NOV - 1 2010

TO: Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: Stuart Wright /S/
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Comparison of First-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2010*, OEI-03-10-00440

This review was conducted in accordance with the statutory mandate for the Office of Inspector General (OIG) to compare 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 estimated the financial impact of lowering reimbursement amounts for drugs that met the 5-percent threshold and additionally examined the potential effect of a July 2010 proposed rule that, among other things, specifies the circumstances under which the Centers for Medicare & Medicaid Services (CMS) will make AMP-based price substitutions.

Since the advent of the ASP reimbursement methodology, OIG has issued 17 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 2010. Of the 318 drugs with complete AMP data in that quarter, 13 met the 5-percent threshold. If CMS's proposed price substitution policy had been in effect, reimbursement amounts for 10 of the 13 drugs would have been reduced, resulting in an estimated savings of $840,000 in the third quarter of 2010. Of the 134 drugs with only partial AMP data in the first quarter of 2010, 25 had ASPs that exceeded the AMPs by at least 5 percent. According to CMS's proposed price substitution policy, reimbursement amounts for drugs with partial AMP data would not be subject to reduction because the partial AMP data may not adequately reflect market trends. However, missing AMPs for 7 of the 25 drugs likely had little influence on the outcome of the pricing comparisons, which means that price reductions may be appropriate in these cases. We could not perform pricing comparisons for an additional 68 drugs because none of the drug products used to establish Medicare reimbursement had corresponding AMP data. Manufacturers for 23 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), section 1847A(d)(3)(A) of the Act states that the Secretary of the Department of Health & Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement amounts.[2] Section 1847A(d)(3)(C) of 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…."

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 over $11 billion for Part B drugs in 2009.[3] Although Medicare paid for nearly 800 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 2009, 64 HCPCS codes accounted for 90 percent of the expenditures for Part B drugs, with only 13 of these codes representing the majority (52 percent) of total Part B drug expenditures.

Reimbursement Methodology for Part B Drugs and Biologicals

Medicare Part B pays for most covered drugs using a reimbursement methodology based on ASPs.[4] As defined by law, an ASP is a manufacturer's sales of a drug to all purchasers in the

[1] Section 1847A(d)(2)(B) of the Act.
[2] 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.
[3] Medicare expenditures for Part B drugs in 2009 were calculated using CMS's Part B Analytics and Reports (PBAR). The PBAR data for 2009 were 98 percent complete when the data were downloaded in March 2010.
[4] Several Part B drugs, including certain vaccines and blood products, are not paid under the ASP methodology.

United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter.[5] 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.[6] 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.[7, 8]

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.[9] 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 2010 Medicare payments for most covered drug codes were based on first-quarter 2010 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.[10] 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.

---

[5] Section 1847A(c) of the Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173.

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

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

[8] 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.

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

[10] 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 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.[11] Under these rebate agreements and pursuant to the Act, manufacturers must provide CMS with the AMPs for each of their NDCs.[12] As further explained in regulation, manufacturers are required to submit AMPs within 30 days after the end of each month and each quarter.[13]

During the first quarter of 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.[14, 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, 1 tablet, 1 capsule).[16]

Penalties for Failure To Report Timely Drug Pricing Data

Under the law, 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.[17, 18] 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 to OIG manufacturers that failed to submit timely AMPs.[19] At the time of our review, no manufacturers had been terminated or formally referred to OIG for failure to report timely ASPs. In September 2010, OIG announced a new enforcement initiative under which OIG would begin imposing civil money penalties on manufacturers that failed to report timely ASPs and/or AMPs.

Office of Inspector General's Monitoring of ASPs and AMPs

In accordance with its statutory mandate, OIG has issued 15 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. In addition, OIG has completed two annual overviews of ASPs and AMPs, which examined data

[11] Sections 1927(a)(1) and (b)(1) of the Act.
[12] Section 1927(b)(3) of the Act.
[13] 42 CFR § 447.510.
[14] Section 1927(k)(1) of the Act.
[15] Effective October 2010, section 2503 of the Patient Protection and Affordable Care Act, P.L. 111-148, changes the definition of AMP in a way that is not relevant for the purposes of this report. However, it may affect pricing comparisons between ASPs and AMPs for the fourth quarter of 2010 and beyond.
[16] As specified in 42 CFR § 447.504(i), a quarterly AMP is calculated as a weighted average of monthly AMPs in the quarter. However, the manufacturer must adjust the AMP for a quarter if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.
[17] Sections 1927(b)(3)(C)(i) and (4)(B)(i) of the Act.
[18] The Secretary delegated to OIG the responsibility to impose civil money penalties for violations of section 1927(b)(3)(C) of the Act in 59 Fed. Reg. 52967 (Oct. 20, 1994).
[19] CMS began referring noncompliant manufacturers to OIG in response to a 2005 report entitled *Deficiencies in the Oversight of the 340B Drug Pricing Program* (OEI-05-02-00072). As part of this report, OIG recommended that CMS consider referring manufacturers whose pricing data submissions do not comply with reporting requirements to OIG so that penalties could be imposed in appropriate cases.

across all four quarters of 2007 and 2008, respectively. A list of all 17 reports is provided in Appendix B.

OIG has consistently recommended that CMS develop a process to adjust payment amounts based on the results of these pricing comparisons and subsequently lower reimbursement for drugs that meet the 5-percent threshold. Although CMS has yet to make any changes to Part B drug reimbursement as a result of these studies, the agency published a proposed rule in July 2010 that, among other things, specifies the circumstances under which AMP-based price substitutions would occur.[20]

CMS's Proposed Price Substitution Policy

Under CMS's 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. 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. Although CMS plans to implement its price substitution policy beginning in 2011, no payment substitutions will occur before a preliminary injunction issued on December 19, 2007, by the United States District Court for the District of Columbia is vacated.[21, 22]

METHODOLOGY

We obtained a file from CMS containing NDC-level ASP data from the first quarter of 2010, which were used to establish Part B drug reimbursement amounts for the third quarter of 2010. 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 29, 2010. We also obtained AMP data from CMS for the first quarter of 2010, which were current as of May 10, 2010.

Analyzing ASP Data From the First Quarter of 2010

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

[20] 75 Fed. Reg. 40040, 40259 (July 13, 2010).
[21] 75 Fed. Reg. 40040, 40158 (July 13, 2010).
[22] The injunction prohibits CMS from using AMPs in a way that affects Medicaid reimbursement rates and from disclosing AMPs to States and the public.

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 2010, CMS had established prices for 529 HCPCS codes based on the ASP reimbursement methodology mandated by section 1847A(b)(6) of the Act. Reimbursement amounts for the 529 HCPCS codes were based on ASP data for 3,203 NDCs.

Analyzing AMP Data From the First Quarter of 2010

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, 1 tablet, 1 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 Administration's NDC directory.[23] 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 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 C provides a more detailed description of the

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

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	318	1,138
Partial AMP Data	134	1,081
No AMP Data	68	260

Source: OIG analysis of first-quarter 2010 ASP and AMP data, 2010.

Comparing First-Quarter 2010 Volume-Weighted ASPs and AMPs for HCPCS Codes With Complete AMP Data

For each of the 318 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 met the 5-percent threshold, we reviewed the associated NDCs to verify the accuracy of the billing unit information. According to our review, none of the HCPCS codes that met the threshold based on complete AMP data were associated with questionable billing units. However, we excluded one HCPCS code from our findings because the manufacturer of the corresponding NDC indicated to OIG that the AMP data were not correct.[24]

For each of the remaining HCPCS codes that met the 5-percent threshold, we estimated the monetary impact of lowering reimbursement to 103 percent of the AMP.[25] First we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the third-quarter 2010 reimbursement amount for the HCPCS code. To estimate the financial effect for the third quarter of 2010, we then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2009, as reported in the PBAR.[26, 27] 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

[24] In the course of a previous study (see OEI-03-09-00350), a manufacturer notified us that the AMP data for one of its NDCs were incorrect for all four quarters of 2008. The first-quarter 2010 AMP for that NDC was the same as the fourth-quarter 2008 AMP identified by the manufacturer as incorrect; therefore, we assumed that the first-quarter 2010 AMP was incorrect as well. We will provide the name of this manufacturer to CMS for followup.

[25] 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.

[26] The PBAR data for 2009 were 98 percent complete when the data were downloaded in March 2010.

[27] All savings estimates in this report assume that the number of services that were allowed by Medicare in 2009 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2009 and 2010.

in two consecutive or three of four quarters. We then totaled the estimated savings for that subset of codes.

Comparing First-Quarter 2010 Volume-Weighted ASPs and AMPs for HCPCS Codes With Partial AMP Data

For each of the 134 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 met the 5-percent threshold, we reviewed the associated NDCs to verify the accuracy of the billing units. According to our review, NDCs 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 results for this code were correct. Therefore, we excluded this HCPCS code from our findings.

For each of the remaining HCPCS codes that met the 5-percent threshold, 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.

To identify HCPCS codes with partial AMP data that met the 5-percent threshold only because AMP data were missing, we reanalyzed pricing data after accounting for the missing values. Specifically, we replaced each missing AMP with its corresponding ASP and recalculated the volume-weighted AMPs using those imputed prices.[28] We then compared those new volume-weighted AMPs to the volume-weighted ASPs originally calculated by CMS.

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

If a HCPCS code continued to meet the 5-percent threshold, we concluded that missing AMPs had little impact on the results of our pricing comparison. These HCPCS codes likely met 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 savings for that subset of codes.

[28] Although an NDC's ASP is not usually the same as its AMP, it is generally within about 5 percent of the AMP on average. 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.

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 318 Drug Codes With Complete AMP Data, Volume-Weighted ASPs for 13 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 2010, 13 of the 318 HCPCS codes with complete AMP data (4 percent) met this 5-percent threshold. Table 2 describes the extent to which ASPs exceeded AMPs for the 13 HCPCS codes. For one of the codes, the volume-weighted ASP exceeded the volume-weighted AMP by more than 20 percent. A list of all 13 HCPCS codes, including their descriptions and HCPCS dosage amounts, is presented in Appendix D.

Table 2: Extent to Which ASPs Exceeded AMPs for 13 HCPCS Codes With Complete AMP Data

Percentage by Which ASP Exceeded AMP	Number of HCPCS Codes
5.00%–9.99%	7
10.00%–19.99%	5
20.00%–29.99%	1
30.00%–39.99%	0
40.00%–49.99%	0
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	0
Total	**13**

Source: OIG analysis of first-quarter 2010 ASP and AMP data, 2010.

Pursuant to section 1847A(d)(3) of the Act, the Secretary may disregard the ASP for a drug that meets 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 13 codes with complete AMP data had been based on 103 percent of the AMPs during the third quarter of 2010, we estimate that Medicare expenditures would have been reduced by $988,000 in that quarter alone.[29] Three of the thirteen HCPCS codes accounted for over 90 percent of the estimated savings. If the reimbursement amounts for codes J9214, J2792, and J2916 had been based on 103 percent of the AMPs during the third quarter of 2010, we estimate that Medicare expenditures would have been reduced by $591,000, $186,000, and $127,000, respectively.

If CMS's proposed price substitution policy had been in effect, reimbursement amounts for 10 of the 13 HCPCS codes would have been reduced. These 10 HCPCS codes had complete AMP data and met the 5-percent threshold in either two consecutive quarters or three of four quarters. If reimbursement amounts for the 10 codes had been based on 103 percent of the AMPs during the third quarter of 2010, Medicare expenditures would have been reduced by an estimated $840,000.

Table 3 presents a list of the 10 HCPCS codes that would have been eligible for price substitution if CMS's proposed policy had been in effect.

Table 3: Ten HCPCS Codes With Complete AMP Data in the First Quarter of 2010 That Would Have Met CMS's Proposed Criteria for Price Substitution

	OIG Reports Comparing ASP and AMP			
HCPCS Code	First Quarter 2010	Fourth Quarter 2009	Third Quarter 2009	Second Quarter 2009
J2765	X	X*	X	X
J2792	X	X	X	X
J2597	X		X	X
J0210	X	X	X	
J1327	X	X	X	
J9214	X	X	X	
J9340	X	X	X	
J9280	X	X		
J9290	X	X		
J9291	X	X		

*This code previously met the 5-percent threshold during the specified quarter based on partial AMP data. For all other quarters, codes met the 5-percent threshold based on complete AMP data. Source: OIG analysis of ASP and AMP data from the second quarter of 2009 through the first quarter of 2010.

[29] All savings estimates in this report assume that the number of services that were allowed by Medicare in 2009 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2009 and 2010.

Of the 134 Drug Codes With Partial AMP Data, Volume-Weighted ASPs for 25 Exceeded the Volume-Weighted AMPs by at Least 5 Percent

In addition to examining HCPCS codes with complete AMP data, we examined 134 HCPCS codes for which only partial AMP data were available. ASPs for 25 of these 134 HCPCS codes (19 percent) exceeded the AMPs by at least 5 percent in the first quarter of 2010. A list of the 25 HCPCS codes, including their descriptions and HCPCS dosage amounts, is presented in Appendix E.

For 7 of the 25 HCPCS codes, missing AMPs likely had little influence on the outcome of the pricing comparisons. Seven of the twenty-five HCPCS codes with partial AMP data continued to meet the threshold when we accounted for missing AMPs, suggesting that the pricing comparisons for these codes were accurately capturing underlying market trends even when 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 seven HCPCS codes, price substitutions may be legitimately warranted in these cases. If reimbursement amounts for the seven codes had been based on 103 percent of the AMPs, we estimate that Medicare expenditures would have been reduced by $27,000 during the third quarter of 2010.

Table 4 describes the extent to which ASPs exceeded AMPs for the seven HCPCS codes. For one of the codes, volume-weighted ASPs exceeded volume-weighted AMPs by almost 70 percent.

Table 4: Extent to Which ASPs Exceeded AMPs for Seven 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%	1
30.00%–39.99%	0
40.00%–49.99%	0
50.00%–59.99%	0
60.00%–69.99%	1
70.00%–79.99%	0
80.00%–89.99%	0
90.00%–99.99%	0
100% and above	0
Total	**7**

Source: OIG analysis of first-quarter 2010 ASP and AMP data, 2010.

For the remaining 18 of 25 HCPCS codes, ASPs no longer exceeded the AMPs by at least 5 percent in the first quarter of 2010, indicating that these codes initially met the threshold because of missing AMP data rather than a genuine pricing disparity between ASPs and AMPs.

Of the seven HCPCS codes on which missing AMPs likely had little influence, four met the 5-percent threshold in either two consecutive or three of four quarters. Although CMS's proposed price substitution policy would not apply to HCPCS codes with partial AMP data, ASPs for these four codes repeatedly met or exceeded the AMPs by at least 5 percent. If reimbursement amounts for the four codes had been substituted with 103 percent of the AMPs, Medicare expenditures would have been reduced by an estimated $10,000 during the third quarter of 2010.

Table 5 presents a list of the four HCPCS codes with partial AMP data that met the threshold in two consecutive or three of four quarters.

Table 5: Four HCPCS Codes With Partial AMP Data in the First Quarter of 2010 That Met the 5-Percent Threshold in Two Consecutive or Three of Four Quarters

	OIG Reports Comparing ASP and AMP			
HCPCS Code	First Quarter 2010	Fourth Quarter 2009	Third Quarter 2009	Second Quarter 2009
J0560	X	X	X*	X
J7509	X	X	X	X
J7506	X		X	X
J1940	X	X		

*This code previously met the 5-percent threshold during the specified quarters based on complete AMP data. For all other quarters, codes met the 5-percent threshold based on partial AMP data. Source: OIG analysis of ASP and AMP data from the second quarter of 2009 through the first quarter of 2010.

Pricing Comparisons Could Not Be Performed on 68 Drug Codes Because No AMP Data Were Available

For 68 HCPCS codes, OIG could not compare ASPs and AMPs because there were no AMP data for any of the 260 NDCs that CMS used when calculating drug reimbursement amounts for these codes. In 2009, Medicare allowances for these 68 codes totaled $345 million.[30]

Manufacturers for 23 percent of the NDCs without AMP data (60 of 260) participated in the Medicaid drug rebate program as of the first quarter of 2010 and were therefore generally required to submit AMP data for their covered outpatient drugs.[31, 32, 33] The majority of these 60 NDCs belonged to 4 manufacturers.

[30] Of the 68 HCPCS codes with no associated AMP data, 4 had no expenditures listed in the 2009 PBAR file. As a result, these codes were not included in the total Medicare allowances for the year.

[31] 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.

[32] 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.

[33] These 60 NDCs were crosswalked to 33 HCPCS codes.

Manufacturers for the remaining 200 of 260 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 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. This is OIG's 18th 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.

In the first quarter of 2010, we identified a total of 38 HCPCS codes that met the threshold for price adjustment specified in the Act. If CMS's proposed price substitution policy had been in effect, reimbursement amounts for 10 of these HCPCS codes would have been lowered to 103 percent of the AMP, resulting in an estimated savings of $840,000 for the quarter. Although CMS's proposed price substitution policy would not apply to codes with partial AMP data, we identified HCPCS codes for which price reductions may be legitimately warranted because missing AMPs likely had little influence on the pricing comparison results. We recognize that the estimated savings associated with these particular HCPCS codes is not substantial; however, by excluding from its policy all codes with partial AMP data, CMS may inadvertently provide drug manufacturers with a disincentive to submit timely AMPs. We could not compare ASPs and AMPs for 68 HCPCS codes because AMP data were not submitted for any of the NDCs that CMS used to calculate reimbursement. Manufacturers for 23 percent 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.[34] 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-03-10-00440 in all correspondence.

[34] For example, OEI-03-08-00450, December 2008; and OEI-03-09-00350, February 2010.

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

- *Comparison of First-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2009*, OEI-03-09-00490, August 2009

- *Comparison of Second-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2009*, OEI-03-09-00640, January 2010

- *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2008*, OEI-03-09-00350, February 2010

- *Comparison of Third-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010*, OEI-03-10-00150, April 2010

- *Comparison of Fourth-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2010*, OEI-03-10-00350, July 2010

APPENDIX C

Detailed Methodology for Converting and Volume-Weighting Average Manufacturer Prices for the First Quarter of 2010

Healthcare Common Procedure Coding System codes with complete average manufacturer price data. Of the 529 Healthcare Common Procedure Coding System (HCPCS) codes with reimbursement amounts based on average sales prices (ASP), 326 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 326 HCPCS codes represented 1,205 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 8 HCPCS codes. We did not include these 8 HCPCS codes (67 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,138 NDCs, we then calculated a volume-weighted AMP for each of the remaining 318 HCPCS codes consistent with CMS's methodology for calculating volume-weighted ASPs.

HCPCS codes with partial AMP data. There were 135 HCPCS codes with AMP data for only some of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 135 HCPCS codes represented a total of 1,738 NDCs. AMP data were either missing or unavailable for 650 of these NDCs, which were then excluded from our calculation of volume-weighted AMPs.[35]

We calculated converted AMPs for each of the remaining 1,088 NDCs. For 7 of the 1,088 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 seven NDCs from our analysis.[36] 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 1,081 NDCs, we then calculated a volume-weighted AMP for each of the remaining 134 HCPCS codes consistent with CMS's methodology for calculating volume-weighted ASPs.

[35] Although AMP data for these 650 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.

[36] 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 68 HCPCS codes, there were no AMP data for any of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 68 HCPCS codes represented 260 NDCs.

APPENDIX D

Thirteen Drug Codes With Complete Average Manufacturer Price Data That Met the 5-Percent Threshold in the First Quarter of 2010

Drug Code	Short Description	Drug Code Dosage
J0210	Methyldopate HCl injection	250 mg
J0834	Cosyntropin cortrosyn injection	0.25 mg
J1020	Methylprednisolone injection	20 mg
J1327	Eptifibatide injection	5 mg
J2597	Desmopressin acetate injection	1 mcg
J2765	Metoclopramide HCl injection	10 mg
J2792	Rho(D) immune globulin injection	100 units
J2916	Na ferric gluconate complex	12.5 mg
J9214	Interferon alfa-2b injection	1 million units
J9280	Mitomycin injection	5 mg
J9290	Mitomycin injection	20 mg
J9291	Mitomycin injection	40 mg
J9340	Thiotepa injection	15 mg

mcg=microgram, mg=milligram
Source: Office of Inspector General analysis of first-quarter 2010 average sales price and average manufacturer price data, 2010.

APPENDIX E

Twenty-five Drug Codes With Partial Average Manufacturer Price Data That Met the 5-Percent Threshold in the First Quarter of 2010

Drug Code	Short Description	Drug Code Dosage
J0207	Amifostine	500 mg
J0560	Penicillin g benzathine injection	600,000 units
J0610	Calcium gluconate injection	10 ml
J0670	Mepivacaine HCl injection	10 ml
J1190	Dexrazoxane HCl injection	250 mg
J1940	Furosemide injection	20 mg
J2700	Oxacillin sodium injection	250 mg
J2790	Rho(D) immune globulin injection	300 mcg
J3130	Testosterone enanthate injection	200 mg
J3260	Tobramycin sulfate injection	80 mg
J3475	Magnesium sulfate injection	500 mg
J7506	Prednisone oral	5 mg
J7509	Methylprednisolone oral	4 mg
J7611	Albuterol, noncompounded, concentrated form	1 mg
J7613	Albuterol, noncompounded, unit dose	1 mg
J7620	Albuterol and ipratropium bromide, noncompounded	2.5 mg/0.5 mg
J9040	Bleomycin sulfate injection	15 units
J9060	Cisplatin injection	10 mg
J9062	Cisplatin injection	50 mg
J9178	Epirubicin HCl injection	2 mg
J9206	Irinotecan injection	20 mg
Q0164	Prochlorperazine maleate	5 mg
Q0165	Prochlorperazine maleate	10 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

mcg=microgram, mg=milligram, and ml=milliliter
Source: Office of Inspector General analysis of first-quarter 2010 average sales price and average manufacturer price data, 2010.