DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

AUG 11 2011

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FROM: /S/
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SUBJECT: Memorandum Report: *Comparison of First-Quarter 2011 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2011*, OEI-03-11-00540

This review was conducted in accordance with the statutory mandate for the Office of Inspector General (OIG) to identify Medicare Part B prescription drugs with average sales prices (ASP) that exceed average manufacturer prices (AMP) by at least 5 percent. This review estimated the financial impact of lowering reimbursement amounts for drugs that met the 5-percent threshold to 103 percent of the AMPs, and additionally examined the potential effect of a July 2011 proposed rule that, among other things, specifies the circumstances under which the Centers for Medicare & Medicaid Services (CMS) will make AMP-based price substitutions.

SUMMARY

Since the implementation of the ASP reimbursement methodology in 2005, OIG has issued 22 reports comparing ASPs with AMPs. This latest comparison examines drugs that exceeded the 5-percent threshold based on either complete or partial AMP data in the first quarter of 2011. Of the 339 drug codes with complete AMP data, 15 exceeded the 5-percent threshold. If reimbursement amounts for all 15 codes had been based on 103 percent of the AMPs in the third quarter of 2011, Medicare would have saved an estimated $788,000. Under CMS's proposed price substitution policy, reimbursement amounts for 7 of the 15 drugs would have been reduced, saving an estimated $654,000. Of the 105 drug codes with partial AMP data, 20 exceeded the 5-percent threshold. CMS has expressed concern that partial AMP data may not adequately reflect market trends and therefore proposes that drugs with partial AMP data not be subject to price reduction. However, we found that pricing comparisons for half of the 20 codes with partial AMP data seemed to accurately capture market trends; price reductions may be appropriate in these cases. We could not perform pricing comparisons for an additional 51 drug codes because none of the associated drug products had corresponding AMP data. Manufacturers for 9 percent of those drug products had Medicaid drug rebate agreements and were therefore generally required to submit AMPs.

BACKGROUND

The Social Security Act (the Act) mandates that OIG compare ASPs to AMPs.[1] If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), the Act states that the Secretary of Health and Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement amounts.[2, 3] The Act further states 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…."[4]

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 the amount of the drug represented by the HCPCS code but does not specify manufacturer or package size information.

Medicare and its beneficiaries spent almost $12 billion for Part B drugs in 2010.[5] Although Medicare paid for more than 600 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 2010, 61 HCPCS codes accounted for 90 percent of the expenditures for Part B drugs, with only 12 of these codes representing the majority of total Part B drug expenditures.

[1] Section 1847A(d)(2)(B) of the Act.
[2] Section 1847A(d)(3)(A) of the Act.
[3] 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.
[4] Section 1847A(d)(3)(C) of the Act.
[5] Medicare expenditures for Part B drugs in 2010 were calculated using CMS's Part B Analytics and Reports (PBAR). The PBAR data for 2010 were 98-percent complete when the data were downloaded in April 2011.

Reimbursement Methodology for Part B Drugs and Biologicals

Medicare Part B pays for most covered drugs using a reimbursement methodology based on ASPs.[6] As defined by law, an ASP is 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.[7] 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.[8] Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in Medicaid's drug rebate program.[9, 10]

Manufacturers that participate in the Medicaid drug rebate program must provide CMS with the ASP and volume of sales for each of their national drug codes (NDC) on a quarterly basis, with submissions due 30 days after the close of each quarter.[11] An NDC is an 11-digit identifier that represents a specific manufacturer, product, and package size.

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 ASPs

Third-quarter 2011 Medicare payments for most covered drug codes were based on first-quarter 2011 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.[12] 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 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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[6] Several Part B drugs, including certain vaccines and blood products, are not paid for under the ASP methodology.
[7] Section 1847A(c) of the Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173.
[8] Section 1847A(c)(3) of the Act.
[9] Section 1847A(c)(2) of the Act.
[10] Pursuant to § 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.
[11] Section 1927(b)(3) of the Act.
[12] The equation that CMS currently uses to calculate volume-weighted ASPs is described in § 1847A(b)(6) of the Act. It is also provided in Appendix A.

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 generally responsible for 20 percent of this amount in the form of coinsurance.

The Medicaid Drug Rebate Program and AMPs

For Federal payment to be available for covered outpatient drugs provided under Medicaid, the Act mandates that drug manufacturers enter into rebate agreements with the Secretary and pay quarterly rebates to State Medicaid agencies.[13] Under these rebate agreements and pursuant to the Act, manufacturers must provide CMS with the AMPs for each of their NDCs.[14] As further explained in regulation, manufacturers are required to submit AMPs within 30 days after the end of each quarter.[15]

The AMP is generally calculated as a weighted average of prices for all of a manufacturer's package sizes of a drug and is reported for the lowest identifiable quantity of the drug (e.g., 1 milliliter, one tablet, one capsule). Effective October 2010, the Patient Protection and Affordable Care Act (Affordable Care Act) revised the definition of AMP to be the average price paid to the manufacturer for the drug in the United States by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from the manufacturer.[16, 17, 18] Because the AMPs calculated under this new definition are expected to be based on higher-priced sales, the new AMPs are likely to be higher than the AMPs calculated before October 2010.[19, 20]

Penalties for Failure To Report Timely Drug Pricing Data

Pursuant to the Act, manufacturers that fail to provide ASP and AMP data on a timely basis may be subject to civil money penalties and/or termination from the drug rebate program.[21, 22] Accordingly, CMS has terminated rebate agreements with a number of manufacturers for failure to report AMPs and, for the purposes of evaluating potential civil money penalties, has referred

[13] Sections 1927(a)(1) and (b)(1) of the Act.
[14] Section 1927(b)(3) of the Act.
[15] 42 CFR § 447.510.
[16] Section 1927(k)(1) of the Act, as amended by § 2503 of the Affordable Care Act, P.L. 111-148.
[17] Pursuant to § 1927(k)(10) of the Act, "retail community pharmacy" means an independent, chain, supermarket, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail; nursing home, long-term care, or hospital pharmacies; clinics; charitable or not-for-profit pharmacies; government pharmacies; or pharmacy benefit managers.
[18] Prior to October 2010, the AMP was generally defined by statute to be 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.
[19] As stated by the Department of Health & Human Services in its comments on a 2010 Government Accountability Office report entitled *Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the Formula under the Patient Protection and Affordable Care Act* (GAO-11-141R).
[20] This anticipated increase in AMPs may lessen the likelihood that a drug's ASP will exceed the 5-percent threshold, effectively making price substitution criteria more stringent.
[21] Sections 1927(b)(3)(C)(i) and (4)(B)(i) of the Act.
[22] The Secretary delegated to OIG the responsibility to impose civil money penalties for violations of § 1927(b)(3)(C) of the Act in 59 Fed. Reg. 52967 (Oct. 20, 1994).

to OIG manufacturers that failed to submit timely ASPs and AMPs. In September 2010, OIG announced an enforcement initiative under which it would begin imposing civil money penalties on manufacturers that failed to report timely ASPs and/or AMPs.[23]

OIG's Monitoring of ASPs and AMPs

In accordance with its statutory mandate, OIG has issued 19 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. In addition, OIG has completed three annual overviews of ASPs and AMPs, which examined data across all four quarters of 2007, 2008, and 2009, respectively.

OIG has consistently recommended that CMS develop a price substitution policy and subsequently lower reimbursement for drugs that exceed the 5-percent threshold as directed by the Act. Although CMS has yet to make any changes to Part B drug reimbursement as a result of OIG's studies, the agency published a proposed rule in July 2011 that, among other things, specifies the circumstances under which AMP-based price substitutions would occur.[24, 25] CMS plans to implement its price substitution policy beginning in the first quarter of 2012.[26]

CMS's Proposed Price Substitution Policy

Under CMS's July 2011 proposed price substitution policy, 103 percent of the AMP would be substituted for the ASP-based reimbursement amount when OIG identifies a HCPCS code that meets the 5-percent threshold in two consecutive quarters or three of four quarters. Because CMS believes that substituted prices based on partial AMP data may not adequately reflect market trends, the agency would lower reimbursement amounts only when ASP and AMP comparisons are based on the same set of NDCs (i.e., based on complete AMP data). HCPCS codes that meet the 5-percent threshold based on partial AMP data would not be eligible for price substitution.

Price substitutions would take effect in the quarter after OIG shares the results of its most recent pricing comparison and would remain in effect for one quarter.[27] To prevent CMS's proposed policy from inadvertently raising the Medicare reimbursement amount, a price substitution would not occur when the substituted amount is greater than the ASP-based payment amount calculated for the quarter in which the price substitution would take effect.[28]

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[23] OIG, *Special Advisory Bulletin: Average Manufacturer Price and Average Sales Price Reporting Requirements*, September 2010. Available online at http://www.oig.hhs.gov.

[24] 76 Fed. Reg. 42772, 42947 (July 19, 2011)

[25] CMS previously proposed a price substitution policy to be used for calendar year 2011 but opted not to finalize that policy based, in part, on impending changes to the definition of AMP (75 Fed. Reg. 73170, 73471).

[26] 76 Fed. Reg. 42772, 42947 (July 19, 2011)

[27] After that one quarter, the reimbursement amount would be either 106 percent of the volume-weighted ASP for the current quarter or, if the HCPCS code continues to meet CMS's price substitution criteria, 103 percent of the volume-weighted AMP for the current quarter.

[28] For example, if the AMP-based substitution amount were $5 and the ASP-based reimbursement amount were $4 for the quarter in which the substitution would take place, CMS would not make the price substitution.

METHODOLOGY

We obtained a file from CMS containing NDC-level ASP data from the first quarter of 2011, which were used to establish Part B drug reimbursement for the third quarter of 2011. 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 23, 2011. We also obtained AMP data from CMS for the first quarter of 2011, which were current as of May 12, 2011.

Analyzing ASP Data From the First Quarter of 2011

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 July 2011, CMS had established prices for 504 HCPCS codes based on the ASP reimbursement methodology mandated by the Act.[29] Reimbursement amounts for the 504 HCPCS codes were based on ASP data for 3,082 NDCs.

Analyzing AMP Data From the First Quarter of 2011

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 complete AMP data—i.e., HCPCS codes with AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs;

(2) HCPCS codes with partial AMP data—i.e., 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—i.e., 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, one tablet, one capsule). In contrast, the ASP is reported for the entire amount of the drug contained in the NDC (e.g., 50 milliliters, 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, Thomson Reuters' *Red Book*, and the Food and Drug

[29] Section 1847A(b)(6) of the Act.

Administration's NDC directory.[30] For certain NDCs, we were unable to identify the amount of the drug reflected by the ASP or AMP and therefore could not calculate a converted AMP. Because of these unsuccessful AMP conversions, nine 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. When calculating the volume-weighted AMP for a HCPCS code with partial AMP data, we excluded any NDCs without AMPs; however, we did not exclude those NDCs from the corresponding volume-weighted ASP. This means that the volume-weighted AMP for a HCPCS code with partial AMP data is based on fewer NDCs than the volume-weighted ASP for that same code. Appendix B 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 Codes	Number of HCPCS Codes	Number of NDCs
Complete AMP Data	339	1,230
Partial AMP Data	105	1,045
No AMP Data	51	220

Source: OIG analysis of first-quarter 2011 ASP and AMP data, 2011.

Comparing First-Quarter 2011 Volume-Weighted ASPs and AMPs for HCPCS Codes With Complete AMP Data

For each of the 339 HCPCS codes with complete AMP data, 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 HCPCS codes that exceeded the 5-percent threshold, we reviewed the associated NDCs to verify the accuracy of the billing unit information. According to our review, one of the HCPCS codes that exceeded the threshold based on complete AMP data was associated with questionable billing units. Because volume-weighted ASPs and AMPs are calculated using this billing unit information, we could not be certain that the results for this code were correct. Therefore, we excluded this HCPCS code from our findings.

[30] We did not calculate converted AMPs for NDCs in the third group because those NDCs had no AMP data.

For each of the remaining HCPCS codes that exceeded the 5-percent threshold, we estimated the monetary impact of lowering reimbursement to 103 percent of the AMP.[31] First, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the third-quarter 2011 reimbursement amount for the HCPCS code. To estimate the financial effect for the third quarter of 2011, we then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2010, as reported in the PBAR.[32, 33]

To determine which HCPCS codes would have been subject to CMS's proposed price substitution policy, we identified codes with complete AMP data that met the 5-percent threshold in two consecutive or three of four quarters. We then totaled the estimated third-quarter 2011 savings for that subset of codes.

Comparing First-Quarter 2011 Volume-Weighted ASPs and AMPs for HCPCS Codes With Partial AMP data

For each of the 105 HCPCS codes with partial AMP data, 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 HCPCS codes that exceeded the 5-percent threshold, we reviewed the associated NDCs to verify the accuracy of the billing units. According to our review, two of the HCPCS codes that exceeded the threshold based on partial AMP data were associated with questionable billing units. 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 excluded these HCPCS codes from our findings.

For each of the remaining HCPCS codes that exceeded the 5-percent threshold based on partial AMP data, we determined whether missing AMPs unduly influenced the results of our pricing comparison. As mentioned previously, the volume-weighted AMP for a HCPCS code with partial AMP data is based on fewer NDCs than the volume-weighted ASP for that same code. Therefore, there may be a disparity between the volume-weighted ASP and AMP that would not exist if AMP data were available for the full set of NDCs. In other words, the volume-weighted ASP for the HCPCS code could exceed the volume-weighted AMP by at least 5 percent only because AMPs for certain NDCs were not represented.

CMS has expressed concern that partial AMP data may not adequately reflect market trends.[34] Therefore, to identify HCPCS codes with partial AMP data that exceeded the 5-percent threshold only because AMP data were missing, we reanalyzed pricing data after accounting for the

[31] Section 1847A(d)(3)(C) of the Act directs the Secretary to replace payment amounts for drugs that exceed 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.
[32] The PBAR data for 2010 were 98-percent complete when the data were downloaded in April 2011.
[33] This estimate assumes that the number of services that were allowed by Medicare in 2010 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2010 and 2011.
[34] 76 Fed. Reg. 42772, 42830 (July 19, 2011)

missing values. Specifically, we replaced each missing AMP with its corresponding ASP and recalculated the volume-weighted AMPs using those imputed prices.[35] We then compared those new volume-weighted AMPs to the volume-weighted ASPs originally calculated by CMS.

If a HCPCS code no longer exceeded the 5-percent threshold, we concluded that the missing AMPs were likely responsible for the HCPCS code initially exceeding the threshold, as opposed to an actual disparity between ASPs and AMPs in the marketplace.

If a HCPCS code continued to exceed the 5-percent threshold, we concluded that missing AMPs had little impact on the results of our pricing comparison. These HCPCS codes likely exceeded the threshold as a result of actual pricing differences between ASPs and AMPs. Because price substitutions for these HCPCS codes may be warranted, we estimated the monetary impact of lowering reimbursement to 103 percent of the new volume-weighted AMPs. We also identified HCPCS codes with partial AMP data that met the threshold in two consecutive or three of four quarters and totaled the estimated third-quarter 2011 savings for that subset of codes.

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 Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

Of the 339 Drug Codes With Complete AMP Data, Volume-Weighted ASPs for 15 Exceeded the Volume-Weighted AMPs by at Least 5 Percent

As mandated by 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 2011, 15 of the 339 HCPCS codes with complete AMP data (4 percent) exceeded this 5-percent threshold. Table 2 describes the extent to which ASPs exceeded AMPs for the 15 HCPCS codes. For three of the codes, the volume-weighted ASP exceeded the volume-weighted AMP by more

[35] Although an NDC's ASP is not usually the same as its AMP, it is generally within about 5 percent of the AMP at the median. Therefore, we believe that ASP acts as a reasonable proxy for AMP, ensuring that the NDC is represented in both the volume-weighted ASP and the volume-weighted AMP for the HCPCS code.

than 70 percent. A list of all 15 HCPCS codes, including their descriptions and HCPCS dosage amounts, is presented in Appendix C.

Table 2: Extent to Which ASPs Exceeded AMPs for 15 HCPCS Codes With Complete AMP Data

Percentage	Number of Codes
5.00–9.99%	6
10.00–19.99%	5
20.00–29.99%	0
30.00–39.99%	1
40.00–49.99%	0
50.00–59.99%	0
60.00–69.99%	0
70.00–79.99%	1
80.00–89.99%	0
90.00–99.99%	1
100% and above	1
Total	**15**

Source: OIG analysis of first-quarter 2011 ASP and AMP data, 2011.

Pursuant to section 1847A(d)(3) of the Act, the Secretary may disregard the ASP for a drug that exceeds the 5-percent threshold and shall substitute the payment amount with the lesser of either the widely available market price or 103 percent of the AMP. If reimbursement amounts for all 15 codes with complete AMP data had been based on 103 percent of the AMPs during the third quarter of 2011, Medicare expenditures would have been reduced by an estimated $788,000 in that quarter alone.[36] One of the fifteen HCPCS codes accounted for over 70 percent of the $788,000. If the reimbursement amount for code J9214 had been based on 103 percent of the AMP during the third quarter of 2011, we estimate that Medicare expenditures would have been reduced by $569,000.

If CMS's proposed price substitution policy had been in effect, reimbursement amounts for almost half of the HCPCS codes (7 of 15) would have been reduced. These seven HCPCS codes had complete AMP data and met the 5-percent threshold in either two consecutive quarters or three of four quarters (see Table 3). If reimbursement amounts for the seven codes had been based on 103 percent of the AMPs during the third quarter of 2011, Medicare expenditures would have been reduced by an estimated $654,000.

[36] All savings estimates in this report assume that the number of services that were allowed by Medicare in 2010 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2010 and 2011.

Table 3: Seven HCPCS Codes With Complete AMP Data in the First Quarter of 2011 That Would Have Met CMS's Proposed Criteria for Price Substitution

HCPCS Code	Previous Comparisons of ASPs and AMPs			
	First Quarter 2011	Fourth Quarter 2010	Third Quarter 2010	Second Quarter 2010
J9214	X	X	X	X
J9060	X	X	X	
J0287	X	X		
J1364	X	X		
J1650	X	X		
J1955	X	X		
J9370	X	X		

In all quarters, codes exceeded the 5-percent threshold based on complete AMP data.
Source: OIG analysis of ASP and AMP data from the second quarter of 2010 through the first quarter of 2011.

Of the 105 Drug Codes With Partial AMP Data, Volume-Weighted ASPs for 20 Exceeded the Volume-Weighted AMPs by at Least 5 Percent

In addition to examining HCPCS codes with complete AMP data, we examined 105 HCPCS codes for which only partial AMP data were available. ASPs for 20 of these 105 HCPCS codes (19 percent) exceeded the AMPs by at least 5 percent in the first quarter of 2011. A list of the 20 HCPCS codes, including their descriptions and HCPCS dosage amounts, is presented in Appendix D.

For half of the HCPCS codes, missing AMPs likely had little influence on the outcome of the pricing comparisons. Ten of the twenty HCPCS codes with partial AMP data continued to exceed the threshold when we accounted for missing AMPs, suggesting that the pricing comparisons for these codes were accurately capturing underlying market trends even though AMP data were not available for the full set of NDCs. Because missing AMPs likely had little influence on the pricing comparison results for these 10 HCPCS codes, price substitutions may be legitimately warranted in these cases. If reimbursement amounts for the 10 codes had been based on 103 percent of the AMPs, we estimate that Medicare expenditures would have been reduced by $651,000 during the third quarter of 2011. Table 4 describes the extent to which ASPs exceeded AMPs for the 10 HCPCS codes.

For the remaining 10 HCPCS codes, ASPs no longer exceeded the AMPs in the first quarter of 2011, indicating that these codes initially exceeded the threshold because of missing AMP data rather than a genuine pricing disparity between the ASPs and AMPs.

Table 4: Extent to Which ASPs Exceeded AMPs for 10 HCPCS Codes With Partial AMP Data

Percentage	Number of Codes
5.00–9.99%	3
10.00–19.99%	5
20.00–29.99%	0
30.00–39.99%	1
40.00–49.99%	0
50.00–59.99%	0
60.00–69.99%	0
70.00–79.99%	1
80.00–89.99%	0
90.00–99.99%	0
100% and above	0
Total	**10**

Source: OIG analysis of first-quarter 2011 ASP and AMP data, 2011.

Of the 10 HCPCS codes on which missing AMPs likely had little influence, 7 met the 5-percent threshold in either 2 consecutive or 3 of 4 quarters. Although CMS's proposed price substitution policy would not apply to HCPCS codes with partial AMP data, ASPs for these seven codes repeatedly met or exceeded the AMPs by at least 5 percent. If reimbursement amounts for the seven codes had been substituted with 103 percent of the AMPs, Medicare expenditures would have been reduced by an estimated $350,000 during the third quarter of 2011. Table 5 presents a list of the seven HCPCS codes and the quarters during which they previously exceeded the 5-percent threshold.

Table 5: Seven HCPCS Codes With Partial AMP Data in the First Quarter of 2011 That Met the 5-Percent Threshold in Two Consecutive or Three of Four Quarters

	Previous Comparisons of ASPs and AMPs			
HCPCS Code	First Quarter 2011	Fourth Quarter 2010	Third Quarter 2010	Second Quarter 2010
J1020	X	X	X*	
J9045	X	X*		X
Q0165	X	X		X
J9190	X		X	X*
J7509	X	X		
Q0164	X	X		
Q0179	X	X		

*These codes previously exceeded the 5-percent threshold during the specified quarters based on complete AMP data. For all other quarters, codes exceeded the 5-percent threshold based on partial AMP data.
Source: OIG analysis of ASP and AMP data from the second quarter of 2010 through the first quarter of 2011.

Pricing Comparisons Could Not Be Performed on 51 Drug Codes Because No AMP Data Were Available

For 51 HCPCS codes, OIG could not compare ASPs and AMPs because there were no AMP data for any of the 220 NDCs that CMS used when calculating drug reimbursement amounts for these codes. In 2010, Medicare allowances for these 51 codes totaled $322 million.[37]

Manufacturers for 9 percent of the NDCs without AMP data (20 of 220) participated in the Medicaid drug rebate program as of the first quarter of 2011 and were therefore generally required to submit AMP data for their covered outpatient drugs.[38, 39, 40]

Manufacturers for the remaining 200 of 220 NDCs did not participate in the Medicaid drug rebate program and therefore were not required to submit AMP data.

CONCLUSION

This is OIG's 23rd 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. To monitor Medicare reimbursement amounts based on ASPs and consistent with its statutory mandate, OIG compared ASPs and AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by at least 5 percent.

We identified 35 HCPCS codes that exceeded the threshold for price adjustment in the first quarter of 2011. Of these, 15 had complete AMP data (i.e., AMP data for every drug product that CMS used to establish reimbursement amounts). If CMS's proposed price substitution policy had been in effect, reimbursement amounts for 7 of the 15 HCPCS codes would have been lowered to 103 percent of the AMP, thereby saving Medicare and its beneficiaries $654,000 in that quarter alone. The remaining 20 of 30 HCPCS codes also exceeded the 5-percent threshold in the first quarter of 2011 but did not have AMP data for every drug product that CMS used when calculating reimbursement. Although CMS's proposed price substitution policy would not apply to codes with partial AMP data, price reductions may be legitimately warranted for half of the 20 codes because missing AMPs likely had little influence on the pricing comparison results. We could not compare ASPs and AMPs for 51 HCPCS codes because AMP data were not submitted for any of the NDCs that CMS used to calculate reimbursement. Manufacturers for 9 percent of these NDCs had Medicaid drug rebate agreements and were therefore generally

[37] Of the 51 HCPCS codes with no associated AMP data, 1 was not listed in the 2010 PBAR file. As a result, this code was not included in the total Medicare allowances for the year.

[38] To determine whether a manufacturer participated in the Medicaid drug rebate program, we consulted CMS's *Participating Drug Companies*, accessed at http://www.cms.gov on July 5, 2011.

[39] 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.

[40] These 20 NDCs were crosswalked to 14 HCPCS codes.

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.

Although we do not make recommendations in this report, some of OIG's previous pricing comparisons have contained recommendations, which we continue to support.[41] In response to OIG's most recent report with recommendations, CMS questioned whether the payoff associated with price substitution justifies the resources that OIG devotes to quarterly pricing comparisons, suggesting that OIG limit its efforts to a single annual report. However, until CMS complies with its statutory responsibility to lower reimbursement amounts for eligible drugs, OIG will continue to meet its statutory mandate by issuing quarterly pricing comparisons along with annual overviews that recommend price substitutions as warranted.

This report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-03-11-00540 in all correspondence.

[41] For example, OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of* 2007, OEI-03-08-00450, December 2008; OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2008*, OEI-03-09-00350, February 2010; and OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2009*, OEI-03-10-00380, April 2011. These reports are available online at https://www.oig.hhs.gov.

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

Detailed Methodology for Converting and Volume-Weighting Average Manufacturer Prices for the First Quarter of 2011

Healthcare Common Procedure Coding System codes with complete average manufacturer price data. Of the 504 Healthcare Common Procedure Coding System (HCPCS) codes with reimbursement amounts based on average sales prices (ASP), 347 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 347 HCPCS codes represented 1,297 NDCs. For 10 NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These 10 NDCs were crosswalked to eight HCPCS codes. We did not include these eight HCPCS codes (67 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,230 NDCs, we calculated a volume-weighted AMP for each of the remaining 339 HCPCS codes consistent with CMS's methodology for calculating volume-weighted ASPs.

HCPCS codes with partial AMP data. There were 106 HCPCS codes with AMP data for only some of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 106 HCPCS codes represented a total of 1,565 NDCs. AMP data were either missing or unavailable for 514 of these NDCs, which were then excluded from our calculation of volume-weighted AMPs.[42]

We calculated converted AMPs for each of the remaining 1,051 NDCs. For 6 of the 1,051 NDCs, we could not identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. We removed these six NDCs from our analysis.[43] 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 1,045 NDCs, we then calculated a volume-weighted AMP for each of the remaining 105 HCPCS codes consistent with CMS's methodology for calculating volume-weighted ASPs.

[42] Although AMP data for these 514 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.

[43] 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 51 HCPCS codes, there were no AMP data for any of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 51 HCPCS codes represented 220 NDCs.

APPENDIX C

Fifteen Drug Codes With Complete Average Manufacturer Price Data That Exceeded the 5-Percent Threshold in the First Quarter of 2011

Drug Code	Short Description	Drug Code Dosage
J0130	Abciximab injection	10 mg
J0287	Amphotericin b lipid complex injection	10 mg
J0720	Chloramphenicol sodium injection	1 g
J1205	Chlorothiazide sodium injection	500 mg
J1364	Erythromycin lactobionate injection	500 mg
J1570	Ganciclovir sodium injection	500 mg
J1580	Garamycin gentamicin injection	80 mg
J1650	Enoxaparin sodium injection	10 mg
J1955	Levocarnitine injection	1 g
J2545	Pentamidine isethionate inhalation solution	300 mg
J2916	Sodium ferric gluconate complex injection	12.5 mg
J9060	Cisplatin injection	10 mg
J9100	Cytarabine HCl injection	100 mg
J9214	Interferon alfa-2b injection	1 million units
J9370	Vincristine sulfate injection	1 mg

mg = milligram, g = gram
Source: Office of Inspector General analysis of first-quarter 2011 average sales price and average manufacturer price data, 2011.

APPENDIX D

Twenty Drug Codes With Partial Average Manufacturer Price Data That Exceeded the 5-Percent Threshold in the First Quarter of 2011

Drug Code	Short Description	Drug Code Dosage
90586	Bcg vaccine, for intravesical use	1 each
J0171	Adrenalin epinephrine injection	0.1 mg
J0290	Ampicillin injection	500 mg
J1020	Methylprednisolone injection	20 mg
J1162	Digoxin immune fab (ovine)	per vial
J1190	Dexrazoxane HCl injection	250 mg
J1644	Heparin sodium injection	1000 units
J2370	Phenylephrine HCl injection	1 mL
J2700	Oxacillin sodium injection	250 mg
J7509	Methylprednisolone, oral	4 mg
J9031	Bcg (intravesical)	1 each
J9045	Carboplatin injection	50 mg
J9190	Fluorouracil injection	500 mg
J9206	Irinotecan injection	20 mg
J9390	Vinorelbine tartrate injection	10 mg
Q0163	Diphenhydramine HCl injection	50 mg
Q0164	Prochlorperazine maleate, oral	5 mg
Q0165	Prochlorperazine maleate, oral	10 mg
Q0179	Ondansetron HCl, oral	8 mg
Q9966	Low osmolar contrast material, 200-299 mg/ml iodine	1 mL

mg = milligram, mL = milliliter
Source: Office of Inspector General analysis of first-quarter 2011 average sales price and average manufacturer price data, 2011.