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SUBJECT: Memorandum Report: *Comparison of Fourth-Quarter 2011 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2012*, OEI-03-12-00410

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 also examined the potential effect of a July 2012 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

To ensure that ASP-based reimbursement amounts do not result in excessive payments, Congress mandated that OIG monitor ASPs by comparing them with AMPs and widely available market prices and directed CMS to lower reimbursement for certain drugs based on OIG's findings. Since the implementation of the ASP payment methodology in 2005, OIG has fulfilled its responsibility by issuing 25 reports comparing ASPs and AMPs. However, CMS has yet to lower reimbursement in response to OIG's findings and recommendations. This latest comparison examines drugs that exceeded the 5-percent threshold based on either complete or partial AMP data in the fourth quarter of 2011. Of the 383 drug codes with complete AMP data, 29 exceeded the 5-percent threshold. If reimbursement amounts for all 29 codes had been based on 103 percent of the AMPs in the second quarter of 2012, Medicare would have saved an estimated \$4.6 million in that quarter alone. Under CMS's proposed price substitution policy, reimbursement amounts for 14 of the 29 drugs would have been reduced, saving an estimated \$4.2 million in the quarter. Of the 63 drug codes with partial AMP data, 10 exceeded the 5-percent threshold. CMS has expressed concern that partial AMP data may not adequately reflect market trends and therefore will not apply its price substitution policy to drugs with

partial AMP data. However, we found that pricing comparisons for half of the 10 codes with partial AMP data seemed to accurately capture market trends; therefore, price reductions may be appropriate in these cases. We could not perform pricing comparisons for an additional 48 drug codes because none of the associated drug products had corresponding AMP data.

Manufacturers for 8 percent of the associated 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 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 Medicare contractors 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 \$12 billion for Part B drugs in 2011.⁵ Although Medicare paid for more than 500 outpatient prescription drug HCPCS codes that year, most of

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 2011 were calculated using CMS's Part B Analytics and Reports (PBAR). The PBAR data for 2011 were 98-percent complete when the data were downloaded in May 2012.

the spending for Part B drugs was concentrated on a relatively small subset of those codes. In 2011, 62 HCPCS codes accounted for 90 percent of the expenditures for Part B drugs, with only 13 of these codes representing the majority 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.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

Second-quarter 2012 Medicare payments for most covered drug codes were based on fourth-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

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.

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.

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). By law, AMP is defined as 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}

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.^{19, 20} 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 Patient Protection and 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 Sections 1927(b)(3)(C)(i) and (4)(B)(i) of the Act.

²⁰ 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 accordance with an enforcement initiative announced in September 2010, OIG has begun imposing civil money penalties on certain manufacturers that fail to report timely ASPs and/or AMPs.²¹

OIG's Monitoring of ASPs and AMPs

To comply with its statutory mandate, OIG has issued 21 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. In addition, OIG has completed four annual overviews of ASPs and AMPs, which examined data across all four quarters of 2007, 2008, 2009, and 2010, respectively.

OIG has consistently recommended that CMS develop a price substitution policy and lower the reimbursement amounts 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 2012 that, among other things, specifies the circumstances under which AMP-based price substitutions will occur, effective January 2013.^{22, 23}

CMS's Price Substitution Policy

According to its July 2012 proposed rule, CMS will substitute 103 percent of the AMP for the ASP-based reimbursement amount when OIG identifies a HCPCS code that exceeds the 5-percent threshold in two consecutive quarters or three of four quarters.²⁴ Because CMS believes that comparisons based on partial AMP data may not adequately reflect market trends, the proposed rule states that HCPCS codes exceeding the 5-percent threshold based on partial AMP data will not be eligible for price substitution. The proposed rule additionally states that price substitutions will take effect in the quarter after OIG shares the results of its most recent

²¹ OIG, *Special Advisory Bulletin: Average Manufacturer Price and Average Sales Price Reporting Requirements*, September 2010. Available online at <http://www.oig.hhs.gov>.

²² 77 Fed. Reg. 44722, 45057 (July 30, 2012).

²³ This is the third time that CMS has pursued rulemaking on AMP-based price substitutions. In July 2010, CMS published a proposed rule that specified the circumstances under which price substitutions would occur, effective January 2011; however, the agency did not to finalize this proposed rule based, in part, on impending changes to the definition of AMP (75 Fed. Reg. 73170, 73471 (Nov. 29, 2010)). In November 2011, CMS published a final rule that again specified circumstances under which price substitutions would occur (76 Fed. Reg. 73026, 73473 (Nov. 28, 2011)). Although that final rule took effect in January 2012, CMS did not implement that policy in light of concerns about drug shortages.

²⁴ 77 Fed. Reg. 44722, 45057 (July 30, 2012).

pricing comparison and remain in effect for one quarter.^{25, 26} Drugs identified by the Food and Drug Administration (FDA) as being in short supply will not be eligible for price substitution.²⁷

METHODOLOGY

We obtained a file from CMS containing NDC-level ASP data from the fourth quarter of 2011, which were used to establish Part B drug reimbursement for the second quarter of 2012. 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 March 23, 2012. We also obtained AMP data from CMS for the fourth quarter of 2011, which were current as of April 10, 2012.

Analyzing ASP Data From the Fourth 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 March 2012, CMS had established prices for 508 HCPCS codes based on the ASP reimbursement methodology mandated by the Act.²⁸ Reimbursement amounts for the 508 HCPCS codes were based on ASP data for 3,144 NDCs.

Analyzing AMP Data From the Fourth 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

²⁵ After that one quarter, the reimbursement amount will 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.

²⁶ To prevent CMS's policy from inadvertently raising the Medicare reimbursement amount, a price substitution will 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. 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.

²⁷ 77 Fed. Reg. 44722, 45057 (July 30, 2012).

²⁸ Section 1847A(b)(6) of the Act.

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, drug labels, Thomson Reuters’ *Red Book*, and the Food and Drug Administration’s NDC directory.²⁹ 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, 14 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	383	1,724
Partial AMP Data	63	708
No AMP Data	48	199

Source: OIG analysis of fourth-quarter 2011 ASP and AMP data, 2012.

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

For each of the 383 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

²⁹ We did not calculate converted AMPs for NDCs in the third group because they had no AMP data.

billing unit information, we could not be certain that the results for this code were correct. Therefore, we excluded this HCPCS code from our count of codes with complete AMP data that exceeded the 5-percent threshold.

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.³⁰ First, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the second-quarter 2012 reimbursement amount for the HCPCS code. To estimate the financial effect for the second quarter of 2012, we then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2011, as reported in the PBAR.^{31, 32}

To determine which HCPCS codes would have been subject to CMS's price substitution policy, we identified codes with complete AMP data that met the 5-percent threshold in two consecutive or three of four quarters and were not identified by FDA as being in short supply. We then totaled the estimated fourth-quarter 2011 savings for that subset of codes.

Comparing Fourth-Quarter 2011 Volume-Weighted ASPs and AMPs for HCPCS Codes With Partial AMP Data

For each of the 63 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, three 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 count of codes with partial AMP data that exceeded the 5-percent threshold.

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.

³⁰ 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.

³¹ The PBAR data for 2011 were 98-percent complete when the data were downloaded in May 2012.

³² This estimate assumes that the number of services allowed by Medicare in 2011 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2011 and 2012.

CMS has expressed concern that partial AMP data may not adequately reflect market trends.³³ 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 missing values. Specifically, we replaced each missing AMP with its corresponding ASP and recalculated the volume-weighted AMPs using those imputed prices.³⁴ 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 also identified which of these HCPCS codes met the threshold in two consecutive or three of four quarters.

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 generally 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 383 Drug Codes With Complete AMP Data, Volume-Weighted ASPs for 29 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 fourth quarter of 2011, 29 of the 383 HCPCS codes with complete AMP data (8 percent) exceeded this 5-percent threshold. Table 2 describes the extent to which ASPs exceeded AMPs for the 29 HCPCS codes.

³³ 76 Fed. Reg. 73026, 73289 (Nov. 28, 2011).

³⁴ Although an NDC's ASP is not usually the same as its AMP, ASPs in 2011 were within 3 percent of the AMPs 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.

For 14 of the codes, the volume-weighted ASP exceeded the volume-weighted AMP by more than 20 percent. A list of all 29 HCPCS codes, including their descriptions and HCPCS dosage amounts, is presented in Appendix C.

Table 2: Extent to Which ASPs Exceeded AMPs for 29 HCPCS Codes With Complete AMP Data

Percentage	Number of Codes
5.00–9.99%	7
10.00–19.99%	8
20.00–29.99%	3
30.00–39.99%	3
40.00–49.99%	2
50.00–59.99%	0
60.00–69.99%	2
70.00–79.99%	0
80.00–89.99%	0
90.00–99.99%	0
100% and above	4
Total	29

Source: OIG analysis of fourth-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 29 codes with complete AMP data had been based on 103 percent of the AMPs during the second quarter of 2012, Medicare expenditures would have been reduced by an estimated \$4.6 million in that quarter alone.³⁵

If CMS’s proposed price substitution policy had been in effect, reimbursement amounts for almost half of the HCPCS codes (14 of 29) would have been reduced. These 14 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).³⁶ If reimbursement amounts for the 14 codes had been based on 103 percent of the AMPs during the second quarter of 2012, Medicare expenditures would have been reduced by an estimated \$4.2 million. One of these HCPCS codes accounted for the vast majority of the \$4.2 million. If the reimbursement amount for HCPCS code J7620 had been based on 103 percent of the AMP during the second quarter of 2012, Medicare expenditures would have been reduced by an estimated \$3.6 million.

³⁵ All savings estimates in this report assume that the number of services allowed by Medicare in 2011 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2011 and 2012.

³⁶ None of the drugs represented by the 14 HCPCS codes were identified by FDA as being in short supply as of July 2012.

Table 3: Fourteen HCPCS Codes With Complete AMP Data in the Fourth Quarter of 2011 That Would Have Met CMS’s Criteria for Price Substitution

Previous Comparisons of ASPs and AMPs				
HCPCS Code	Fourth Quarter 2011	Third Quarter 2011	Second Quarter 2011	First Quarter 2011
J1205	X	X	X	X
J1650	X	X	X	X
J9214	X	X	X	X
J0713	X	X	X	
J1070	X	X	X	
J2501	X	X	X	
J2780	X	X	X	
J3303	X	X	X	
J7620	X	X	X	
J9045	X	X		X*
J0500	X	X		
J1742	X	X		
J2675	X	X		
J9211	X	X		

* In this quarter, the code exceeded the 5-percent threshold based on partial AMP data. Source: OIG analysis of ASP and AMP data from the first through the fourth quarters of 2011.

Of the 63 Drug Codes With Partial AMP Data, Volume-Weighted ASPs for 10 Exceeded the Volume-Weighted AMPs by at Least 5 Percent

In addition to examining HCPCS codes with complete AMP data, we examined 63 HCPCS codes for which only partial AMP data were available. ASPs for 10 of these 63 HCPCS codes (16 percent) exceeded the AMPs by at least 5 percent in the fourth quarter of 2011. A list of the 10 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. Five of the ten 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 five HCPCS codes, price substitutions may be legitimately warranted in these cases. ASPs for four of these five HCPCS codes repeatedly exceeded the 5-percent threshold in either two consecutive or three of four quarters.

For the remaining 5 of 10 HCPCS codes, ASPs no longer exceeded the AMPs by at least 5 percent in the fourth quarter of 2011, suggesting that these codes initially exceeded the

threshold because of missing AMPs rather than a genuine pricing disparity between the ASPs and AMPs.

Pricing Comparisons Could Not Be Performed on 48 Drug Codes Because No AMP Data Were Available

For 48 HCPCS codes, OIG could not compare ASPs and AMPs because there were no AMP data for any of the 199 NDCs that CMS used when calculating drug reimbursement amounts for these codes. In 2011, Medicare allowances for these 48 codes totaled \$337 million.³⁷

Manufacturers for 8 percent of the NDCs without AMP data (16 of 199) participated in the Medicaid drug rebate program as of the fourth quarter of 2011 and were therefore generally required to submit AMP data for their covered outpatient drugs.^{38, 39, 40}

Manufacturers for the remaining 183 of 199 NDCs did not participate in the Medicaid drug rebate program and therefore were not required to submit AMP data.

CONCLUSION

When Congress established ASP as the basis for Medicare Part B drug reimbursement, it also provided a mechanism for ensuring that the new reimbursement methodology did not result in excessive payments. Specifically, Congress mandated that OIG monitor ASPs by comparing them with AMPs and widely available market prices and directed CMS to lower reimbursement for certain drugs based on OIG's findings. Since the ASP payment methodology took effect in January 2005, OIG has fulfilled its responsibility to monitor ASP-based payment amounts by issuing 25 comparisons between ASPs and AMPs, each of which identified Part B drugs that would have been eligible for price reductions under the law. However, CMS has yet to lower reimbursement in response to OIG's findings and recommendations.

In this current report, we identified 39 HCPCS codes that exceeded the threshold for price adjustment in the fourth quarter of 2011. Of these, 29 had complete AMP data (i.e., AMP data for every drug product that CMS used to establish reimbursement amounts). If reimbursement amounts for all 29 codes had been based on 103 percent of the AMPs in the second quarter of 2012, Medicare would have saved an estimated \$4.6 million in that quarter alone. Under CMS's proposed price substitution policy, reimbursement amounts for 14 of the 29 HCPCS codes would have been lowered to 103 percent of the AMP, thereby saving Medicare and its beneficiaries

³⁷ Of the 48 HCPCS codes with no associated AMP data, one was not listed in the 2011 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 April 30, 2012.

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 16 NDCs were crosswalked to 12 HCPCS codes.

\$4.2 million. The remaining 10 of 39 HCPCS codes also exceeded the threshold for price adjustment in the fourth quarter of 2011 but did so based on partial AMP data. Although CMS's price substitution policy will not apply to codes with partial AMP data, price reductions may be legitimately warranted for half of the 10 codes because missing AMPs likely had little influence on the pricing comparison results. We could not compare ASPs and AMPs for 48 HCPCS codes because AMP data were not submitted for any of the NDCs that CMS used to calculate reimbursement. Manufacturers for 8 percent of these NDCs had Medicaid drug rebate agreements and were therefore generally required to submit AMPs.

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 expressed uncertainty about the payoff associated with quarterly pricing comparisons, stating that the proposed price substitution policy will generate minor savings for the program. Although we acknowledge that the savings from any single OIG report may be modest relative to total expenditures for Part B drugs, significant savings would have accrued had CMS taken action immediately after OIG issued its first pricing comparison. In the long term, savings achieved through price substitution could reduce waste and conserve taxpayer funds at a time when increased focus has been placed on rising health care costs and fiscal responsibility.

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-03-12-00410 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; OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2009*, OEI-03-10-00380, April 2011; and OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2010*, OEI-03-11-00410, November 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).

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

APPENDIX B

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

Healthcare Common Procedure Coding System codes with complete average manufacturer price data. Of the 508 Healthcare Common Procedure Coding System (HCPCS) codes with reimbursement amounts based on average sales prices (ASP), 396 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 396 HCPCS codes represented 1,956 NDCs. For 30 NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These 30 NDCs were crosswalked to 13 HCPCS codes. We did not include these 13 HCPCS codes (232 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,724 NDCs, we calculated a volume-weighted AMP for each of the remaining 383 HCPCS codes consistent with CMS's methodology for calculating volume-weighted ASPs.

HCPCS codes with partial AMP data. There were 64 HCPCS codes with AMP data for only some of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 64 HCPCS codes represented a total of 989 NDCs. AMP data were either missing or unavailable for 273 of these NDCs, which were then excluded from our calculation of volume-weighted AMPs.⁴²

We calculated converted AMPs for each of the remaining 716 NDCs. For 8 of the 716 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 8 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 708 NDCs, we then calculated a volume-weighted AMP for each of the remaining 63 HCPCS codes consistent with CMS's methodology for calculating volume-weighted ASPs.

⁴² Although AMP data for these 273 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 48 HCPCS codes, there were no AMP data for any of the NDCs that CMS used in its calculation of volume-weighted ASPs. These 48 HCPCS codes represented 199 NDCs.

APPENDIX C**Twenty-Nine Drug Codes With Complete Average Manufacturer Price Data That Exceeded the 5-Percent Threshold in the Fourth Quarter of 2011**

Drug Code	Short Description	Drug Code Dosage
J0456	Azithromycin injection	500 mg
J0500	Dicyclomine injection	20 mg
J0515	Benzotropine mesylate injection	1 mg
J0595	Butorphanol tartrate injection	1 mg
J0610	Calcium gluconate injection	10 mL
J0670	Mepivacaine HCl injection	10 mL
J0713	Ceftazidime injection	500 mg
J0770	Colistimethate sodium injection	150 mg
J1070	Testosterone cypionate injection	100 mg
J1205	Chlorothiazide sodium injection	500 mg
J1650	Enoxaparin sodium injection	10 mg
J1742	Ibutilide fumarate injection	1 mg
J1756	Iron sucrose injection	1 mg
J1955	Levocarnitine injection	1 g
J2501	Paricalcitol injection	1 mcg
J2675	Progesterone injection	50 mg
J2780	Ranitidine HCl injection	25 mg
J3303	Triamcinolone hexacetonide injection	5 mg
J3411	Thiamine HCl injection	100 mg
J7620	Albuterol and ipratropium bromide, noncompounded	2.5 mg/0.5 mg
J7631	Cromolyn sodium, noncompounded, unit dose form	10 mg
J8510	Busulfan, oral	2 mg
J9045	Carboplatin injection	50 mg
J9065	Cladribine injection	1 mg
J9211	Idarubicin HCl injection	5 mg
J9214	Interferon alfa-2b injection	1 million units
J9280	Mitomycin injection	5 mg
J9293	Mitoxantrone HCl injection	5 mg
Q0167	Dronabinol, oral	2.5 mg

g=gram, mcg=microgram, mg=milligram, mL=milliliter

Source: Office of Inspector General analysis of fourth-quarter 2011 average sales price and average manufacturer price data, 2012.

APPENDIX D

Ten Drug Codes With Partial Average Manufacturer Price Data That Exceeded the 5-Percent Threshold in the Fourth 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
J1190	Dexrazoxane HCl injection	250 mg
J2700	Oxacillin sodium injection	250 mg
J2930*	Methylprednisolone injection	125 mg
J9031	Bcg live intravesical vaccine	1 each
Q0162*	Ondansetron, oral	1 mg
Q0163*	Diphenhydramine HCl, oral	50 mg
Q0164*	Prochlorperazine maleate, oral	5 mg
Q0165*	Prochlorperazine maleate, oral	10 mg

mg=milligram

*These drug codes continued to exceed the 5-percent threshold after the Office of Inspector General (OIG) accounted for missing average manufacturer prices (AMP).

Source: OIG analysis of fourth-quarter 2011 average sales price and AMPs, 2012.