MAY - 6 2008

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

FROM: Daniel R. Levinson Daniel R. Levinson
Inspector General

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

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 third quarter of 2007. It also determines the impact of lowering reimbursement amounts for drugs that meet the 5-percent threshold.

This is the Office of Inspector General's (OIG) sixth report comparing ASPs to AMPs.[1] Unlike most of OIG's previous pricing comparisons, this report considers both the current ASP payment methodology and a revised ASP payment methodology recently mandated by statute. Specifically, in December 2007, the Medicare, Medicaid, and SCHIP Extension Act of 2007, P.L. 110-173, amended section 1847A(b) of the Social Security Act (the Act) and changed the way in which the Centers for Medicare & Medicaid Services (CMS) calculates volume-weighted ASPs, effective April 1, 2008.

Using CMS's current ASP payment amount methodology, we identified 41 of 369 drug codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2007. Of the 41 codes, 31 also met the threshold for price adjustments in at least one of the prior OIG studies comparing ASPs to AMPs. If reimbursement amounts for all 41 codes were based on 103 percent of AMP, we estimate that Medicare expenditures would be reduced by $16 million during the first quarter of 2008 alone.

[1]Since the current average sales price (ASP) reimbursement methodology for Part B prescription drugs was implemented in January 2005, the Office of Inspector General (OIG) has completed five other reports comparing ASPs to average manufacturer prices (AMP): OEI-03-04-00430, April 2006; OEI-03-06-00370, July 2006; OEI-03-07-00140, July 2007; OEI-03-07-00530, September 2007; and OEI-03-08-00010, December 2007.

Under the revised payment methodology effective in April 2008, ASPs for 35 of 369 drug codes would have exceeded AMPs by at least 5 percent. Of these 35 codes, 32 also met the 5-percent threshold under CMS's current method for volume-weighting data. An additional three Healthcare Common Procedure Coding System (HCPCS) codes would have met the 5-percent threshold using the revised ASP payment methodology but not the current methodology. If reimbursement amounts for these 35 codes were based on 103 percent of the AMP, we estimate that Medicare expenditures would be reduced by $13 million during the first quarter of 2008.

BACKGROUND

Section 1847A(d)(2)(B) of the Act mandates that OIG compare ASPs with 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. 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 carriers, 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 carriers using procedure codes. CMS established the 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 about $11 billion for Part B drugs in 2006. Although Medicare paid for more than 650 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 2006, 56 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.

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.[2] 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.[3] 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.[4] [5]

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.[6]

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 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

[2] 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." Prior to 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.

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

[4] 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.

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

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

each NDC when developing its crosswalk files. The equation that CMS currently uses to calculate volume-weighted ASPs is provided in Appendix A.

Third-quarter 2007 ASP submissions from manufacturers served as the basis for first-quarter 2008 Medicare allowances for most covered drug codes. Under the ASP pricing methodology, the Medicare allowance for most Part B drugs is equal to 106 percent of the ASP for the HCPCS code. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

Recent Changes to the Calculation of Volume-Weighted Average Sales Prices

In December 2007, the Medicare, Medicaid, and SCHIP Extension Act of 2007 was enacted. Section 112(a) of this law changed section 1847A(b)(6) of the Act to require that CMS compute volume-weighted ASP 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 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.[7]

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. Prior to the passage of the Deficit Reduction Act of 2005 (DRA), P.L. No. 109-171, 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.[8] In July 2007, CMS published a final rule (72 FR 39142) (July 17, 2007), which, 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.[9]

[7] Section 6001(b)(1)(A) of the Deficit Reduction Act of 2005 (DRA) 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.

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

[9] 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.

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 milligram, 1 milliliter, 1 tablet, 1 capsule).

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 completed five reports comparing ASPs to AMPs. A description of each report is provided in Appendix B.

Although CMS has acknowledged the Secretary's authority to adjust ASP payment limits based on the findings of these studies, the agency has yet to make any changes to Part B drug reimbursement as a result of OIG's pricing comparisons. In commenting on one of OIG's reports, CMS expressed a desire to better understand fluctuating differences between ASPs and AMPs, with the intent of developing a process to adjust payment amounts based on the results of OIG's pricing comparisons.[10] 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.

METHODOLOGY

We obtained from CMS NDC-level ASP data from the third quarter of 2007, which were used to establish Part B drug reimbursement amounts for the first quarter of 2008. In addition, we obtained the file that CMS used to crosswalk NDCs to their corresponding HCPCS codes. Both the ASP data and the crosswalk file were current as of January 5, 2008. We also obtained AMP data from CMS for the third quarter of 2007, which was current as of November 9, 2007.

Analysis of Average Sales Price Data

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 January 2008, CMS had established prices for 521 HCPCS codes based on the current ASP reimbursement methodology.[11] Reimbursement amounts for the 521 HCPCS codes were based on ASP data for 3,262 NDCs.

[10] OEI-03-07-00140, July 2007.

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

To anticipate how the statutorily mandated revised ASP payment methodology would affect OIG's pricing comparisons, we used the revised equation to calculate an alternate volume-weighted ASP for each of the 521 HCPCS codes included in this study. To determine what the Medicare reimbursement amount would be according to the revised methodology, we then multiplied the alternate volume-weighted ASPs for the 521 codes by 1.06.[12]

Analysis of Average Manufacturer Price Data

An AMP is reported for the lowest identifiable quantity of the drug contained in the NDC (e.g., 1 milligram, 1 milliliter, 1 tablet, 1 capsule). In contrast, an 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.

In making these conversions, we examined AMPs only for those 3,262 NDCs that CMS used in its calculation of volume-weighted ASPs for the 521 codes. If AMP data were not available for one or more of these NDCs, we excluded the corresponding HCPCS code from our analysis. We excluded a total of 138 HCPCS codes using this conservative approach. The remaining 383 HCPCS codes had AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs. These 383 HCPCS codes represented 1,956 NDCs.

We then multiplied the AMPs for these 1,956 NDCs 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. We will refer to the resulting amounts as converted AMPs. For eight NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These eight NDCs were crosswalked to 14 HCPCS codes. We did not include these 14 HCPCS codes (66 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,890 NDCs, we then calculated two different volume-weighted AMPs for each of the codes, consistent with the two methodologies for calculating volume-weighted ASPs. The first volume-weighted AMP was calculated using the current method for volume-weighting data, and the second volume-weighted AMP was calculated using the revised method for volume-weighting data. We calculated volume-weighted AMPs for a total of 369 HCPCS codes. We did not verify the accuracy of manufacturer-reported ASP and AMP data.

Comparing Volume-Weighted ASPs to Volume-Weighted AMPs

For each of the 369 HCPCS codes included in our study, we then compared the volume-weighted ASPs and AMPs that resulted from CMS's current calculation. We also compared the volume-weighted ASPs and AMPs that resulted from the revised calculation.

[12]We multiplied the alternate volume-weighted ASPs by 1.06 because Medicare reimbursement amounts are based on 106 percent of volume-weighted ASPs.

We identified codes with an ASP that exceeded the AMP by at least 5 percent according to either the current or revised calculation.

For those HCPCS codes that met or exceeded the 5-percent threshold, we conducted a review of the associated NDCs to verify the accuracy of the billing unit information. According to our review, an NDC for one code 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 result for this code was correct. Therefore, we did not include this code in our findings.

For the remaining HCPCS codes, we then estimated the monetary impact of lowering reimbursement to 103 percent of the AMP.[13] For each of the HCPCS codes that met the 5-percent threshold under CMS's current payment methodology, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the first-quarter 2008 reimbursement amount for the HCPCS code, which is equal to 106 percent of the volume-weighted ASP. For each of the codes that met the 5-percent threshold under the revised payment methodology, we subtracted 103 percent of the revised volume-weighted AMP from the alternate reimbursement amount for the HCPCS code (106 percent of the revised volume-weighted ASP). To estimate the financial effect for the first quarter of 2008, we then multiplied the differences by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2006, as reported in CMS's Part B Extract and Summary System.[14] This estimate assumes that the number of services that were allowed by Medicare in 2006 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2006 and 2007.

Limitations

The definition of AMP changed in January 2007, such that AMPs must now be determined without regard to customary prompt pay discounts.[15] Because manufacturers are still required to include customary prompt pay discounts in their ASP calculations, the dynamic between ASPs and AMPs may be different in this report as compared to that in previous OIG reports monitoring ASPs and AMPs.

[13] Pursuant to section 1847A(d)(3) of the Act, if the ASP for a drug exceeds the AMP by at least 5 percent, the Secretary of the Department of Health and Human Services has authority to disregard the ASP for that drug and replace the payment amount for the drug code 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.

[14] At the time of extraction, 2006 Part B Extract and Summary System (BESS) data were 99 percent complete.

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

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

Under CMS's Current Payment Methodology, Volume-Weighted ASPs for 41 of 369 HCPCS Codes 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 third quarter of 2007, 41 of the 369 HCPCS codes included in our review (11 percent) met this 5-percent threshold. A list of the 41 HCPCS codes, their descriptions, and their HCPCS dosage amounts is presented in Appendix C.

Table 1 below describes the extent to which ASPs exceeded AMPs for the 41 HCPCS codes.[16] For 17 of the 41 codes, 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 1: Extent to Which ASPs Exceeded AMPs for 41 HCPCS Codes

Percentage Difference Between ASP and AMP	Number of HCPCS Codes
5.00%–9.99%	12
10.00%–19.99%	12
20.00%–29.99%	7
30.00%–39.99%	1
40.00%–49.99%	0
50.00%–59.99%	0
60.00%–69.99%	4
70.00%–79.99%	1
80.00%–89.99%	2
90.00%–99.99%	0
100% and above	2
Total	**41**

Source: OIG analysis of third-quarter 2007 ASP and AMP data, 2007.

Over three-quarters of the HCPCS codes (31 of 41) were previously identified by OIG as having ASPs that exceeded the AMPs by at least 5 percent. Four HCPCS codes (J7620, J3410, J9214, and J2690) met the 5-percent threshold in five of OIG's six reports comparing

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

ASPs to AMPs, dating back over 3 years.[17] An additional three HCPCS codes met the 5-percent threshold in four of OIG's six pricing comparisons. Table 2 presents a breakdown of the 31 HCPCS codes that previously met the threshold for price adjustments.

Table 2: Thirty-one HCPCS Codes That Met the 5-Percent Threshold in Third-Quarter 2007 and Previous Quarters (According to CMS's Current Payment Methodology)

HCPCS Code	OIG Comparisons of ASPs to AMPs					
	Third-Quarter 2007	Second-Quarter 2007	First-Quarter 2007	Third-Quarter 2006	Fourth-Quarter 2005	Third-Quarter 2004
J9214	X	X	X	X	X	
J7620	X	X	X	X	X	
J2690	X	X	X		X	X
J3410	X		X	X	X	X
J7608	X	X	X	X		
J3475	X		X	X	X	
J1364	X		X	X		X
Q0169	X	X	X			
J2060	X	X	X			
J7505	X	X	X			
J0280	X	X	X			
J2800	X	X	X			
J3010	X		X	X		
J7500	X		X	X		
J9065	X		X	X		
J0610	X			X	X	
J1240	X				X	X
J1120	X	X				
J0476	X	X				
J9250	X		X			
J9260	X		X			
Q0176	X		X			
J2700	X			X		
J0636	X			X		
J7631	X			X		
J1850	X				X	
J3000	X				X	
J9190	X				X	
J2675	X					X
J2730	X					X
Q0175	X					X

Source: OIG analysis of ASP and AMP data from third quarter 2007, second quarter 2007, first quarter 2007, third quarter 2006, fourth quarter 2005, and third quarter 2004.

[17] If the revised method for volume-weighting data had been used, two of these four Healthcare Common Procedure Coding System (HCPCS) codes (J9214 and J3410) would not have met the 5-percent threshold in the third quarter of 2007. We did not determine whether these codes would have met the threshold in previous quarters if the revised methodology had been used.

Lowering reimbursement amounts for the 41 HCPCS codes to 103 percent of the AMPs would reduce Medicare allowances by an estimated $16 million in the first 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 . . . ."[18] In this study, we identified 41 HCPCS codes that met the 5-percent threshold specified in the Act. If reimbursement amounts for these 41 codes were based on 103 percent of the AMPs during the first quarter of 2008, we estimate that Medicare expenditures would be reduced by $16 million in that quarter alone.[19]

Two of the forty-one HCPCS codes accounted for 90 percent of the $16 million. If the reimbursement amounts for codes J7620 and J0800 had been based on 103 percent of the AMP during the first quarter of 2008, Medicare expenditures would have been reduced by an estimated $9 million and $5 million, respectively.

In addition to meeting the 5-percent threshold in this report, HCPCS code J7620 met the 5-percent threshold in four previous OIG reports. As in this current review, the estimated savings for code J7620 accounted for the largest single share of the total savings identified in each of the four other OIG pricing comparisons, with estimated quarterly savings for this code ranging from $6 million to $8 million.

Under the Revised Payment Methodology, Volume-Weighted ASPs for 35 of 369 HCPCS Codes Would Have Exceeded the Volume-Weighted AMPs by at Least 5 Percent

If the revised ASP payment methodology had been used to volume-weight pricing data in the third quarter of 2007, 35 of the 369 HCPCS codes included in our review (9 percent) would have met the 5-percent threshold specified in section 1847A(d)(3) of the Act.

Thirty-two of the thirty-five HCPCS codes also met the 5-percent threshold under CMS's current method for volume-weighting data. For 18 of these 32 codes, the percentage difference between the ASPs and AMPs was the same regardless of which calculation was used. For the remaining codes, the extent to which ASPs exceeded AMPs differed. For seven codes, the percentage difference between the ASP and AMP was greater under the revised methodology. For an additional seven codes, the difference was less. All 32 HCPCS

[18] 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.

[19] This savings estimate is based on the Centers for Medicare & Medicaid Services' (CMS) current method for volume-weighting data and was calculated using one-fourth of the number of estimated services allowed by Medicare for each HCPCS code in 2006. The estimate assumes that the number of services that were allowed by Medicare in 2006 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2006 and 2007. Two HCPCS codes, Q0175 and Q0176, were not listed in the 2006 BESS data. Therefore, we could not estimate savings for these codes.

codes that met the 5-percent threshold using both the current and revised calculations are identified in Appendix C.

An additional three HCPCS codes would have met the 5-percent threshold using the revised ASP payment methodology but not the current methodology. ASPs for HCPCS codes J2370, J2560, and J7679 would have exceeded the AMPs by at least 5 percent under the revised payment methodology which will take effect in April 2008; however, these codes did not meet the 5-percent threshold under CMS's current payment methodology.

Lowering reimbursement amounts for the 35 HCPCS codes to 103 percent of the AMPs would have reduced Medicare allowances by an estimated $13 million in the first quarter of 2008.[20] As with CMS's current ASP payment methodology, HCPCS codes J7620 and J0800 accounted for the majority of the estimated savings under the revised method for volume-weighting data. If the reimbursement amounts for these two codes had been based on 103 percent of the AMPs during the first quarter of 2008, Medicare expenditures would have been reduced by an estimated $7 million and $5 million, respectively.

CONCLUSION

For the purpose of monitoring 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 review is the sixth such comparison conducted by OIG, and we identified a total of 44 HCPCS codes that met the threshold for price adjustment under either the current ASP payment methodology or a revised methodology recently mandated by statute. ASPs for 32 of the 44 HCPCS codes exceeded AMPs by at least 5 percent regardless of whether the current or revised ASP payment methodology was used. An additional nine codes met the 5-percent threshold using CMS's current calculation but not the revised calculation. Another three codes met the 5-percent threshold using the revised calculation but not the current calculation. Of the 41 codes that met the threshold under CMS's current payment methodology, 31 were previously identified by OIG as having ASPs that exceeded AMPs by at least 5 percent. ASPs for 4 of the 31 HCPCS codes exceeded AMPs by at least 5 percent in five of OIG's six reports comparing ASPs to AMPs, dating back over 3 years.

We note that previous OIG 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-03-08-00130 in all correspondence.

[20] This savings estimate is based on the revised method for volume-weighting data and was calculated using one-fourth of the number of estimated services allowed by Medicare for each HCPCS code in 2006. The estimate assumes that the number of services that were allowed by Medicare in 2006 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2006 and 2007. Two HCPCS codes, Q0175 and Q0176, were not listed in the 2006 BESS data; therefore, we could not estimate savings for these codes.

APPENDIX A

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 Equation Currently Used by the Centers for Medicare & Medicaid Services To Calculate a Volume-Weighted Average Sales Price (ASP)

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

2. The Revised Equation Specified in Section 112(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007

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

APPENDIX B

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

In April 2006, the Office of Inspector General (OIG) released the first of its reports comparing average sales prices (ASP) to average manufacturer prices (AMP). That report, entitled "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices" (OEI-03-04-00430), identified 51 drug codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004. Because OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology, the Centers for Medicare & Medicaid Services (CMS) opted not to take action in response to OIG's findings.

Three months later, OIG released a second report comparing ASPs to AMPs, entitled "Comparison of Fourth-Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2006" (OEI-03-06-00370). According to this follow-up study, which used data from the fourth quarter of 2005, 46 of 341 drug codes had ASPs that exceeded AMPs by at least 5 percent. Twenty of these forty-six codes had also met the 5-percent threshold in OIG's initial pricing comparison of third-quarter 2004 ASPs and AMPs.

In July 2007, OIG released its third comparison between ASPs and AMPs, entitled "Comparison of Third-Quarter 2006 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007" (OEI-03-07-00140). This report identified 39 of 326 drug codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2006. Of these 39 codes, 4 met the threshold for price adjustments in all three of OIG's studies comparing ASPs to AMPs. An additional eight drug codes were previously eligible for price adjustments as a result of OIG's second report. OIG recommended that CMS adjust Medicare reimbursement amounts for the 39 codes meeting the 5-percent threshold in the third quarter of 2006.

OIG released its fourth pricing comparison 2 months later, entitled "Comparison of First-Quarter 2007 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2007" (OEI-03-07-00530). According to this report, ASPs for 34 of 371 drug codes exceeded AMPs by at least 5 percent in the first quarter of 2007. Of these 34 codes, 20 also met the threshold for price adjustments in at least one of the prior OIG studies comparing ASPs to AMPs.

In December 2007, OIG released its fifth comparison of ASPs to AMPs, entitled "Comparison of Second-Quarter 2007 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2007" (OEI-03-08-00010). This report identified 22 of 292 drug codes with ASPs that exceeded AMPs by at least 5 percent in the second quarter of 2007. Sixteen of the twenty-two codes also met the threshold for price adjustments in at least one of the prior OIG studies comparing ASPs to AMPs.

APPENDIX C

Forty-One Healthcare Common Procedure Coding System Codes With Average Sales Prices That Exceeded Average Manufacturer Prices by at Least 5 Percent Under the Current Payment Methodology

HCPCS Code	Short Description	HCPCS Code Dosage
J0210*	Methyldopate HCl injection	250 mg
J0280	Aminophyllin 250 MG injection	250 mg
J0476*	Baclofen intrathecal trial	50 mcg
J0610	Calcium gluconate injection	10 mL
J0636*	Calcitriol injection	0.1 mcg
J0800*	Corticotropin injection	40 units
J1120*	Acetazolamid sodium injection	500 mg
J1240*	Dimenhydrinate injection	50 mg
J1364*	Erythro lactobionate	500 mg
J1580*	Garamycin gentamicin injection	80 mg
J1631	Haloperidol decanoate injection	50 mg
J1800*	Propranolol injection	1 mg
J1840*	Kanamycin sulfate injection	500 mg
J1850*	Kanamycin sulfate injection	75 mg
J2060	Lorazepam injection	2 mg
J2150*	Mannitol injection	50 mL
J2430*	Pamidronate disodium	30 mg
J2675*	Progesterone injection	50 mg
J2690*	Procainamide HCl injection	1 g
J2700*	Oxacillin sodium injection	250 mg
J2730*	Pralidoxime chloride injection	1 g
J2800*	Methocarbamol injection	10 mL
J3000*	Streptomycin injection	1 g
J3010	Fentanyl citrate injection	0.1 mg
J3410	Hydroxyzine HCl injection	25 mg
J3475	Magnesium sulfate injection	500 mg
J7500*	Azathioprine oral	50 mg
J7505*	Monoclonal antibodies	5 mg
J7608	Acetylcysteine inhalation solution unit dose	1 g
J7620*	Albuterol ipratrop non-compounded	2.5 MG/0.5 mg
J7631*	Cromolyn sodium inhalation solution unit dose	10 mg
J9050*	Carmus bischl nitro injection	100 mg
J9065*	Cladribine injection	1 mg
J9190*	Fluorouracil injection	500 mg
J9208*	Ifosfamide injection	1 g

HCPCS Code	Short Description	HCPCS Code Dosage
J9214	Interferon alfa-2b injection	1 million units
J9250*	Methotrexate sodium injection	5 mg
J9260*	Methotrexate sodium injection	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 third-quarter 2007 average sales prices and average manufacuturer prices data, 2008.

Codes marked with an asterisk (*) also met the 5-percent threshold according to the revised method of volume-weighting the data.