Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COMPARISON OF AVERAGE SALES PRICES AND AVERAGE MANUFACTURER PRICES: AN OVERVIEW OF 2009

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EXECUTIVE SUMMARY

OBJECTIVES

1. To identify drugs with average sales prices (ASP) that exceeded average manufacturer prices (AMP) by at least 5 percent in any quarter of 2009.
2. To examine the impact of missing and unavailable AMP data on the Office of Inspector General's (OIG) pricing comparisons in 2009.

BACKGROUND

By law, OIG must compare ASPs with AMPs. As generally defined in statute, 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, net of any price concessions. Generally, manufacturers must provide the Centers for Medicare & Medicaid Services (CMS) with the ASP for each of their national drug codes (NDC) on a quarterly basis. For most Part B prescription drug Healthcare Common Procedure Coding System (HCPCS) codes, the Medicare reimbursement is equal to 106 percent of the volume-weighted ASPs for the associated NDCs.

During 2009, the AMP was generally defined as 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. Manufacturers that participate in the Medicaid drug rebate program must provide CMS with the AMP for each of their NDCs on a quarterly basis, with certain exceptions.

If OIG finds that the ASP for a HCPCS code exceeds the AMP by a certain percentage (5 percent through 2011), the Secretary of Health & Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement and shall substitute the payment amount with the lesser of either the widely available market price or 103 percent of the AMP. In July 2010, CMS published a proposed rule that, among other things, specified the circumstances under which AMP-based price substitutions would occur. Generally, CMS proposed to lower reimbursement amounts only for HCPCS codes with complete AMP data that exceed the 5-percent threshold in two consecutive or three of four quarters. However, the agency has opted not to finalize the price substitution policy from the proposed rule, thereby suspending any plans to lower reimbursement amounts based on the results of OIG's pricing comparisons.

To date, OIG has issued 19 reports comparing ASPs with AMPs. This current overview examines data across all four quarters of 2009. To identify HCPCS codes that exceeded the 5-percent threshold at least once during the year based on either complete or partial AMP data, we merged the results of our pricing comparisons for each quarter of 2009. To determine whether missing or unavailable AMPs unduly influenced the results of our pricing comparisons, we reanalyzed pricing data for HCPCS codes with partial AMP data after accounting for the missing values. We also identified the number of HCPCS codes that were removed from OIG's pricing comparisons because they did not have AMP data in 2009.

FINDINGS

In 2009, 34 HCPCS codes with complete AMP data exceeded the 5-percent threshold in one or more quarters. If reimbursement amounts for all 34 codes with complete AMP data had been lowered to 103 percent of the AMPs during the applicable quarters, we estimate that Medicare expenditures would have been reduced by $4.4 million between the third quarter of 2009 and the second quarter of 2010.

Of the 34 HCPCS codes, 11 would have been eligible for price reduction under CMS's proposed price substitution policy. If reimbursement amounts for these 11 HCPCS codes had been substituted during the applicable quarters, we estimate that Medicare expenditures would have been reduced by $1.9 million over four quarters.

In 2009, 34 HCPCS codes with partial AMP data exceeded the 5-percent threshold in one or more quarters. When we accounted for missing and unavailable AMPs, 13 of the 34 HCPCS codes continued to exceed the threshold in at least one quarter of 2009, 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 and unavailable AMP data had seemingly little influence on the pricing comparison results for these 13 HCPCS codes, price substitutions may be legitimately warranted in these cases.

For the remaining 21 of 34 HCPCS codes, ASPs no longer exceeded the AMPs in any quarter, indicating that these codes initially exceeded the threshold because of missing AMP data rather than a genuine pricing disparity between the ASPs and AMPs.

Because of NDCs without AMP data, the number of pricing comparisons performed in 2009 was reduced by at least 10 percent in each quarter. In total, 89 HCPCS codes were excluded from OIG's pricing comparisons in one or more quarters of 2009 because none of the associated NDCs had AMP data. For 46 of the 89 codes, we were unable to perform any pricing comparisons in 2009 because of NDCs without AMP data. Over 70 percent of these HCPCS codes (33 of 46) would never have been subject to our pricing comparisons because they were associated exclusively with NDCs for which manufacturers were not required to report AMP data.

RECOMMENDATIONS

The Social Security Act provides the Secretary authority to lower reimbursement amounts for drugs with ASPs that exceed AMPs by at least 5 percent. However, CMS has yet to adjust Part B reimbursement amounts based on the findings of OIG's pricing comparisons. Although CMS outlined a price substitution policy in a July 2010 proposed rule, the agency has opted not to finalize that policy.

OIG acknowledges that operational issues associated with potential price substitutions may be complex and that the concerns of relevant stakeholders, including beneficiaries and taxpayers, should be taken into consideration. However, to ensure that Medicare and its beneficiaries are paying appropriately for Part B drugs, the gap between ASPs and AMPs for certain drugs should be addressed. We therefore recommend that CMS:

Finalize the price substitution policy from the proposed rule and subsequently lower Medicare reimbursement amounts for drugs that exceed the 5-percent threshold.

Consider expanding the price substitution policy to include certain HCPCS codes with partial AMP data.

Consider seeking a legislative change to directly require all manufacturers of Part B-covered drugs to submit both ASPs and AMPs.

Continue to evaluate and pursue appropriate actions against manufacturers that fail to comply with price reporting requirements, including referring to OIG manufacturers that fail to submit timely ASP data.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Of the four recommendations included in our report, CMS concurred only with the recommendation intended to ensure timely reporting of pricing data. Specifically, CMS stated that it will continue referring to OIG any manufacturers that repeatedly fail to submit timely and/or accurate ASPs. However, CMS did not concur with OIG's two recommendations regarding the implementation of a price substitution policy, nor did it concur with our recommendation concerning the possible expansion of manufacturer reporting requirements for Part B drugs. According to its comments, CMS will proceed cautiously with respect to any future price substitution policy, particularly as it assesses the impact of changes to the definition of AMP. CMS also 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.

Since the ASP payment methodology took effect in January 2005, OIG has fulfilled its statutory responsibility to monitor ASP-based payment amounts by issuing 19 pricing comparisons identifying Part B drugs that are eligible for price reduction under the law. CMS has declined to take any action in response to OIG's findings and recommendations.

At present, CMS's primary obstacle to finalizing a price substitution policy appears to be the uncertainty surrounding changes in the definition of AMP. However, because AMPs are widely expected to increase under the new rule, CMS could proceed under the assumption that a drug's ASP may actually be less likely to exceed the 5-percent threshold, effectively making price substitution criteria more stringent. Once a price substitution policy has been implemented, OIG's quarterly pricing comparisons would enable CMS to make timely, responsive, short-term payment adjustments that prevent Medicare and its beneficiaries from overspending. In fact, significant savings would have accrued if CMS had taken action immediately after OIG issued its first pricing comparison.

Until the statutory mandate is changed or CMS complies with the law as written, OIG will continue to issue quarterly pricing comparisons, along with annual overviews that recommend price substitutions as warranted.

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INTRODUCTION

OBJECTIVES

1. To identify drugs with average sales prices (ASP) that exceeded average manufacturer prices (AMP) by at least 5 percent in any quarter of 2009.
2. To examine the impact of missing and unavailable AMP data on the Office of Inspector General's (OIG) pricing comparisons in 2009.

BACKGROUND

The Social Security Act (the Act) mandates that OIG compare ASPs with AMPs.[1] If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (5 percent through 2011), 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:

> … 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

The Centers for Medicare & Medicaid Services (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, physicians and suppliers submit claims to their

[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.

MACs using Healthcare Common Procedure Coding System (HCPCS) codes. CMS established the HCPCS to provide a standardized coding system for describing the specific items and services provided in the delivery of health care. In the case of prescription drugs, each HCPCS code defines the drug name and the amount of drug represented by the HCPCS code but does not specify the manufacturer or the package size.

Medicare and its beneficiaries spent over $11 billion for Part B drugs in 2009.[5] 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

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 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 the Medicaid 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

[5] 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 downloaded in March 2010.

[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 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.

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 Average Sales Prices

To calculate a volume-weighted ASP, CMS uses an equation that involves the following variables: the ASP for the 11-digit NDC as reported by the manufacturer, the volume of sales for the NDC as reported by the manufacturer, and the number of billing units in the NDC as determined by CMS.[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.

Under the ASP pricing methodology, the Medicare reimbursement for most Part B drugs is equal to 106 percent of the volume-weighted ASP for the HCPCS code.[13] However, a two-quarter lag exists between the sales period for which ASPs are reported and the effective date of the reimbursement amounts. For example, ASPs from the first quarter of 2009 were used to establish reimbursement amounts for the third quarter of 2009, and ASPs from the fourth quarter of 2009 were used to establish reimbursement amounts for the second quarter of 2010.

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

[12] 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.

[13] Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

The Medicaid Drug Rebate Program and Average Manufacturer Prices

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.[14] Under these rebate agreements and pursuant to the Act, manufacturers must provide CMS with the AMPs for each of their NDCs.[15] As further explained in the regulation, manufacturers are required to submit AMPs within 30 days after the end of each month and each quarter.[16]

During 2009, 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.[17, 18] 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).[19]

Penalties for Failure To Report Timely Drug Pricing Data

Pursuant to the Act, manufacturers that fail to provide ASP and AMP by the statutory deadline may be subject to civil money penalties and/or termination from the drug rebate program.[20, 21] Accordingly, CMS has terminated rebate agreements with a number of manufacturers for failure to report AMP data and, for the purposes of evaluating potential civil money penalties, has provided OIG with information about manufacturers that failed to submit timely

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[14] Sections 1927(a)(1) and (b)(1) of the Act.

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

[16] 42 CFR § 447.510.

[17] Section 1927(k)(1) of the Act.

[18] Effective October 2010, section 2503 of the Patient Protection and Affordable Care Act (Affordable Care Act), P.L. 111-148, changes the definition of AMP in a way that is not relevant to the findings of this report. However, it may affect pricing comparisons between ASPs and AMPs for the fourth quarter of 2010 and beyond.

[19] During 2009, 42 CFR § 447.504(i) specified that a quarterly AMP should be calculated as a weighted average of monthly AMPs in the quarter.

[20] Sections 1927(b)(3)(C)(i) and (4)(B)(i) of the Act.

[21] 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).

AMPs.[22] Recently, CMS also referred a manufacturer to OIG for failure to report timely ASP data.[23] 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 17 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. In addition, OIG completed two annual overviews of ASPs and AMPs, which examined data across all four quarters of 2007 and 2008, respectively. A list of all 19 reports is provided in Appendix B.

Although OIG has consistently recommended that CMS develop a price substitution policy and subsequently lower reimbursement for drugs that exceed the 5-percent threshold, no price substitutions have been made to date. In July 2010, CMS published a proposed rule that, among other things, specified the circumstances under which AMP-based price substitutions would occur.[24] However, the agency recently announced that it will not finalize the price substitution policy from the proposed rule, thereby suspending any plans to lower reimbursement amounts based on the results of OIG's pricing comparisons.[25]

CMS's price substitution policy in the July 2010 proposed rule. Under the unimplemented price substitution policy initially outlined in the July 2010 proposed rule, CMS would have substituted 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. Because CMS believes that substituted prices based on partial AMP data may not adequately

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[22] 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 to OIG manufacturers whose pricing data submissions do not comply with reporting requirements so that penalties could be imposed in appropriate cases.

[23] In a February 2010 report entitled *Average Sales Prices: Manufacturer Reporting and CMS Oversight,* OIG found that, from the first quarter of 2007 through the second quarter of 2008, between 41 and 52 percent of manufacturers in each quarter provided ASPs after the statutorily defined due date. In November 2010, CMS referred a manufacturer to OIG for failure to comply with ASP reporting requirements.

[24] 75 Fed. Reg. 40040, 40259 (July 13, 2010).

[25] 75 Fed. Reg. 73170, 73471 (Nov. 29, 2010).

reflect market trends, the agency would have lowered reimbursement amounts for HCPCS codes only if ASP and AMP comparisons were based on the same set of NDCs (i.e., based on complete AMP data). HCPCS codes that exceeded the 5-percent threshold based on partial AMP data would not have been eligible for price substitution.

Price substitutions would have taken effect in the quarter after OIG shared the results of its most recent pricing comparison and would have remained in effect for one quarter. To prevent CMS's proposed policy from inadvertently raising the Medicare reimbursement amount, a price substitution would not have been applied if the substituted amount were greater than the ASP-based payment amount calculated for the quarter in which the price substitution would take effect. Although CMS planned to implement its price substitution policy beginning in 2011, no price adjustments would have occurred before a preliminary injunction issued on December 19, 2007, by the U.S. District Court for the District of Columbia had been vacated.[26] This injunction prohibits CMS from using AMPs in a way that affects Medicaid reimbursement rates and from disclosing AMPs to States and the public.

CMS's price substitution policy in the November 2010 final rule. In a November 2010 final rule, CMS stated that it would not finalize the price substitution policy outlined in the July 2010 proposed rule.[27] CMS cited a number of factors in making this decision, including the ongoing preliminary injunction and upcoming regulations that will implement section 2503 of the Affordable Care Act, which amended the definition of AMP.[28] According to the final rule, CMS remains committed to proceeding cautiously as it continues to evaluate the impact of any future policy developments in this area. About 2 weeks after CMS published its final rule, the preliminary injunction was vacated.

METHODOLOGY

We obtained files from CMS containing NDC-level ASP data from the first through fourth quarters of 2009, which were used to establish

[26] 75 Fed. Reg. 40040, 40158 (July 13, 2010).

[27] 75 Fed. Reg. 73170, 73471 (Nov. 29, 2010).

[28] The Affordable Care Act was enacted on March 23, 2010. Section 2503 of the Affordable Care Act changes the definition of AMP, effective October 2010.

Part B drug reimbursement amounts for the third quarter of 2009 through the second quarter of 2010, respectively. These files also include information that crosswalks NDCs to their corresponding HCPCS codes. We also obtained AMP data from CMS for the first through fourth quarters of 2009.[29]

Calculating Volume-Weighted ASPs and Volume-Weighted AMPs for 2009

As mentioned previously, Medicare does not base reimbursement for covered drugs on NDCs; instead, it uses HCPCS codes. Therefore, CMS uses quarterly 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 part of our analysis for each of the 2009 quarterly reports, we calculated a volume-weighted AMP for each HCPCS code, consistent with CMS's methodology for calculating volume-weighted ASPs. To ensure that the broadest range of drug codes is subject to OIG's pricing comparisons, we examined 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), as well as 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). 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 methods used to calculate volume-weighted AMPs for HCPCS codes using complete or partial AMP data.

Comparing Volume-Weighted ASPs to Volume-Weighted AMPs for 2009

In each of our 2009 quarterly reports, we compared the volume-weighted ASPs and AMPs and identified HCPCS codes with ASPs that exceeded the AMPs by at least 5 percent using either

[29] ASP and crosswalk data from the first through fourth quarters of 2009 were current as of June 2009, October 2009, December 2009, and April 2010, respectively. AMP data from the first through fourth quarters of 2009 were current as of May 2009, September 2009, November 2009, and February 2010, respectively.

complete or partial AMP data. For those HCPCS codes that exceeded the 5-percent threshold, we conducted a review of the associated NDCs to verify the accuracy of the billing unit information for the quarter(s) in which the threshold was exceeded. If HCPCS codes had potentially inaccurate billing units, we excluded them from our findings.

As part of our 2009 annual overview, we merged the results of the four quarterly pricing comparisons to identify HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in one or more quarters of 2009. For each of the HCPCS codes we identified, we conducted additional analyses that differed depending on whether the HCPCS code had complete or partial AMP data.

Additional analysis of HCPCS codes with complete AMP data. For each of the HCPCS codes with complete AMP data that exceeded the 5-percent threshold in at least one quarter of 2009, we estimated the monetary impact of lowering reimbursement to 103 percent of the AMP.[30] In our separate quarterly pricing comparisons for 2009, savings estimates for codes that exceeded the threshold in the first through third quarters were based on CMS's PBAR data from 2008, whereas savings estimates for codes in the fourth quarter were based on PBAR data from 2009. To ensure that the savings estimates were consistent and reflective of the most current Medicare expenditures, we recalculated the savings estimates for the codes that exceeded the threshold in one or more quarters of 2009 using updated PBAR data for 2009. As a result, the estimated savings presented in this annual overview may differ from the savings presented in each of the separate quarterly reports previously published by OIG. Appendix D provides a more detailed description of the methods we used to estimate savings for HCPCS codes that exceeded the 5-percent threshold using complete AMP data.

At the time of our analysis, CMS had yet to publish its November 2010 final rule stating that the proposed price substitution policy would not be finalized. Because we assumed at the time that the price substitution policy would likely be implemented, we examined the

[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 (WAMP) 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 WAMPs had been available for these drugs and had been lower than 103 percent of the AMP, the savings estimate presented in this report would have been greater.

potential effect of the policy as part of our annual overview. To determine which HCPCS codes would have been subject to price reduction if CMS's proposed price substitution policy had been in effect during 2009, we identified codes with complete AMP data that exceeded the 5-percent threshold in two consecutive quarters or three of four quarters in 2009. We then totaled the estimated savings for that subset of codes.

Additional analysis of HCPCS codes with partial AMP data. For each of the HCPCS codes with partial AMP data that exceeded the 5-percent threshold in at least one quarter of 2009, we determined whether missing or unavailable AMP unduly influenced the results of our pricing comparisons.[31] 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.

As part of our annual overview, we identified HCPCS codes with partial AMP data that exceeded the 5-percent threshold in 2009 only because AMP data were missing or unavailable. To do this, we reanalyzed pricing data after accounting for the missing values. Specifically, we replaced each missing value with its corresponding ASP and recalculated the volume-weighted AMPs using those imputed prices.[32] 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 in a given quarter, we concluded that the missing or unavailable AMPs

[31] For the purposes of this study, an AMP was considered "missing" if the manufacturer had a Medicaid rebate agreement in 2009 but did not submit a price for the quarter. An AMP was considered "unavailable" for an NDC if the manufacturer did not participate in the Medicaid drug rebate program and was therefore not required to submit AMP data to CMS. To determine whether a manufacturer participated in the Medicaid drug rebate program in 2009, we consulted the list of participating drug companies posted on CMS's Web site.

[32] 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.

were likely responsible for the HCPCS code initially exceeding the threshold in that quarter, as opposed to an actual disparity between ASPs and AMPs in the marketplace.

If a HCPCS code continued to exceed the 5-percent threshold in a given quarter, we concluded that missing and unavailable AMPs had little impact on the results of our pricing comparison for that quarter. For these cases, the 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 for these codes to 103 percent of the new volume-weighted AMPs. We also determined which of these codes exceeded the threshold in two consecutive or three of four quarters in 2009 and totaled the estimated savings for that subset of codes.

Analyzing HCPCS Codes With No AMP Data in 2009

In each of our pricing comparisons for 2009, we excluded HCPCS codes that had missing or unavailable AMP data for all of the NDCs CMS used to calculate Medicare reimbursement. To identify the total number of HCPCS codes that were excluded from OIG pricing comparisons in 2009, we merged the results from each of the four quarterly reports. We then identified the number of HCPCS codes that were never included in OIG's pricing comparisons in 2009 because of missing or unavailable AMP data.

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. We also 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 within 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 any revised and/or missing 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.

FINDINGS

In 2009, 34 HCPCS codes with complete AMP data exceeded the 5-percent threshold in one or more quarters

Consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs with AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by a threshold of 5 percent. Of the 493 HCPCS codes examined during 2009, 34 exceeded this 5-percent threshold in at least one quarter based on complete AMP data only. Appendix E presents a list of the 34 HCPCS codes, including the quarter(s) during which the codes exceeded the 5-percent threshold.

Pursuant to sections 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 WAMP or 103 percent of the AMP. If reimbursement amounts for all 34 codes with complete AMP data had been lowered to 103 percent of the AMPs during the applicable quarters, we estimate that Medicare expenditures would have been reduced by $4.4 million between the third quarter of 2009 and the second quarter of 2010.[33]

Under CMS's proposed price substitution policy, reimbursement amounts for almost one-third of the 34 HCPCS codes would have been reduced, resulting in an estimated savings of almost $2 million over 1 year

If CMS's proposed price substitution policy had been in effect during 2009, reimbursement amounts for 11 of the 34 HCPCS codes would have been reduced in at least one quarter. These 11 HCPCS codes had complete AMP data and exceeded the 5-percent threshold in either two consecutive quarters or three of the four quarters in 2009. If reimbursement amounts for these 11 codes had been based on 103 percent of the AMPs during the applicable quarters, Medicare expenditures would have been reduced by an estimated $1.9 million between the third quarter of 2009 and the second quarter of 2010.

A list of the 11 HCPCS codes is included in Appendix E.

[33] ASP data from the first through fourth quarters of 2009 were used to establish reimbursement amounts for the third quarter of 2009 through the second quarter of 2010, respectively.

In 2009, 34 HCPCS codes with partial AMP data exceeded the 5-percent threshold in one or more quarters

Of the 493 HCPCS codes examined during 2009, 34 were eligible for price substitution in at least one quarter based on partial AMP data. Thirty-two of these 34 HCPCS codes exceeded the 5-percent threshold in any given quarter using only partial AMP data, whereas the remaining two codes exceeded the 5-percent threshold based on a mix of partial and complete AMP data. Appendix F presents a list of the 34 HCPCS codes, including the quarter(s) during which the codes exceeded the 5-percent threshold.

For over one-third of the HCPCS codes (13 of 34), missing and unavailable AMPs likely had little influence on the outcome of the pricing comparisons

When we accounted for missing and unavailable AMPs, 13 of the 34 HCPCS codes continued to exceed the threshold in at least one quarter of 2009, 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 and unavailable AMP data had seemingly little influence on the pricing comparison results for these 13 HCPCS codes, price substitutions may be legitimately warranted in these cases. If reimbursement amounts for the 13 codes had been based on 103 percent of the AMPs during the applicable quarters, we estimate that Medicare expenditures would have been reduced by $54,000 between the third quarter of 2009 and the second quarter of 2010. A list of the 13 HCPCS codes is included in Appendix F.

For the remaining 21 of 34 HCPCS codes, ASPs no longer exceeded the AMPs in any quarter, indicating that these codes initially exceeded the threshold because of missing AMP data rather than a genuine pricing disparity between the ASPs and AMPs.

Of the 13 HCPCS codes on which missing and unavailable AMPs likely had little influence, 7 exceeded the 5-percent threshold in two consecutive or three of the four quarters in 2009

ASPs for 7 of 13 HCPCS codes repeatedly exceeded the AMPs by at least 5 percent. In 2009, one of these HCPCS codes exceeded the 5-percent threshold in every quarter. An additional three HCPCS codes exceeded the 5-percent threshold in three of the four quarters. If reimbursement amounts for all seven codes had been lowered to 103 percent of the AMPs during the applicable quarters, we estimate

that Medicare expenditures would have been reduced by $33,000 between the third quarter of 2009 and the second quarter of 2010.

Because of NDCs without AMP data, the number of pricing comparisons performed in 2009 was reduced by at least 10 percent in each quarter

If a HCPCS code had no AMPs for any of its associated NDCs, we could not evaluate that code pursuant to sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act. In 2009, from 10 to 12 percent of HCPCS codes were excluded from OIG's pricing comparisons in each quarter because AMP data were missing or unavailable for all of the associated NDCs.[34, 35] Table 1 lists the number and percentage of HCPCS codes in each quarter that were excluded from our analysis and specifies the number of codes that were based on unavailable NDCs, missing NDCs, or a combination of both.

In total, 89 HCPCS codes were excluded from OIG's pricing comparisons in one or more quarters of 2009 because AMP data were missing or unavailable for all of the NDCs that CMS used to calculate Medicare reimbursement for that quarter. For 46 of the 89 codes, we were never able to perform pricing comparisons in 2009 because AMPs were always missing or unavailable for all of the associated NDCs. Over 70 percent of these HCPCS codes (33 of 46) would never have been subject to our pricing comparisons because they were associated exclusively with NDCs for which manufacturers were not required to report AMP data. In 2009, Medicare and its beneficiaries spent $100 million on these 33 drugs.[36]

[34] Relative to the total number of HCPCS codes in each quarter with Medicare reimbursement amounts based on the ASP payment methodology.

[35] For the purposes of this study, an AMP was considered "missing" if the manufacturer had a Medicaid rebate agreement in 2009 but did not submit a price for the quarter. An AMP was considered "unavailable" for an NDC if the manufacturer did not participate in the Medicaid drug rebate program and was therefore not required to submit AMP data.

[36] One of the 33 HCPCS codes had no expenditures listed in the 2009 PBAR file. Therefore, that code was not included in the $100 million total.

Table 1: HCPCS Codes That Were Excluded From 2009 Pricing Comparisons

Quarter in 2009	Number of HCPCS Codes Excluded Because None of the Corresponding NDCs Had AMP Data	Percentage of HCPCS Codes Excluded Because of NDCs Without AMP Data
First Quarter	**61**	**12%**
Codes with unavailable AMPs only	39	
Codes with missing AMPs only	17	
Codes with a mix of missing and unavailable AMPs	5	
Second Quarter	**51**	**10%**
Codes with unavailable AMPs only	36	
Codes with missing AMPs only	11	
Codes with a mix of missing and unavailable AMPs	4	
Third Quarter	**66**	**12%**
Codes with unavailable AMPs only	39	
Codes with missing AMPs only	21	
Codes with a mix of missing and unavailable AMPs	6	
Fourth Quarter	**62**	**12%**
Codes with unavailable AMPs only	38	
Codes with missing AMPs only	17	
Codes with a mix of missing and unavailable AMPs	7	

Source: OIG analysis of ASP and AMP data from the first through fourth quarters of 2009.

RECOMMENDATIONS

Section 1847A(d)(3)(C) of the Act directs the Secretary to lower reimbursement amounts for drugs with ASPs that exceed AMPs by at least 5 percent. However, CMS has yet to adjust Part B reimbursement amounts based on the findings of OIG's pricing comparisons. Although CMS outlined a price substitution policy in a July 2010 proposed rule, the agency has opted not to finalize that policy. In other words, CMS has suspended its plans to lower reimbursement amounts based on OIG's findings.

This current overview, which summarizes data across all four quarters of 2009, identified 34 drug codes that exceeded the 5-percent threshold using complete AMP data. If CMS's proposed price substitution policy had been in effect during 2009, reimbursement amounts for 11 of the 34 HCPCS codes would have been lowered to 103 percent of the AMPs, thereby saving Medicare and its beneficiaries an estimated $1.9 million.

An additional 34 HCPCS codes exceeded the 5-percent threshold using partial AMP data. We found that missing and unavailable AMPs for certain codes likely had little influence on the outcome of the pricing comparisons. Therefore, price substitution may be legitimately warranted for those HCPCS codes.

Furthermore, 10 to 12 percent of HCPCS codes were excluded from OIG's pricing comparisons in each quarter of 2009 because AMPs were missing or unavailable for all of the associated NDCs. Thirty-three HCPCS codes were never subject to our 2009 pricing comparisons because they were associated exclusively with NDCs for which manufacturers were not required to report AMP data.

OIG acknowledges that the operational issues associated with potential price substitutions may be complex and that the concerns of relevant stakeholders, including beneficiaries and taxpayers, should be taken into consideration. However, to ensure that Medicare and its beneficiaries are paying appropriately for Part B drugs, the gap between ASPs and AMPs for certain drugs should be addressed. We therefore recommend that CMS:

Finalize the price substitution policy from the proposed rule and subsequently lower Medicare reimbursement amounts for drugs that exceed the 5-percent threshold

CMS's proposed policy represented a positive step toward meeting statutory price substitution requirements and addressing the gap between ASPs and AMPs for certain Part B drugs. We recommend that CMS move forward with finalizing and applying this policy.

Consider expanding the price substitution policy to include certain HCPCS codes with partial AMP data

Because CMS believes that volume-weighted AMPs based on partial AMP data may not adequately account for market-related drug price changes and may lead to artificially low price substitutions, codes that exceed the 5-percent threshold using partial AMP data would not have been eligible for price reduction under CMS's proposed price substitution policy. However, for 13 HCPCS codes with partial AMP data in 2009, missing and unavailable AMPs likely had little influence on the outcome of the pricing comparisons. When we accounted for missing AMPs, these 13 HCPCS codes continued to exceed the threshold, indicating that the pricing comparisons were accurately capturing underlying market trends even though AMP data were not available for the full set of NDCs. Because the risk of substituting ASP-based reimbursement with an artificially low volume-weighted AMP is greatly diminished for these types of HCPCS codes, we suggest that CMS expand any future price substitution policy to include HCPCS codes identified by OIG as exceeding the threshold when missing AMPs have been imputed.

We recognize that substituting ASP-based reimbursement amounts for these particular HCPCS codes would not have resulted in substantial savings between the third quarter of 2009 and the second quarter of 2010; however, by including in any future policy at least certain codes with partial AMP data, CMS can avoid inadvertently providing drug manufacturers with a disincentive to submit timely AMPs.

Consider seeking a legislative change to directly require all manufacturers of Part B-covered drugs to submit both ASPs and AMPs

During 2009, between 36 and 39 HCPCS codes in each quarter could not be included in OIG's pricing comparisons because all of the associated NDCs belonged to manufacturers that did not have Medicaid rebate agreements and were therefore not required to provide AMP data to CMS. Thirty-three of these drugs had unavailable AMP data in all four quarters of 2009. Although Medicare and its beneficiaries spent $100 million for these drugs during that year, payment amounts for the drugs could not be monitored through pricing comparisons with AMPs. To ensure that Part B reimbursement reflects market trends for all covered drugs and is subject to regular price monitoring, CMS could seek a legislative change requiring all manufacturers of Part B-covered drugs to submit ASPs and AMPs, regardless of whether those manufacturers have rebate agreements.

Continue to evaluate and pursue appropriate actions against manufacturers that fail to comply with price reporting requirements, including referring to OIG manufacturers that fail to submit timely ASP data

We recognize that CMS has taken steps to ensure that certain pricing data are reported in a timely manner, including terminating manufacturers' rebate agreements for failure to report AMPs and referring manufacturers with untimely AMPs to OIG to face possible civil money penalties. Recently, CMS also referred a manufacturer to OIG for failure to report timely ASP data. If manufacturers repeatedly fail to report ASP data or repeatedly submit such data late, those manufacturers should face possible penalties.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

Of the four recommendations included in our report, CMS concurred only with the recommendation intended to ensure timely reporting of pricing data. Specifically, CMS stated that it will continue referring to OIG any manufacturers that repeatedly fail to submit timely and/or accurate ASPs.

CMS did not concur with our recommendation regarding the possible expansion of manufacturers' reporting requirements for Part B drugs. However, the Agency stated that it will continue to monitor manufacturer reporting trends and their effects on current payment policies.

CMS also did not concur with OIG's two recommendations regarding the implementation of a price substitution policy. In its comments, CMS reiterated that the proposed policy had not been finalized because of both the preliminary injunction and amendments to the definition of AMP required by the Affordable Care Act. Although the injunction has been recently vacated, CMS indicated that it will proceed cautiously with respect to any future price substitution policy, particularly as it assesses the impact of changes to the AMP definition.

In addition, CMS questioned whether the payoff associated with price substitution justifies the resources that OIG devotes to quarterly pricing comparisons, noting that the proposed price substitution policy would have saved only about $2 million in 2009. Because the Act provides discretion in determining the frequency of pricing comparisons, CMS suggested that OIG limit its efforts to a single annual report and pursue activities with higher potential rates of return.

OIG notes that 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 WAMPs 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 19 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 declined to take any action in response to OIG's findings and recommendations.

During the past six years, CMS has offered differing reasons for not complying with its statutory requirement to adjust reimbursement based on OIG's studies. At present, CMS's primary obstacle to finalizing a price substitution policy appears to be the uncertainty surrounding changes to the definition of AMP required by the Affordable Care Act. However, the impact of these changes is not so unpredictable as to warrant suspension of CMS's plans to lower reimbursement for eligible drugs. In response to a report issued by the Government Accountability Office (GAO), the Department of Health & Human Services acknowledged that the new AMPs, which are expected to be based on higher-priced sales, are likely to be higher than the AMPs calculated before October 2010.[37] 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.

Furthermore, if no payoff has been realized based on OIG's quarterly studies, it is only because CMS has yet to lower Part B reimbursement amounts for eligible drugs. Once a price substitution policy has been implemented, quarterly pricing comparisons would enable CMS to make responsive, short-term payment adjustments (as required by Federal law) that prevent Medicare and its beneficiaries from overspending. Such timely adjustments would not be possible with only annual OIG pricing comparisons.

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[37] GAO, *Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the Formula under the Patient Protection and Affordable Care Act*, GAO-11-141R.

Finally, OIG believes that CMS's comments regarding the $2 million in savings identified in this report fail to recognize the broader impact of price substitution over time. Although the savings from any single OIG report may have been small 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. OIG remains concerned that CMS has yet to lower ASP-based payment amounts as directed.

Until the statutory mandate is changed or CMS complies with the law as written, OIG will continue to issue quarterly pricing comparisons, along with annual overviews that recommend price substitutions as warranted.

For the full text of CMS's comments, please see Appendix G.

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

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- *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

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

- *Comparison of Second-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2010*, OEI-03-11-00030, February 2011

APPENDIX ~ C

Detailed Methodology for Calculating Volume-Weighted Average Manufacturer Prices for 2009

Before computing quarterly volume-weighted average manufacturer prices (AMP) for 2009, it was necessary to identify the national drug codes (NDC) that should be included in each quarter's calculations. To ensure that the broadest range of drug codes is subject to the Office of Inspector General's (OIG) pricing comparisons, we examined Healthcare Common Procedure Coding System (HCPCS) codes with complete AMP data (i.e., HCPCS codes with AMP data for every NDC that was used to calculate Medicare reimbursement), as well as HCPCS codes with partial AMP data (i.e., HCPCS codes with AMP data for only some of the NDCs that were used to calculate Medicare reimbursement).[38]

Calculating Converted Average Manufacturer Prices

An AMP is reported for the lowest identifiable quantity of the drug contained in the NDC (e.g., 1 milligram, 1 milliliter, one tablet, one capsule). In contrast, an ASP is reported for the entire amount of the drug contained in the NDC (e.g., for 50 milliliters, for 100 tablets). To ensure that AMPs would be comparable to ASPs, it was necessary to convert the AMPs for each NDC in each quarter so that they represented the total amount of the drug contained in that NDC.

To calculate "converted AMPs" for the NDCs included in each of our quarterly reports, we multiplied the AMP by the total amount of the drug contained in each NDC, as identified by sources such as the Centers for Medicare & Medicaid Services' crosswalk file, manufacturer Web sites, Thomson Reuters' *Red Book*, and the Food and Drug Administration's NDC directory.

For some NDCs, we could not identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. The extent to which NDCs with problematic AMP conversions affected our analysis differed depending on whether the associated HCPCS code had complete AMP data or partial AMP data.

[38] We excluded NDCs without AMPs when calculating volume-weighted AMPs for HCPCS codes with partial AMP data; however, the corresponding average sales prices (ASP) 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.

HCPCS codes with complete AMP data. If a HCPCS code with complete AMP data had one or more NDCs with a problematic AMP conversion, we automatically excluded that HCPCS code from our pricing comparison for the quarter.

HCPCS codes with partial AMP data. If a HCPCS code with partial AMP data had one or more NDCs with a problematic AMP conversion, we did not automatically exclude that HCPCS code from our pricing comparison. Rather, we removed only the NDCs with problematic AMP conversions. However, if all of the NDCs associated with the HCPCS code had problematic AMP conversions, we dropped the HCPCS code from that quarter's analysis.

Calculating Volume-Weighted Average Manufacturer Prices

Using the remaining NDCs with successful AMP conversions, we calculated a volume-weighted AMP for each of the corresponding HCPCS codes, consistent with the revised methodology for calculating volume-weighted ASPs.

APPENDIX ~ D

Detailed Methodology for Estimating Savings for Drug Codes That Exceeded the 5-Percent Threshold in 2009

If the average sales price (ASP) for a Healthcare Common Procedure Coding System (HCPCS) code exceeded the average manufacturer price (AMP) by at least 5 percent in any quarter of 2009, we estimated the savings associated with substituting the reimbursement amount for that code with 103 percent of the AMP.

A two-quarter lag exists between the sales period for which ASPs are reported and the effective date of the reimbursement amounts. As a result of this lag period, estimated savings for HCPCS codes that exceeded the 5-percent threshold during the first through fourth quarters of 2009 were applied to the third quarter of 2009 through the second quarter of 2010, respectively. We estimated savings only for the time period(s) during which a HCPCS code exceeded the 5-percent threshold.

For each of the HCPCS codes that exceeded the 5-percent threshold in a given quarter of 2009, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the reimbursement amount for the HCPCS code, which is equal to 106 percent of the volume-weighted ASP. To estimate the financial effect of lowering reimbursement for the applicable quarter, we 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 Centers for Medicare & Medicaid Services' Part B Analytics and Reports (PBAR).[39]

[39] The PBAR data for 2009 were downloaded in March 2010.

APPENDIX ~ E

Thirty-Four Drug Codes With Complete Average Manufacturer Price Data That Exceeded the 5-Percent Threshold in 2009

Drug Code	Quarter(s) in Which the Codes Exceeded the 5-Percent Threshold			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
J0210*			X	X
J0270		X		
J0475*	X	X		
J0476			X	
J0735		X		X
J1230	X			
J1327*			X	X
J1364*	X	X	X	
J1655	X			
J1955	X			
J2020		X		
J2597*	X	X	X	
J2675				X
J2690		X		
J2792*		X	X	X
J2820		X		
J2993*		X	X	
J3470	X		X	
J7500*	X	X		
J7606			X	
J8515	X			
J9155			X	
J9178		X		
J9214*			X	X
J9225	X			
J9280				X
J9290				X
J9291				X
J9340*			X	X
Q0166*			X	X
Q0169	X			
Q0171			X	
Q0175	X			
Q0176	X			

* These codes would have exceeded the Centers for Medicare & Medicaid Services' criteria for price substitution in at least one quarter if the price substitution policy had been in effect during 2009.
Source: Office of Inspector General analysis of average sales price and average manufacturer price data from 2009.

APPENDIX ~ F

Thirty-Four Drug Codes With Partial Average Manufacturer Price Data That Exceeded the 5-Percent Threshold in 2009

	Quarter(s) in Which the Codes Exceeded the 5-Percent Threshold			
Drug Code	**First Quarter**	**Second Quarter**	**Third Quarter**	**Fourth Quarter**
90376				X
90586				X
J0170*	X			X
J0461				X
J0560*†	X	X	X	X
J0592				X
J1170				X
J1190	X	X	X	X
J1642	X			
J1885*			X	
J1940*				X
J2175				X
J2310*	X	X		
J2360*				X
J2590*		X		
J2700			X	X
J2765*†	X	X	X	X
J3010				X
J7506*	X	X	X	
J7509*		X	X	X
J7613			X	
J9027		X		
J9031				X
J9100				X
J9185				X
J9250				X
J9260				X
Q0163*		X	X	
Q0165*		X		
Q0170*			X	X
Q0179				X

continued on next page

Thirty-Four Drug Codes With Partial Average Manufacturer Price Data That Exceeded the 5-Percent Threshold in 2009 (Continued)

	Quarter(s) in Which the Codes Exceeded the 5-Percent Threshold			
Drug Code	**First Quarter**	**Second Quarter**	**Third Quarter**	**Fourth Quarter**
Q9965	X	X	X	X
Q9966	X	X	X	X
Q9967	X			

* For these codes, missing average manufacturer prices (AMP) likely had little influence on the outcomes of the pricing comparisons.

† These codes exceeded the 5-percent threshold based on complete AMPs in some quarters and partial AMPs in others.

Source: Office of Inspector General's analysis of average sales price data and AMP data from 2009.

APPENDIX ~ G

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: FEB 0 3 2011

TO: Daniel R. Levinson
Inspector General

/S/

FROM: Donald M. Berwick, M.D.
Administrator

SUBJECT: Office of Inspector General Draft Report: Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2009 (OEI-03-10-00380)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and respond to the Office of Inspector General's (OIG) draft report titled "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2009". This report is part of a series of average sales price (ASP) and average manufacturer price (AMP) comparisons required under section 1847A(d) of the Social Security Act (the Act).

The OIG stated two objectives for the 2009 overview: to identify drugs with an ASP that exceeded AMP by at least 5-percent in any quarter of 2009, and to examine the impact of missing and unavailable data on the OIG's 2009 pricing comparisons. The 2009 overview found that 34 of 439 Healthcare Common Procedure Coding System (HCPCS) codes with complete data (i.e., AMP data was available for all national drug codes (NDC) used in the ASP calculation for a code) met the 5-percent threshold in at least one quarter. Of these 34 codes, 11 would have been subject to the price substitution policy that was proposed but not finalized in the 2011 Physician Fee Schedule Rule and would have reduced Medicare expenditures by an estimated $1.9 million over a four-quarter period. Another 34 HCPCS codes with partial data (i.e., AMP data was available only for some of the NDCs used in the ASP calculation for a code) met the 5-percent threshold, and the OIG determined that missing data for 13 of these codes appeared to have little influence on the outcome of the comparison since the available data accurately captured underlying market trends. The OIG also noted that at least 10 percent of HCPCS codes were excluded from the comparison each quarter due to missing or unavailable AMP data.

While we appreciate the OIG's continuing efforts to examine payment made under the ASP methodology, we are uncertain of the payoff from quarterly reports on ASP and AMP comparisons. We note that the price substitution policy in the CMS proposed rule (based on OIG quarterly studies for 2009) would save roughly $2 million in Medicare allowed charges.

While the statute requires the OIG to conduct studies to determine the widely available market price of Part B drugs, it also provides discretion in determining the frequency of the

studies. Given that annual Medicare spending is approximately $450 billion, of which roughly $15 billion on Part B drugs, we respectfully suggest reducing the frequency of the reports in this series (e.g., a single annual report containing separate analysis of each the quarters of a year) and redeploying those resources to activities that may have higher potential rates of return.

OIG Recommendation:

Finalize the price substitution policy from the proposed rule and subsequently lower Medicare reimbursement amounts for drugs that meet the 5-percent threshold.

CMS Response:

We non-concur with this recommendation. We did not finalize the proposed price substitution policy in the calendar year (CY) 2011 Physician Fee Schedule Final Rule, published on November 29, 2010, due to the preliminary injunction prohibiting the disclosure of AMP to the public and amendments to the definition of AMP outlined in section 2503 of the Affordable Care Act. Shortly after the rule was published, the preliminary injunction was vacated; however, regulations that will implement section 2503 of the Affordable Care Act have not been finalized. As stated in CMS responses to previous OIG studies, CMS remains committed to proceeding cautiously as it continues to evaluate the impact of any future policy developments in this area. Although we are non-concurring with the recommendation, we will continue to pay close attention to the issues surrounding the price substitution policy, including the updated definition of AMP, and will revisit this subject as needed.

OIG Recommendation:

Consider expanding the price substitution policy to include certain HCPCS codes with partial AMP data.

CMS Response:

We non-concur with this recommendation. In the CY 2011 Physician Fee Schedule Proposed Rule, we limited our price substitution proposal, in part, to only those situations where ASP and AMP comparisons are based on the same set of NDCs for a billing code. We made this distinction, because we were concerned that partial AMP data comparisons did not adequately account for market-related drug price changes and may lead to the substitution of incomplete and inaccurate volume-weighted prices. Such substitutions may impact physician and beneficiary access to drugs.

While the OIG's analysis seems to infer that price substitutions for 13 partial AMP comparisons may be valid because the missing and unavailable AMP data had seemingly little influence on the pricing comparison results for these codes, CMS believes that is necessary to assess the full impact of the amendments to the AMP definition, as mentioned above, before proceeding with any price substitution proposal. Though the OIG indicates in this report that ASP prices are

usually within about 5-percent of the AMP on average, we note that changes to the definition of AMP resulting from the Affordable Care Act may affect this comparison.

OIG Recommendation:

Consider seeking a legislative change to directly require all manufacturers of Part B-covered drugs to submit both ASPs and AMPs.

CMS Response:

We non-concur with this recommendation. The President's budget for fiscal year 2011 does not include any proposals to require manufacturers to submit ASPs and AMPs regardless of whether they have a Medicaid drug rebate agreement. However, we will continue to monitor manufacturer reporting trends and their effects on our current payment policies.

OIG Recommendation:

Continue to evaluate and pursue appropriate actions against manufacturers that fail to comply with price reporting requirements, including referring to OIG manufacturers that fail to submit timely ASP data.

CMS Response:

We concur with this recommendation and will continue to refer to the OIG any manufacturers who repeatedly fail to submit timely and/or accurate ASP data.

We thank the OIG for presenting its findings, and we appreciate their perspective on these issues.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

Lauren McNulty served as the team leader for this study. Central office staff who contributed to this report include Kevin Manley and Natasha Franklin.

Office of Inspector General

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The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.