
J2760	X	X		X	
J3315	X	X			X
J1457	X			X	X
J0300	X	X			
J2700	X		X		

Source: OIG analysis of ASP and AMP data from the first quarter of 2008 and all four quarters of 2007.

Lowering reimbursement amounts for the 16 HCPCS codes to 103 percent of the AMPs would have reduced Medicare allowances by an estimated $5.1 million in the third quarter of 2008. Sections 1847A(d)(3)(A) and (B) of the Act provide that the Secretary may disregard the ASP pricing methodology for a drug with an ASP that exceeds the AMP by at least 5 percent. Pursuant to section 1847A(d)(3)(C) of the Act, ". . . the Secretary shall, effective as of the next quarter, substitute for the amount of payment . . . the lesser of (i) the widely available market price . . . (if any); or (ii) 103 percent of the average manufacturer price . . . ."[22] In this study, we identified 16 HCPCS codes that met the 5-percent threshold specified in the Act. If reimbursement amounts for these 16 codes had been based on 103 percent of the AMPs during the third quarter of 2008, we estimate that Medicare expenditures would have been reduced by $5.1 million in that quarter alone.[23]

[21] We compared results from this report to those in a recent OIG report (OEI-03-08-00450) that examined ASPs and AMPs for all four quarters of 2007 using the revised methodology.

[22] For the purposes of this study, we used 103 percent of the AMP to estimate the impact of lowering reimbursement amounts. If widely available market prices had been available for these drugs and lower than 103 percent of the AMP, the savings estimates presented in this report would have been greater.

[23] This savings estimate assumes that the number of services that were allowed by Medicare in 2007 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2007 and 2008.

Two of the 16 HCPCS codes accounted for 90 percent of the $5.1 million. If the reimbursement amounts for codes J9202 and J3315 had been based on 103 percent of the AMP during the third quarter of 2008, Medicare expenditures would have been reduced by an estimated $3.3 million and $1.3 million, respectively.

Of the 129 Drug Codes With Partial AMP Data, Volume-Weighted ASPs for 25 Exceeded the Volume-Weighted AMPs by at Least 5 Percent

In previous quarters, OIG has examined only those HCPCS codes with AMP data for every NDC that was used to establish the Medicare reimbursement amount. To ensure that a broader range of drugs was included in OIG's pricing comparisons for this quarter, we also examined 129 HCPCS codes for which only partial AMP data were available. Under the revised payment methodology, ASPs for 25 of these 129 HCPCS codes (19 percent) exceeded the AMPs by at least 5 percent in the first quarter of 2008. A list of the 25 HCPCS codes, including their descriptions and HCPCS dosage amounts, is presented in Appendix E.

Table 4 describes the extent to which ASPs exceeded AMPs for the 25 HCPCS codes.[24] For 28 percent of the codes (7 of 25), volume-weighted ASPs exceeded volume-weighted AMPs by 20 percent or more. The ASP for one of these codes was more than double the AMP.

Table 4: Extent to Which ASPs Exceeded AMPs for 25 HCPCS Codes With Partial AMP Data

Percentage by Which ASP Exceeded AMP	Number of HCPCS Codes
5.00%–9.99%	5
10.00%–19.99%	13
20.00%–29.99%	1
30.00%–39.99%	1
40.00%–49.99%	1
50.00%–59.99%	0
60.00%–69.99%	1
70.00%–79.99%	1
80.00%–89.99%	1
90.00%–99.99%	0
100% and above	1
Total	**25**

Source: OIG analysis of first-quarter 2008 ASP and AMP data, 2008.

[24] The information in the table is presented in ranges because of the confidential nature of ASP data.

Lowering reimbursement amounts for the 25 HCPCS codes to 103 percent of the AMPs would have reduced Medicare allowances by an estimated $2.6 million in the third quarter of 2008.[25] [26] Two of the 25 HCPCS codes accounted for almost 75 percent of the $2.6 million. If the reimbursement amounts for codes J1626 and J2430 had been based on 103 percent of the AMP during the third quarter of 2008, Medicare expenditures would have been reduced by an estimated $1.2 million and $811,000, respectively.

Pricing Comparisons Could Not Be Performed on 76 Drug Codes Because No AMP Data Were Available

For 76 HCPCS codes, OIG could not compare ASPs and AMPs because there were no AMP data for any of the 436 NDCs that CMS used when calculating drug reimbursement amounts for these codes. In 2007, Medicare allowances for these 76 codes totaled $144 million.

More than one-fifth of NDCs without AMP data belonged to manufacturers with Medicaid drug rebate agreements.[27] Manufacturers for 23 percent of the NDCs without AMP data (99 of 436) participated in the Medicaid drug rebate program as of the first quarter of 2008 and were therefore required to submit AMP data.[28] [29] The majority (59 percent) of these 99 NDCs belonged to three manufacturers.

Manufacturers for the remaining 337 of 436 NDCs did not participate in the Medicaid drug rebate program and therefore were not required to submit AMP data.

CONCLUSION

To monitor Medicare reimbursement amounts based on ASPs and consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs and AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by at least 5 percent. This is OIG's ninth report comparing ASPs and AMPs. Unlike OIG's previous pricing comparisons, this report considers HCPCS codes with AMP data for every NDC that CMS used to establish reimbursement amounts, as well as HCPCS codes with only partial AMP data.

[25] For the purposes of this study, we used 103 percent of the AMP to estimate the impact of lowering reimbursement amounts. If widely available market prices had been available for these drugs and lower than 103 percent of the AMP, the savings estimates presented in this report would have been greater.

[26] This savings estimate assumes that the number of services that were allowed by Medicare in 2007 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2007 and 2008.

[27] To determine whether a manufacturer participated in the Medicaid drug rebate program in 2007, we consulted the list of participating drug companies posted on CMS's Web site.

[28] Although manufacturers with rebate agreements are generally required to submit AMP data, there may be valid reasons as to why an AMP was not provided for a specific NDC in a given quarter. For example, a manufacturer may not have been required to submit an AMP if the drug product had been terminated and there was no drug utilization during the quarter.

[29] These 99 NDCs were crosswalked to 41 HCPCS codes.

Using the revised ASP payment methodology recently implemented by CMS, we identified a total of 41 HCPCS codes in the first quarter of 2008 that met the threshold for price adjustment. Sixteen of the forty-one HCPCS codes had complete AMP data. Of these 16 codes, 8 were previously identified by OIG as having ASPs that exceeded the AMPs by at least 5 percent under the revised payment methodology. Three of the eight HCPCS codes (J1364, J2690, and Q0169) met the 5-percent threshold in each of the past five quarters, dating back to the first quarter of 2007. The remaining 25 of 41 HCPCS codes also met the 5-percent threshold in the first quarter of 2008 but did not have AMP data for every NDC that CMS used when calculating reimbursement. Finally, we could not compare ASPs and AMPs for 76 HCPCS codes because AMP data were not submitted for any of the NDCs that CMS used to calculate reimbursement. Manufacturers for more than one-fifth of these NDCs had a Medicaid drug rebate agreement and were therefore generally required to submit AMPs. OIG is working with CMS to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data.

Some of OIG's previous reports comparing ASPs and AMPs have contained recommendations. We are not making additional recommendations in this report and, as such, are issuing the report directly in final form. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-03-08-00530 in all correspondence.

APPENDIX A

Equations Used by the Centers for Medicare & Medicaid Services To Calculate Volume-Weighted Average Sales Prices

In the following equations, a "billing unit" is defined as the number of Healthcare Common Procedure Coding System (HCPCS) code units that are contained in a national drug code (NDC).

1. The Revised Equation Used by the Centers for Medicare & Medicaid Services (CMS) To Calculate Volume-Weighted Average Sales Prices (ASP) Beginning April 1, 2008

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of (ASP for NDC * Number of NDCs Sold)}}{\text{Sum of (Number of NDCs Sold * Billing Units in NDC)}}$$

2. The Equation Used by CMS To Calculate Volume-Weighted ASPs Before April 1, 2008

$$\text{Volume-Weighted ASP for the Billing Unit of HCPCS Code} = \frac{\text{Sum of } \left[\frac{\text{ASP for NDC}}{\text{Billing Units in NDC}} * \text{Number of NDCs Sold} \right]}{\text{Sum of Number of NDCs Sold}}$$

APPENDIX B

Previous Office of Inspector General Reports Comparing Average Sales Prices and Average Manufacturer Prices

- "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices" (OEI-03-04-00430), April 2006

- "Comparison of Fourth-Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2006" (OEI-03-06-00370), July 2006

- "Comparison of Third-Quarter 2006 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007" (OEI-03-07-00140), July 2007

- "Comparison of First-Quarter 2007 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2007" (OEI-03-07-00530), September 2007

- "Comparison of Second-Quarter 2007 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2007" (OEI-03-08-00010), December 2007

- "Comparison of Third-Quarter 2007 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2008" (OEI-03-08-00130), May 2008

- "Comparison of Fourth-Quarter 2007 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2008" (OEI-03-08-00340), August 2008

- "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007" (OEI-03-08-00450), December 2008

APPENDIX C

Detailed Methodology for Converting and Volume-Weighting Average Manufacturer Prices for the First Quarter of 2008

Healthcare Common Procedure Coding System codes with complete average manufacturer price data. Of the 527 Healthcare Common Procedure Coding System (HCPCS) codes with reimbursement amounts based on average sales prices (ASP), 320 had average manufacturer prices (AMP) for every national drug code (NDC) that the Centers for Medicare & Medicaid Services (CMS) used to calculate volume-weighted ASPs. These 320 HCPCS codes represented 1,358 NDCs. For 12 NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These 12 NDCs were crosswalked to 8 HCPCS codes. We did not include these 8 HCPCS codes (75 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,283 NDCs, we then calculated a volume-weighted AMP for each of the remaining 312 HCPCS codes consistent with the revised methodology for calculating volume-weighted ASPs.

HCPCS codes with partial AMP data. There were 131 HCPCS codes with AMP data for only some of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 131 HCPCS codes represented a total of 1,590 NDCs. AMP data were either missing or unavailable for 420 of these NDCs, which we then excluded from our calculation of volume-weighted AMPs.[30]

We calculated converted AMPs for each of the remaining 1,170 NDCs. For 41 of the 1,170 NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. We removed these 41 NDCs from our analysis.[31] As a result, two HCPCS codes no longer had any NDCs with AMP data. Therefore, these two HCPCS codes were removed from our analysis.

Using the converted AMPs for the remaining 1,129 NDCs, we then calculated a volume-weighted AMP for each of the remaining 129 HCPCS codes consistent with the revised methodology for calculating volume-weighted ASPs.

[30] Although AMP data for these 420 NDCs were excluded from our calculation of volume-weighted AMPs, the corresponding ASPs were not excluded from the volume-weighted ASPs as determined by CMS. Volume-weighted ASPs remained the same, regardless of the availability of AMP data.

[31] Although we removed NDCs with problematic AMP conversions, we did not remove the corresponding HCPCS codes, provided that other NDCs for those drug codes had usable AMP data. This differs from our analysis of HCPCS codes with complete AMP data, in which we removed not only the NDCs with problematic AMP conversions, but also the corresponding HCPCS codes.

HCPCS codes with no AMP data. For 76 HCPCS codes, there were no AMP data for any of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 76 HCPCS codes represented 436 NDCs.

APPENDIX D

Sixteen Drug Codes With Complete Average Manufacturer Price Data That Met the 5-Percent Threshold in the First Quarter of 2008

Drug Code	Short Description	Drug Code Dosage
J0278	Amikacin sulfate injection	100 mg
J0300	Amobarbital injection	125 mg
J1020	Methylprednisolone injection	20 mg
J1364	Erythro lactobionate	500 mg
J1457	Gallium nitrate injection	1 mg
J1955	Levocarnitine injection	1 g
J2690	Procainamide HCl injection	1 g
J2700	Oxacillin sodium injection	250 mg
J2760	Phentolaine mesylate injection	5 mg
J2792	Rho(D) immune globulin	100 units
J3315	Triptorelin pamoate	3.75 mg
J7310	Ganciclovir long-acting implant	4.5 mg
J9202	Goserelin acetate implant	3.6 mg
J9320	Streptozocin injection	1 g
Q0166	Granisetron HCl oral	1 mg
Q0169	Promethazine HCl oral	12.5 mg

Source: Office of Inspector General analysis of first-quarter 2008 average sales price and average manufacturer price data, 2008.

APPENDIX E

Twenty-Five Drug Codes With Partial Average Manufacturer Price Data That Met the 5-Percent Threshold in the First Quarter of 2008

Drug Code	Short Description	Drug Code Dosage
J0170	Adrenalin epinephrin injection	1 mL
J0560	Penicillin G benzathine injection	600,000 units
J0610	Calcium gluconate injection	10 mL
J0670	Nepivacaine HCl injection	10 mL
J1190	Dexrazoxane HCl injection	250 mg
J1626	Granisetron HCl injection	100 mcg
J1631	Haloperidol decanoate injection	50 mg
J1940	Furosemide injection	20 mg
J2310	Naloxone HCl injection	1 mg
J2430	Pamidronate disodium	30 mg
J2680	Fluphenazine decanoate	25 mg
J2790	Rho(D) immune globulin injection	300 mcg
J3370	Vancomycin HCl injection	500 mg
J3410	Hydroxyzine HCl injection	25 mg
J3475	Magnesium sulfate injection	500 mg
J9000	Doxorubicin HCl	10 mg
J9027	Clofarabine injection	1 mg
J9060	Cisplatin injection	10 mg
J9062	Cisplatin injection	50 mg
J9181	Etoposide injection	10 mg
J9182	Etoposide injection	100 mg
J9250	Methotrexate sodium injection	5 mg
J9260	Methotrexate sodium injection	50 mg
J9293	Mitoxantrone HCl	5 mg
Q0164	Prochlorperazine maleate	5 mg

Source: Office of Inspector General analysis of first-quarter 2008 average sales price and average manufacturer price data, 2008.