AUG 14 2009

TO: Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services

/S/

FROM: Stuart Wright
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SUBJECT: Memorandum Report: "Comparison of First-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2009," OEI-03-09-00490

This review was conducted in accordance with the congressional mandate for the Office of Inspector General (OIG) to review average sales prices (ASP) and average manufacturer prices (AMP) for Medicare Part B prescription drugs and identify ASPs that exceed AMPs by at least 5 percent. The review also determined the impact of lowering reimbursement amounts for drugs that meet the 5-percent threshold.

Since the advent of the ASP reimbursement methodology in 2005, OIG has issued 12 reports comparing ASPs to AMPs. This latest pricing comparison examines drugs that met the 5-percent threshold based on either complete or partial AMP data in the first quarter of 2009. Of the 360 drugs with complete AMP data in that quarter, 14 met the 5-percent threshold. Eleven of these fourteen drugs were also eligible for price adjustments in 2008, with two drugs meeting the 5-percent threshold throughout that entire year. If reimbursement amounts for all 14 drugs had been based on 103 percent of the AMPs, we estimate that Medicare expenditures would have been reduced by almost $1 million in the third quarter of 2009. Of the 93 drugs with only partial AMP data in the first quarter of 2009, 9 had ASPs that exceeded the AMPs by at least 5 percent. All nine of these drugs previously met the 5-percent threshold in at least one quarter of 2008. We estimate that Medicare expenditures would have been reduced by $2.8 million during the third quarter of 2009 if reimbursement amounts for all nine drugs had been based on 103 percent of the AMPs. We could not perform pricing comparisons for an additional 61 drugs because none of the drug products used to establish Medicare reimbursement had corresponding AMP data. Manufacturers for almost one-fifth of those drug products had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. OIG will continue to work with the Centers for Medicare & Medicaid Services (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.[1] 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, health care providers 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 over $11 billion for Part B drugs in 2008.[2] Although Medicare paid for more than 700 outpatient prescription drug HCPCS codes that year, most of the spending for Part B drugs was concentrated on a relatively small subset of those codes. In 2008, 60 codes accounted for 90 percent of the expenditures for Part B drugs, with only 12 of these drugs representing half of the total Part B drug expenditures.

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,

[1] Section 1847A(d)(3)(B)(ii) of the Act provides the Secretary with authority to adjust the applicable threshold percentage in 2006 and subsequent years; however, the threshold percentage has been maintained at 5 percent.
[2] Medicare expenditures for Part B drugs in 2008 were calculated using CMS's Part B Analytics and Reports (PBAR). PBAR data were downloaded on July 8, 2009.
[3] Several Part B drugs, including certain vaccines and blood products, are not paid under the ASP methodology.

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

Third-quarter 2009 Medicare payments for most covered drug codes were based on first-quarter 2009 ASP submissions from manufacturers, which were volume-weighted using 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.[8] 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.

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.

[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.

[8] The equation that CMS currently uses to calculate volume-weighted ASPs is described in section 1847A(b)(6) of the Act. It is also provided in Appendix A.

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.[9]

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.[10] 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.[11]

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.[12] 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 rebate agreements with a number of manufacturers for failure to report drug-pricing data as required by section 1927 of the Act. For the purposes of evaluating potential civil monetary penalty actions, CMS has also provided OIG with information about manufacturers that failed to submit drug pricing data.

[9] 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.

[10] CMS's "Bulletin for Participating Drug Manufacturers," Release No. 76 (December 15, 2006), instructed manufacturers to exclude customary prompt pay discounts from their AMP calculations as of January 2007.

[11] In December 2007, the U.S. 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.

[12] Pursuant to section 1927(b)(3)(C) of the Act.

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

In accordance with its congressional mandate, OIG has issued 11 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. In addition, OIG completed an annual overview of ASPs and AMPs, which examined data across all four quarters of 2007.[13] A list of all 12 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.[14] 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.[15] 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 a file from CMS containing NDC-level ASP data from the first quarter of 2009, which were used to establish Part B drug reimbursement amounts for the third quarter of 2009. This file also includes information that crosswalks NDCs to their corresponding HCPCS codes. Both the ASP data and the crosswalk data were current as of June 24, 2009. We also obtained AMP data from CMS for the first quarter of 2009, which were current as of May 8, 2009.

Analysis of Average Sales Price Data From the First Quarter of 2009

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.

As of June 2009, CMS had established prices for 524 HCPCS codes based on the ASP reimbursement methodology mandated by section 1847A(b)(6) of the Act. Reimbursement amounts for the 524 HCPCS codes were based on ASP data for 3,335 NDCs.

[13] OIG is currently preparing an annual overview of ASPs and AMPs for 2008, which will be released later in 2009.
[14] OEI-03-08-00450, December 2008.
[15] OEI-03-07-00140, July 2007, and OEI-03-08-00450, December 2008.

Analysis of Average Manufacturer Price Data From the First Quarter of 2009
To ensure that the broadest range of drug codes is subject to OIG's pricing comparisons, 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 it represented the total amount of the drug contained in that NDC.

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. Because of these unsuccessful AMP conversions, a total of 10 HCPCS codes were removed from our analysis.

Using NDCs with successful AMP conversions, we then calculated a volume-weighted AMP for each of the corresponding HCPCS codes, consistent with CMS's methodology for calculating volume-weighted ASPs. Appendix C provides a more detailed description of the methods we used to both 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	360	1,635
Partial AMP Data	93	893
No AMP Data	61	249

Source: OIG analysis of first-quarter 2009 ASP and AMP data, 2009.

Comparing First-Quarter 2009 Volume-Weighted ASPs to Volume-Weighted AMPs
For each of the HCPCS codes included in our study, we compared the volume-weighted ASP and AMP and determined whether the ASP for the code 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 five 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 five 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.[16] For each of the HCPCS codes that met the 5-percent threshold, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the third-quarter 2009 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 2009, we then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2008, as reported in PBAR.[17] This estimate assumes that the number of services that were allowed by Medicare in 2008 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2008 and 2009.

Identifying Codes That Would Have Met the 5-Percent Threshold in Previous Quarters
We determined whether codes meeting the 5-percent threshold in the first quarter of 2009 would have also met the 5-percent threshold in any of the four previous quarters, dating back to the first quarter of 2008.

[16] 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.
[17] 2008 PBAR data were downloaded on July 8, 2009.

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. Furthermore, we did not verify the accuracy of CMS's crosswalk files or examine NDCs that CMS opted to exclude from its calculation of Part B drug reimbursement amounts.

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 determine whether manufacturers provided additional or revised pricing data to CMS at a later date.

Standards
This study was conducted in accordance with the "Quality Standards for Inspections" approved by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

Of the 360 Drug Codes With Complete AMP Data, Volume-Weighted ASPs for 14 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. In the first quarter of 2009, 14 of the 360 HCPCS codes with complete AMP data (4 percent) met this 5-percent threshold. A list of the 14 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 14 HCPCS codes.[18] For three of the codes, 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.

Over three-fourths of the HCPCS codes (11 of 14) also met the 5-percent threshold in one or more quarters of 2008. For two HCPCS codes (J1364 and Q0169), ASPs exceeded AMPs in each of the past five quarters, dating back to the first quarter of 2008. An additional two HCPCS codes met the 5-percent threshold in four of the past five quarters. Table 3 presents a breakdown of the 11 HCPCS codes that were also eligible for price adjustments in 2008.

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

Table 2: Extent to Which ASPs Exceeded AMPs for 14 HCPCS Codes With Complete AMP Data

Percentage by Which ASP Exceeded AMP	Number of HCPCS Codes
5.00%–9.99%	8
10.00%–19.99%	3
20.00%–29.99%	1
30.00%–39.99%	0
40.00%–49.99%	1
50.00%–59.99%	0
60.00%–69.99%	0
70.00%–79.99%	0
80.00%–89.99%	0
90.00%–99.99%	0
100% and above	1
Total	**14**

Source: OIG analysis of first-quarter 2009 ASP and AMP data, 2009.

Table 3: Eleven HCPCS Codes That Met the 5-Percent Threshold in the First Quarter of 2009 and Previous Quarters Using Complete AMP Data

	OIG Reports Comparing ASP and AMP				
HCPCS Code	First Quarter 2009	Fourth Quarter 2008	Third Quarter 2008	Second Quarter 2008	First Quarter 2008
J1364	X	X	X	X	X
Q0169	X	X	X	X	X
J8515	X	X	X	X	
J9225	X	X	X	X	
J2765	X	X	X		
J0475	X	X			
J2597	X	X			
J7500	X		X		
Q0175	X			X*	
Q0176	X			X*	
J1955	X				X

*These codes previously met the 5-percent threshold during the specified quarters based on partial AMP data.
Source: OIG analysis of ASP and AMP data from the first quarter of 2009 and all four quarters of 2008.

Lowering reimbursement amounts for the 14 HCPCS codes to 103 percent of the AMPs would have reduced Medicare allowances by almost $1 million in the third quarter of 2009. 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 . . . ."[19] In this study, we identified 14 HCPCS codes that met the 5-percent threshold specified in the Act. If reimbursement amounts for these 14 codes had been based on 103 percent of the AMPs during the third quarter of 2009, we estimate that Medicare expenditures would have been reduced by $939,000 in that quarter alone.[20] [21]

Two of the fourteen HCPCS codes accounted for 97 percent of the estimated savings. If the reimbursement amounts for codes J9225 and J0475 had been based on 103 percent of the AMPs during the third quarter of 2009, Medicare expenditures would have been reduced by an estimated $513,000 and $402,000, respectively.

Of the 93 Drug Codes With Partial AMP Data, Volume-Weighted ASPs for 9 Exceeded the Volume-Weighted AMPs by at Least 5 Percent

In addition to examining HCPCS codes with complete AMP data, we examined 93 HCPCS codes for which only partial AMP data were available. ASPs for 9 of these 93 HCPCS codes (10 percent) exceeded the AMPs by at least 5 percent in the first quarter of 2009. A list of the 9 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 nine HCPCS codes.[22] For almost half of the codes (four of nine), 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.

[19] 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.

[20] This savings estimate assumes that the number of services that were allowed by Medicare in 2008 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2008 and 2009.

[21] One of the fourteen HCPCS codes was not listed in the 2008 PBAR file. An additional three HCPCS codes were listed in the PBAR file but had zero services. As a result, savings estimates were not calculated for these four codes.

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

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

Percentage by Which ASP Exceeded AMP	Number of HCPCS Codes
5.00%–9.99%	2
10.00%–19.99%	3
20.00%–29.99%	0
30.00%–39.99%	0
40.00%–49.99%	0
50.00%–59.99%	0
60.00%–69.99%	0
70.00%–79.99%	2
80.00%–89.99%	0
90.00%–99.99%	0
100% and above	2
Total	**9**

Source: OIG analysis of first-quarter 2009 ASP and AMP data, 2009.

All nine of the HCPCS codes with partial AMP data also met the 5-percent threshold in one or more quarters of 2008. For three HCPCS codes (J0560, J1190, and J2310), ASPs exceeded AMPs in each of the past five quarters, dating back to the beginning of 2008. Another two HCPCS codes met the 5-percent threshold in four of the past five quarters. Table 5 presents a breakdown of the nine HCPCS codes that were also eligible for price adjustments in 2008.

Table 5: Nine HCPCS Codes That Met the 5-Percent Threshold in the First Quarter of 2009 and Previous Quarters Using Partial AMP Data

	OIG Reports Comparing ASP and AMP				
HCPCS Code	First Quarter 2009	Fourth Quarter 2008	Third Quarter 2008	Second Quarter 2008	First Quarter 2008
J0560	X	X	X	X	X
J1190	X	X	X	X	X
J2310	X	X	X	X	X
J1642	X	X	X	X	
J0170	X	X	X		X
Q9965	X	X	X		
Q9966	X	X	X		
J7506	X		X	X	
Q9967	X	X			

Note: All of these codes met the 5-percent threshold during 2008 using partial AMP data.
Source: OIG analysis of ASP and AMP data from the first quarter of 2009 and all four quarters of 2008.

Lowering reimbursement amounts for the nine HCPCS codes to 103 percent of the AMPs would have reduced Medicare allowances by an estimated $2.8 million in the third quarter of 2009.[23] [24] Two of the nine HCPCS codes accounted for over 80 percent of the $2.8 million. If the reimbursement amounts for codes Q9965 and Q9967 had been based on 103 percent of the AMPs during the third quarter of 2009, Medicare expenditures would have been reduced by an estimated $1.7 million and $591,000, respectively.

Pricing Comparisons Could Not Be Performed on 61 Drug Codes Because No AMP Data Were Available

For 61 HCPCS codes, OIG could not compare ASPs and AMPs because there were no AMP data for any of the 249 NDCs that CMS used when calculating drug reimbursement amounts for these codes. In 2008, Medicare allowances for these 61 codes totaled $251 million.[25]

Almost one-fifth of NDCs without AMP data belonged to manufacturers with Medicaid drug rebate agreements.[26] Manufacturers for 17 percent of the NDCs without AMP data (43 of 249) participated in the Medicaid drug rebate program as of the first quarter of 2009 and were therefore generally required to submit AMP data for their covered outpatient drugs.[27] [28] Almost 45 percent of these 43 NDCs belonged to only two manufacturers.

Manufacturers for the remaining 206 of 249 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 13th report comparing ASPs and AMPs, and it examines 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.

[23] 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 had been lower than 103 percent of the AMP, the savings estimates presented in this report would have been greater.

[24] This savings estimate assumes that the number of services that were allowed by Medicare in 2008 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2008 and 2009.

[25] Of the 61 HCPCS codes with no associated AMP data, 15 were not listed in the 2008 PBAR file. As a result, these codes were not included in the total Medicare allowances for the year.

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

[27] Although manufacturers with rebate agreements are required to submit AMP data for their covered outpatient drugs, there may be valid reasons 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.

[28] These 43 NDCs were crosswalked to 22 HCPCS codes.

In the first quarter of 2009, we identified a total of 23 HCPCS codes that met the threshold for price adjustment. Of these 23 HCPCS codes, 20 were previously identified by OIG as having ASPs that exceeded the AMPs by at least 5 percent. Finally, we could not compare ASPs and AMPs for 61 HCPCS codes because AMP data were not submitted for any of the NDCs that CMS used to calculate reimbursement. Manufacturers for almost one-fifth of these NDCs had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. OIG will continue to work 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, which we continue to support.[29] 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-03-09-00490 in all correspondence.

[29] For example, OIG, "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007," OEI-03-08-00450, December 2008.

APPENDIX A

The Equation Used by the Centers for Medicare & Medicaid Services To Calculate Volume-Weighted Average Sales Prices On or After April 1, 2008

A volume-weighted average sales price (ASP) is calculated for the dosage amount associated with the Healthcare Common Procedure Coding System (HCPCS) code. In the following equation, the "number of billing units" represents the number of HCPCS code doses that are contained in a national drug code (NDC).

$$\textit{Volume-Weighted ASP For Dosage Amount of HCPCS Code} = \frac{\textit{Sum of (ASP for NDC * Number of NDCs Sold)}}{\textit{Sum of (Number of NDCs Sold * Number of Billing Units in NDC)}}$$

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

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

- "Comparison of Second-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2008" (OEI-03-09-00050), February 2009

- "Comparison of Third-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2009" (OEI-03-09-00150), April 2009

- "Comparison of Fourth-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2009" (OEI-03-09-00340), August 2009

APPENDIX C

Detailed Methodology for Converting and Volume-Weighting Average Manufacturer Prices for the First Quarter of 2009

Healthcare Common Procedure Coding System codes with complete average manufacturer price data. Of the 524 Healthcare Common Procedure Coding System (HCPCS) codes with reimbursement amounts based on average sales prices (ASP), 369 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 369 HCPCS codes represented 1,733 NDCs. For 13 NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These 13 NDCs were crosswalked to nine HCPCS codes. We did not include these nine HCPCS codes (98 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,635 NDCs, we then calculated a volume-weighted AMP for each of the remaining 360 HCPCS codes consistent with CMS's methodology for calculating volume-weighted ASPs.

HCPCS codes with partial AMP data. There were 94 HCPCS codes with AMP data for only some of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 94 HCPCS codes represented a total of 1,353 NDCs. AMP data were either missing or unavailable for 451 of these NDCs, which were then excluded from our calculation of volume-weighted AMPs.[30]

We calculated converted AMPs for each of the remaining 902 NDCs. For nine of the nine hundred and two 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 9 NDCs from our analysis.[31] As a result, one HCPCS code no longer had any NDCs with AMP data. Therefore, this HCPCS code was removed from our analysis.

Using the converted AMPs for the remaining 893 NDCs, we then calculated a volume-weighted AMP for each of the remaining 93 HCPCS codes consistent with CMS's methodology for calculating volume-weighted ASPs.

[30] Although AMP data for these 451 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 61 HCPCS codes, there were no AMP data for any of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 61 HCPCS codes represented 249 NDCs.

APPENDIX D

Fourteen Drug Codes With Complete Average Manufacturer Price Data That Met the 5-Percent Threshold in the First Quarter of 2009

Drug Code	Short Description	Drug Code Dosage
J0475	Baclofen injection	10 mg
J1230	Methadone injection	10 mg
J1364	Erythro lactobionate	500 mg
J1655	Tinzaparin sodium	1,000 units
J1955	Levocarnitine injection	1 g
J2597	Desmopressin acetate injection	1 mcg
J2765	Metoclopramide HCl injection	10 mg
J3470	Hyaluronidase injection	150 units
J7500	Azathioprine, oral	50 mg
J8515	Cabergoline, oral	0.25 mg
J9225	Histrelin implant	50 mg
Q0169	Promethazine HCl, oral	12.5 mg
Q0175	Perphenazine, oral	4 mg
Q0176	Perphenazine, oral	8 mg

Source: Office of Inspector General analysis of first-quarter 2009 average sales price and average manufacturer price data, 2009.

APPENDIX E

Nine Drug Codes With Partial Average Manufacturer Price Data That Met the 5-Percent Threshold in the First Quarter of 2009

Drug Code	Short Description	Drug Code Dosage
J0170	Adrenalin epinephrin injection	1 ml
J0560	Penicillin g benzathine injection	600,000 units
J1190	Dexrazoxane HCl injection	250 mg
J1642	Heparin sodium injection	10 units
J2310	Naloxone hydrochloride injection	1 mg
J7506	Prednisone, oral	5 mg
Q9965	Low osmolar contrast material,100-199 mg/mL iodine	1 ml
Q9966	Low osmolar contrast material, 200-299 mg/mL iodine	1 ml
Q9967	Low osmolar contrast material, 300-399 mg/mL iodine	1 ml

Source: Office of Inspector General analysis of first-quarter 2009 average sales price and average manufacturer price data, 2009.