Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COMPARISON OF AVERAGE SALES PRICES AND AVERAGE MANUFACTURER PRICES: AN OVERVIEW OF 2008

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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 2008.
2. To determine why ASPs for certain drug products exceeded the AMPs.
3. To examine the impact of missing or unavailable AMP data on mandated comparisons between ASPs and AMPs in 2008.

BACKGROUND

Since January 2005, Medicare Part B has been paying for most covered drugs using a reimbursement methodology based on ASPs. In general terms, 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. Manufacturers report ASPs by national drug codes (NDC) and must provide the Centers for Medicare & Medicaid Services (CMS) with the ASP and volume of sales for each of their NDCs on a quarterly basis. Under the ASP reimbursement methodology, Medicare's allowance for most Part B prescription drug Healthcare Common Procedure Coding System (HCPCS) codes is equal to 106 percent of the volume-weighted ASPs for the NDCs associated with each HCPCS code.

By law, the Office of Inspector General (OIG) must compare ASPs with AMPs. As generally defined in statute, the AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers whose drugs are covered by Medicaid generally must provide CMS with the AMP for each of their NDCs on a quarterly basis as part of the Medicaid drug rebate program.

If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), the Secretary of Health and 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.

Since the ASP reimbursement methodology was implemented in 2005, OIG has issued 14 reports comparing ASPs to AMPs. This current comparison examines data across all four quarters of 2008 using the volume-weighted ASP pricing methodology implemented by the Medicare, Medicaid, and SCHIP Extension Act of 2007.

For this study, we obtained ASP and AMP data submitted by manufacturers for all four quarters of 2008. We compared the volume-weighted ASP and AMP for each HCPCS code in each quarter and identified codes with ASPs that exceeded AMPs by at least 5 percent in one or more quarters of 2008. We also asked three manufacturers to describe why the ASPs for certain drug products were higher than the AMPs throughout 2008.

In addition, we identified the number of NDCs for which AMP data were missing or unavailable in 2008, as well as the number of HCPCS codes that were removed from OIG's pricing comparisons because AMPs were missing or unavailable.

FINDINGS

In 2008, ASPs for 80 HCPCS codes exceeded AMPs by at least 5 percent in one or more quarters. Of the 482 HCPCS codes examined during 2008, 80 met the 5-percent threshold for price adjustment in at least one quarter. Over 40 percent of these codes (33 of 80) met the 5-percent threshold in multiple quarters, with five codes meeting the 5-percent threshold in every quarter. If reimbursement amounts for all 80 HCPCS codes had been lowered to 103 percent of the AMPs during the applicable quarter(s), we estimate that Medicare expenditures would have been reduced by $21.9 million from the third quarter of 2008 through the second quarter of 2009.

Manufacturers identified several reasons why ASPs for certain drugs consistently exceeded AMPs. According to manufacturers associated with the five HCPCS codes that met the 5-percent threshold in every quarter, ASPs can exceed AMPs as a result of many factors, including the way in which AMPs were weighted, the types of sales included in ASPs and AMPs, differential pricing arrangements among purchasers, and errors in the calculation of AMPs.

Missing and unavailable AMP data in 2008 prevented OIG from conducting thorough drug-pricing comparisons. A total of 1,431 NDCs had no AMP data during one or more quarters of 2008. Manufacturers for almost 60 percent of these drug products participated

in the Medicaid drug rebate program in 2008 and were therefore generally required to submit AMP data for their products. Because some NDCs had missing or unavailable AMPs, the number of pricing comparisons performed for 2008 was reduced by 12 percent to 14 percent in each quarter and 43 HCPCS codes were never evaluated.

RECOMMENDATIONS

The Social Security Act (the Act) directs the Secretary to lower reimbursement amounts for drugs with ASPs that exceed AMPs by at least 5 percent. Although CMS has acknowledged the Secretary's authority to adjust Part B reimbursement amounts based on the findings of OIG's pricing comparisons, the agency has yet to make any changes as a result of these studies. CMS also has yet to specify the process by which it would make reimbursement adjustments for drugs that meet the 5-percent threshold.

OIG acknowledges that developing a price substitution policy involves complex decisions, including the circumstances under which substitutions would be made, the effective date of such substitutions, and the time period for which the substitutions would remain in effect. However, the gap between ASPs and AMPs for certain Part B drugs indicates that Medicare and its beneficiaries may be overpaying for those drugs. Therefore, to ensure the appropriateness of Medicare Part B drug payments, and to be consistent with the congressional mandate, we recommend that CMS:

develop a process to adjust payment amounts based on the results of OIG's pricing comparisons;

lower Medicare reimbursement amounts for drugs with ASPs that meet the 5-percent threshold specified in section 1847A(d)(3) of the Act; and

continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with OIG about administrative remedies for noncompliance.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our first and third recommendations but does not currently concur with our second recommendation. With regard to our

second recommendation, CMS stated that in light of the drug price volatility identified by OIG, making price substitutions could have a significant negative impact on both providers and beneficiaries. CMS expressed a desire to better understand differences between ASPs and AMPs, engage stakeholders affected by potential price substitutions, and provide adequate notice when developing its price substitution policies.

Although OIG has issued 14 reports demonstrating differences between ASPs and AMPs over the past 5 years, CMS has yet to use our data to propose or evaluate any concrete strategies for making price substitutions. OIG acknowledges that CMS must make complex decisions regarding price substitutions and that ASPs and AMPs will inevitably fluctuate to some extent; however, OIG has not identified significant volatility in the ASPs and AMPs for 33 of the 80 HCPCS codes identified in this report. Rather, these codes have repeatedly been identified as having ASPs at or above the 5-percent threshold. OIG will continue to assist CMS, both in developing a price substitution policy and in taking appropriate action against manufacturers that fail to comply with AMP-reporting requirements.

TABLE OF CONTENTS

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS 10

In 2008, ASPs for 80 HCPCS codes exceeded AMPs by at least 5 percent in one or more quarters 10

Manufacturers identified several reasons why ASPs for certain drugs consistently exceeded AMPs 11

Missing and unavailable AMP data in 2008 prevented OIG from conducting thorough drug-pricing comparisons. 12

RECOMMENDATIONS 14

Agency Comments and Office of Inspector General Response . . . 15

APPENDIXES 18

A: Equations Used by the Centers for Medicare & Medicaid Services To Calculate Volume-Weighted Average Sales Prices. 18

B: Previous Office of Inspector General Reports Comparing Average Sales Prices and Average Manufacturer Prices. 19

C: Detailed Methodology for Calculating Volume-Weighted Average Manufacturer Prices for 2008 21

D: Detailed Methodology for Estimating Savings for Drug Codes That Met the 5-Percent Threshold in 2008 23

E: Eighty Drug Codes With Average Sales Prices That Exceeded Average Manufacturer Prices by at Least 5 Percent in 2008 24

F: Agency Comments 27

ACKNOWLEDGMENTS 30

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 2008.
2. To determine why ASPs for certain drug products exceeded the AMPs.
3. To examine the impact of missing or unavailable AMP data on mandated comparisons between ASPs and AMPs in 2008.

BACKGROUND

Section 1847A(d)(2)(B) of the Social Security Act (the Act) mandates that the Office of Inspector General (OIG) compare ASPs to AMPs. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), section 1847A(d)(3)(A) of the Act states that the Secretary of Health and Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement amounts.[1] Section 1847A(d)(3)(C) of the Act goes on to state that ". . . the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment . . . the lesser of (i) the widely available market price . . . (if any); or (ii) 103 percent of the average manufacturer price . . . ."

Medicare Part B Coverage of Prescription Drugs

Medicare Part B covers only a limited number of outpatient prescription drugs. Covered drugs include injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

Medicare Part B Payments for Prescription Drugs

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

[1] 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.

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

Medicare and its beneficiaries spent over $11 billion for Part B drugs in 2008.[2] Although Medicare paid for more than 700 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 2008, 60 HCPCS codes accounted for 90 percent of the expenditures for Part B drugs, with only 12 of these codes representing half of the total Part B drug expenditures.

Reimbursement Methodology for Part B Drugs

Medicare Part B pays for most covered outpatient drugs using a reimbursement methodology based on ASPs. Section 1847A(c) of the Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, defines an ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program.[3] Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.[4, 5]

Manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the manufacturer, product dosage form, and package size of the drug. Manufacturers must provide CMS with

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[2] Medicare expenditures for Part B drugs in 2008 were calculated using CMS's Part B Analytics and Reports (PBAR). The PBAR data were downloaded on July 8, 2009.

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

[4] Pursuant to section 1927(c)(1)(C)(i) of the Act, "best price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.

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

the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of each quarter.[6]

Because Medicare Part B reimbursement for outpatient drugs is based on HCPCS codes rather than NDCs and more than one NDC may meet the definition of a particular HCPCS code, CMS has developed a file that "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this crosswalk file to calculate volume-weighted ASPs for covered HCPCS codes.

Calculation of Volume-Weighted Average Sales Prices

To calculate volume-weighted ASPs, CMS uses an equation that involves the following variables: the ASP for the 11-digit NDC as reported by the manufacturer, the volume of sales for the NDC as reported by the manufacturer, and the number of billing units in the NDC as determined by CMS. The amount of the drug contained in an NDC may differ from the amount of the drug specified by the HCPCS code that providers use to bill Medicare. Therefore, the number of billing units in an NDC describes the number of HCPCS code units that are in that NDC. For instance, an NDC may contain a total of 10 milliliters of Drug A, but the corresponding HCPCS code may be defined as only 5 milliliters of Drug A. In this case, there are two billing units in the NDC. CMS calculates the number of billing units in each NDC when developing its crosswalk files.

Before April 2008, CMS calculated volume-weighted ASPs using the equation presented in Appendix A. However, section 112(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007, P.L. No. 110-173, changed section 1847A(b) of the Act to require that CMS compute volume-weighted ASPs using a revised methodology, effective April 2008.[7] The revised equation for calculating volume-weighted ASPs is also provided in Appendix A.

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.[8] However, there is a two-quarter lag between the

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

[7] This revised methodology was proposed by OIG in a February 2006 report entitled *Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs*, OEI-03-05-00310.

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

sales period for which ASPs are reported and the effective date of the reimbursement amounts. For example, ASPs from the first quarter of 2008 were used to establish reimbursement amounts for the third quarter of 2008, and ASPs from the fourth quarter of 2008 were used to establish reimbursement amounts for the second quarter of 2009.

As a result of this lag period, the methodological changes that went into effect in April 2008 were applied to ASP data from two quarters prior, i.e., the fourth quarter of 2007. Therefore, CMS used the revised methodology to volume-weight ASP data submitted by manufacturers for all four quarters of 2008.

The Medicaid Drug Rebate Program and Average Manufacturer Prices

For Federal payment to be available for covered outpatient drugs provided under Medicaid, sections 1927(a)(1) and (b)(1) of the Act mandate that drug manufacturers enter into rebate agreements with the Secretary and pay quarterly rebates to State Medicaid agencies. Under these rebate agreements and pursuant to section 1927(b)(3) of the Act, manufacturers must provide CMS with the AMP for each of their NDCs on a quarterly basis, with submissions due 30 days after the close of each quarter.[9]

As generally defined in section 1927(k)(1) of the Act, the AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. Before the passage of the DRA, manufacturers were required to deduct customary prompt pay discounts when calculating AMPs. However, section 6001(c)(1) of the DRA amended section 1927(k)(1) of the Act such that AMPs must be determined without regard to customary prompt pay discounts, effective January 2007.[10] In July 2007, CMS published a final rule at 72 Fed. Reg. 39142 (July 17, 2007) that, among other things, implements section 6001(c)(1) of the DRA and

[9] Section 6001(b)(1)(A) of the Deficit Reduction Act of 2005 (DRA), P.L. No. 109-171, changed section 1927(b) of the Act to require that manufacturers also report AMPs on a monthly basis, effective January 2007. Drug manufacturers will continue to report quarterly AMP data in addition to their monthly submissions.

[10] In addition, section 6001(b) of the DRA amended section 1927(b)(3) of the Act such that AMPs must be provided to States on a monthly basis and through a Web site that is publicly accessible. However, in December 2007, the United States District Court for the District of Columbia preliminarily enjoined the disclosure of AMP data to States and the public for certain purposes not related to this report. Section 203 of the Medicare Improvements for Patients and Providers Act of 2008 also delayed public disclosure of AMP data.

clarifies the way in which the AMP must be calculated. Specifically, 42 CFR § 447.504 of the final regulation clarifies the manner in which the AMP is to be determined.[11]

The AMP is generally calculated as a weighted average of prices for all of a manufacturer's package sizes of a drug sold during a given quarter and is reported for the lowest identifiable quantity of the drug (e.g., 1 milliliter, 1 tablet, 1 capsule).

Pursuant to section 1927(b)(3)(C) of the Act, manufacturers that fail to provide AMP data on a timely basis may be subject to either monetary penalties or termination from the drug rebate program. The responsibility to impose penalties pursuant to section 1927(b)(3)(C) of the Act has been delegated to OIG by the Secretary.[12] Pursuant to section 1927(b)(4)(B) of the Act, CMS also has authority to terminate the rebate agreements of manufacturers that fail to report timely AMP data.[13] CMS has terminated a number of manufacturers' rebate agreements for failure to report drug pricing data as required. For the purposes of evaluating potential civil monetary penalty actions, CMS has also been providing OIG with information about manufacturers that repeatedly failed to submit timely drug-pricing data.

Office of Inspector General's Monitoring of Average Sales Prices and Average Manufacturer Prices

In accordance with its congressional mandate, OIG has issued 13 quarterly pricing comparisons since the ASP reimbursement methodology for Part B drugs was implemented in January 2005. In addition, OIG completed an annual overview of ASPs and AMPs, which examined data across all four quarters of 2007 using the revised methodology mandated by statute. A list of all 14 reports is provided in Appendix B. OIG has recommended that CMS develop a process to adjust payment amounts based on the results of these pricing comparisons and subsequently lower reimbursement for drugs that meet the 5-percent threshold.

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[11] In December 2007, the United States District Court for the District of Columbia also preliminarily enjoined the implementation of this regulation for certain purposes not relevant to this report. Section 203 of the Medicare Improvements for Patients and Providers Act of 2008 also delayed the implementation of certain aspects of the regulation. Again, those aspects are not relevant for the purposes of this report.

[12] 59 Fed. Reg. 52967 (Oct. 20, 1994).

[13] Specifically, CMS may terminate a rebate agreement "for violation of the requirements of the agreement or other good cause shown."

Although CMS has acknowledged the Secretary's authority to adjust ASP payment limits based on the findings of OIG's pricing comparisons, CMS has yet to make any changes to Part B drug reimbursement as a result of these studies. Rather, CMS has emphasized both the complexity of substituting payment amounts and the importance of proceeding cautiously to avoid unintended consequences.[14] In commenting on OIG's reports, CMS has expressed a desire to both better understand fluctuating differences between ASPs and AMPs and engage stakeholders, with the intent of developing a process for making price substitutions.[15] However, CMS has not specified what, if any, steps it will take to adjust Medicare reimbursement amounts for drugs that meet the 5-percent threshold specified in section 1847A(d)(3) of the Act.

This current report is OIG's second annual overview of ASPs and AMPs, and it examines data across all four quarters of 2008 using the revised volume-weighted ASP methodology mandated by statute.

OIG will continue to meet its congressional mandate by issuing reports based on quarterly pricing comparisons, along with annual overviews to summarize findings across each calendar year.

METHODOLOGY

We obtained files from CMS containing NDC-level ASP data from the first through fourth quarters of 2008, which were used to establish Part B drug reimbursement amounts for the third quarter of 2008 through the second quarter of 2009, 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 2008.[16]

Calculation of Volume-Weighted Average Sales Prices and Volume-Weighted Average Manufacturer Prices for 2008

As mentioned previously, Medicare does not base reimbursement for covered drugs on NDCs; instead, it uses HCPCS codes. Therefore, CMS

[14] OEI-03-08-00450, December 2008.

[15] OEI-03-07-00140, July 2007, and OEI-03-08-00450, December 2008.

[16] ASP and crosswalk data from the first through fourth quarters of 2008 were current as of June 2008, September 2008, December 2008, and March 2009, respectively. AMP data from the first through fourth quarters of 2008 were current as of May 2008, August 2008, November 2008, and February 2009, respectively.

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 2008 quarterly reports, we calculated a volume-weighted AMP for each HCPCS code, consistent with CMS's methodology for calculating volume-weighted ASPs. Prior to 2008, OIG computed volume-weighted AMPs only for those HCPCS codes with AMP data for every drug product used by CMS to calculate the Medicare reimbursement amount. As a result, the number of comparisons performed in 2007 was reduced by at least 25 percent in each quarter and over 100 HCPCS codes were never evaluated pursuant to section 1847A(d)(2)(B) of the Act. To ensure that a broader range of drug codes was subject to OIG's pricing comparisons in 2008, we began additionally examining drug codes with only partial AMP data (i.e., drug codes with AMP data for some, but not all, of the products used to establish Medicare reimbursement). Appendix C provides a 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 2008

In each of our 2008 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 complete or partial AMP data.

For those HCPCS codes that met or exceeded the 5-percent threshold, we conducted a review of the associated NDCs to verify the accuracy of the billing unit information for the quarter(s) in which the threshold was met. If HCPCS codes had potentially inaccurate billing units, we did not include them in our findings.

To identify codes with ASPs that exceeded AMPs by at least 5 percent in one or more quarters of 2008, we then merged the results of the pricing comparisons from all four quarters.

Estimating the monetary impact of lowering reimbursement. We additionally estimated the monetary impact of lowering reimbursement to 103 percent of the AMP for codes that met the 5-percent threshold in

at least one quarter of 2008.[17] In our separate quarterly pricing comparisons for 2008, savings estimates for codes that met the threshold in the first through third quarters were based on CMS's Part B Extract and Summary System (BESS) data from 2007, whereas savings estimates for codes in the fourth quarter were based on BESS data from 2008. 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 met the threshold in one or more quarters of 2008 using updated PBAR data for 2008.[18] As a result, the estimated savings presented in this yearend 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 were eligible for price adjustment.

Manufacturer followup. For HCPCS codes that met the 5-percent threshold in every quarter of 2008, we identified any corresponding NDCs that had ASPs that exceeded the AMPs. To determine why ASPs repeatedly exceeded AMPs for certain drug products, we contacted the manufacturers associated with these NDCs. Using written data collection instruments distributed by mail, we asked the manufacturers to verify 2008 ASPs and AMPs for the NDCs in question and to explain why the ASPs for those NDCs were higher than the AMPs throughout 2008.

Analysis of Average Manufacturer Price Data That Were Missing or Unavailable in 2008

We examined the number of NDCs for which manufacturers submitted ASP data but not AMP data across all four quarters of 2008. For the purposes of this study, an AMP was considered "missing" if the manufacturer had a Medicaid rebate agreement in 2008 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

[17] Section 1847A(d)(3)(C) of the Act directs the Secretary to replace payment amounts for drugs that meet the 5-percent threshold with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP. For the purposes of this study, we used 103 percent of the AMP to estimate the impact of lowering reimbursement amounts. If widely available market prices had been available for these drugs and lower than 103 percent of the AMP, the savings estimate presented in this report would have been greater.

[18] CMS replaced BESS with PBAR in 2009, populating PBAR with data from both current and prior years.

rebate program and was therefore not required to submit AMP data to CMS.[19]

In each of our pricing comparisons for 2008, 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 2008, we merged the results from each of the four quarterly reports. We then determined the number of HCPCS codes that were never included in OIG's pricing comparisons in 2008 because of missing or unavailable AMP data.

Limitations

We did not verify the accuracy of all manufacturer-reported ASP and AMP data, nor did we verify the underlying methodology used by manufacturers to calculate ASPs and AMPs. Manufacturers' explanations as to why certain ASPs consistently exceeded AMPs were self-reported. We did not verify whether these explanations were accurate. 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 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 Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

[19] To determine whether a manufacturer participated in the Medicaid drug rebate program in 2008, we consulted the list of participating drug companies posted on CMS's Web site.

In 2008, ASPs for 80 HCPCS codes exceeded AMPs by at least 5 percent in one or more quarters

Consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs to AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by a threshold of 5 percent. Of the 482 HCPCS codes examined during 2008, 80 met this 5-percent threshold in at least one quarter using either complete AMP data or partial AMP data.

Appendix E presents a list of the 80 HCPCS codes, including the quarter(s) during which the codes met the 5-percent threshold, and indicates whether each met the threshold using complete or partial AMP data.

Thirty-three of the eighty HCPCS codes met the 5-percent threshold during multiple quarters of 2008

In 2008, ASPs for five HCPCS codes (J0560, J1190, J1364, J2310, and Q0169) exceeded the AMPs by at least 5 percent in every quarter. An additional 10 HCPCS codes met the 5-percent threshold in three of the four quarters. For another 18 HCPCS codes, ASPs exceeded AMPs by at least 5 percent in two quarters.

Lowering reimbursement amounts for the 80 HCPCS codes to 103 percent of the AMPs would have reduced Medicare payments by almost $22 million over a four-quarter period

Sections 1847A(d)(3)(A) and (B) of the Act provide that the Secretary may disregard the ASP pricing methodology for a drug with an ASP that exceeds the AMP by at least 5 percent. Pursuant to section 1847A(d)(3)(C) of the Act, ". . . the Secretary shall, effective as of the next quarter, substitute for the amount of payment . . . the lesser of (i) the widely available market price . . . (if any); or (ii) 103 percent of the average manufacturer price . . . ." In this study, we identified 80 HCPCS codes that met the 5-percent threshold in at least one quarter of 2008. If reimbursement amounts for these 80 codes had been lowered to 103 percent of the AMPs during the applicable quarters, we estimate that Medicare expenditures would have been reduced by $21.9 million between the third quarter of 2008 and the second quarter of 2009.[20]

[20] ASP data from the first through fourth quarters of 2008 were used to establish reimbursement amounts for the third quarter of 2008 through the second quarter of 2009, respectively.

Manufacturers identified several reasons why ASPs for certain drugs consistently exceeded AMPs

For the five HCPCS codes that met the 5-percent threshold in every quarter of 2008, we identified any corresponding NDCs with ASPs that exceeded the AMPs during each period (a total of six NDCs). We then contacted the three manufacturers associated with those six NDCs to verify their pricing data and to determine why ASPs for those products repeatedly exceeded the AMPs. These manufacturers confirmed that the ASPs for their drugs exceeded the AMPs based on the pricing data provided to CMS and identified a number of reasons as to why this occurred.

The manufacturer of one drug product cited differences in the ways in which ASPs and AMPs are calculated. ASPs are calculated for a specific package size of a drug (i.e., at the 11-digit NDC level). AMPs are calculated as an average across all package sizes of a drug, and that average price is then reported for each of the corresponding package sizes. The manufacturer noted that because the AMPs for that drug were weighted toward the lower priced, higher volume products, the ASPs for the drug exceeded the AMPs.

According to another manufacturer, AMPs for three drug products were low because the limited number of customers purchasing those drug products in the retail pharmacy class of trade had access to very aggressive prices negotiated by hospital group purchasing organizations (GPO). The ASPs for those three products, which included a broader range of customers and prices, were higher by comparison.

The same manufacturer reported that the ASPs for another of its products exceeded the AMPs because of differential adjustments to the price agreements governing sales of the product in different settings. Specifically, the sales included in the ASPs were based on annually adjusted price agreements with hospital GPOs, whereas the sales included in the AMPs were based on long-term agreements without incremental price adjustments.

According to the manufacturer of the remaining drug product, ASPs exceeded AMPs in each quarter of 2008 because the AMPs were incorrectly determined by the manufacturer.[21] If the manufacturer had

[21] For each of the other five NDCs included in our review, manufacturers verified that the 2008 quarterly ASPs and AMPs were correct.

calculated the AMPs correctly in 2008, ASPs would not have exceeded AMPs for this drug product and the corresponding HCPCS code would not have met the 5-percent threshold in any quarter.[22]

We will provide CMS with more detailed information regarding manufacturers' explanations for why ASPs exceeded AMPs.

Missing and unavailable AMP data in 2008 prevented OIG from conducting thorough drug-pricing comparisons

Missing or unavailable AMP data can significantly reduce the number of drug codes that are evaluated pursuant to sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act. By including HCPCS codes with partial AMP data in its pricing comparisons for 2008, OIG was able to compare ASPs and AMPs for more HCPCS codes than in the previous year. However, missing and unavailable AMP data in 2008 continued to prevent OIG from conducting thorough drug pricing comparisons.

Almost 60 percent of NDCs without AMP data belonged to manufacturers with Medicaid drug rebate agreements

A total of 1,431 NDCs had no AMP data during one or more quarters of 2008. Manufacturers for 59 percent of these NDCs (843 of 1,431) participated in the Medicaid drug rebate program during 2008 and were therefore generally required to submit AMP data.[23, 24] For 5 percent of these NDCs (45 of 843), manufacturers did not submit AMP data for any quarter of 2008. The majority (57 percent) of the 843 NDCs with missing AMP data belonged to 3 manufacturers.

Manufacturers for the remaining 588 of 1,431 NDCs did not participate in the Medicaid drug rebate program in 2008 and therefore were not required to submit AMP data during that time.

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[22] The HCPCS code in question did not have any allowed services during 2008 and therefore would not affect the savings estimate included in this report.

[23] Although manufacturers with rebate agreements are generally required to submit AMP data, there may be valid reasons as to why AMP data were not provided for a specific NDC in a given quarter. For example, a manufacturer may not necessarily be required to submit an AMP if the drug product has been terminated and there was no Medicaid drug utilization during the quarter.

[24] Manufacturers for 7 of the 843 NDCs had rebate agreements during some, but not all, of the quarters for which the NDCs had no AMP data. We considered the AMPs for these seven NDCs to be missing in the quarters for which manufacturers had rebate agreements and unavailable during the quarters in which they did not.

As a result of NDCs without AMP data, the number of pricing comparisons performed in 2008 was reduced by at least 12 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 2008, between 12 percent and 14 percent of HCPCS codes were excluded from OIG's pricing comparisons in each quarter because no AMPs were available for any of the NDCs associated with the HCPCS codes.[25] Table 1 lists the number and percentage of HCPCS codes in each quarter that were excluded from our analysis, as well as the number of NDCs associated with the excluded HCPCS codes.

Table 1: HCPCS Codes That Were Excluded From 2008 Pricing Comparisons

Quarter in 2008	Number of NDCs Associated With the Excluded HCPCS Codes	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	**436**	**76**	**14%**
Missing	*99*		
Unavailable	*337*		
Second Quarter	**433**	**68**	**13%**
Missing	*81*		
Unavailable	*352*		
Third Quarter	**222**	**67**	**13%**
Missing	*65*		
Unavailable	*157*		
Fourth Quarter	**209**	**65**	**12%**
Missing	*51*		
Unavailable	*158*		

Source: OIG analysis of ASP and AMP data from the first through fourth quarters of 2008.

In total, 111 different HCPCS codes were excluded from OIG's pricing comparisons in one or more quarters of 2008 because AMP data were missing or unavailable for all of the NDCs that CMS used to calculate Medicare reimbursement for that quarter. For 43 of the 111 codes, we were never able to perform pricing comparisons in 2008 because AMPs were always missing or unavailable for all of the associated NDCs. Just over half of these HCPCS codes (22 of 43) were associated only with NDCs that had unavailable AMP data. Therefore, we would never have been able to include these 22 codes in our pricing comparisons.

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

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. CMS has acknowledged the Secretary's authority to adjust Part B reimbursement amounts based on the findings of OIG's pricing comparisons; however, the agency has not made any changes as a result of these studies. CMS also has yet to specify the process by which it would make reimbursement adjustments for drugs that meet the 5-percent threshold.

This current study, which summarizes data across all four quarters of 2008, identified 80 drug codes that were eligible for price adjustment based on either complete or partial AMP data. Thirty-three of the eighty drug codes met the 5-percent threshold during multiple quarters of 2008. If reimbursement amounts for all 80 codes had been lowered to 103 percent of the AMPs during the applicable quarters, Medicare and its beneficiaries would have saved an estimated $21.9 million.

According to manufacturers associated with drugs that met the 5-percent threshold in every quarter, ASPs can exceed AMPs as a result of many factors, including the way in which AMPs were weighted, the types of sales included in ASPs and AMPs, differential pricing arrangements among purchasers, and errors in the calculation of AMPs.

By including HCPCS codes with partial AMP data in its pricing comparisons for 2008, OIG was able to compare ASPs and AMPs for more HCPCS codes than in the previous year; however, missing and unavailable AMP data continued to limit OIG's ability to conduct thorough drug pricing comparisons.

OIG acknowledges that developing a price substitution policy involves complex decisions, including the circumstances under which substitutions would be made, the effective date of such substitutions, and the time period for which the substitutions would remain in effect. However, the gap between ASPs and AMPs for certain Part B drugs indicates that Medicare and its beneficiaries may be overpaying for those drugs. Therefore, to ensure the appropriateness of Medicare Part B drug payments and to be consistent with the congressional mandate, we recommend that CMS:

Develop a process to adjust payment amounts based on the results of OIG's pricing comparisons

In developing a process to adjust payments, CMS could specify the circumstances under which it will make adjustments, the time period(s) to which the adjustments would apply, and the length of time the

adjustments would remain in effect. CMS may also wish to conduct additional analysis of the differences between ASPs and AMPs and the quality of the data reported by manufacturers.

CMS should also determine whether the current 5-percent threshold is appropriate for initiating price substitution. Pursuant to section 1847A(d)(3)(B)(ii) of the Act, CMS has authority to adjust the threshold percentage used in OIG's comparisons of ASPs and AMPs. In its comments on previous OIG pricing comparisons, CMS stressed the importance of proceeding cautiously while it seeks to further understand the appropriate threshold percentage for price substitutions. However, CMS has yet to make any changes to the threshold percentage, and it is unclear what steps, if any, CMS has taken to determine a more appropriate cutoff. If CMS believes that 5 percent is not the most appropriate threshold for price substitution, it should adjust the percentage as necessary.

Lower Medicare reimbursement amounts for drugs with ASPs that meet the 5-percent threshold specified in section 1847A(d)(3) of the Act

CMS may want to focus specifically on those drugs that, according to OIG's yearend review, met the 5-percent threshold in multiple quarters.

Continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with OIG about administrative remedies for noncompliance

We recognize that CMS has taken steps to ensure that quarterly AMP data are reported by manufacturers in a timely manner. If and when CMS is permitted to publicly disclose AMP data, the resulting transparency may lead to more timely and accurate reporting of pricing data. In the meantime, CMS should continue to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data by the statutory deadline. This may include termination actions and referrals to OIG for the pursuit of civil monetary penalty actions. In doing so, CMS could focus on those manufacturers with either a relatively large percentage of missing AMP data or manufacturers that consistently fail to submit AMP data by the statutory deadline.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In response to OIG's report, CMS conducted additional analysis and noted that it is difficult to identify a causal relationship that explains

why the ASP for a particular HCPCS code would exceed the AMP by 5 percent or more. According to CMS, the OIG report and CMS analysis demonstrate the complexity of making price substitutions.

CMS concurred with our first recommendation to develop a process for adjusting payment amounts based on the results of OIG's pricing comparisons. However, CMS does not currently concur with our second recommendation to lower Medicare reimbursement for drugs that meet the 5-percent threshold. CMS stated that in light of the drug price volatility identified by OIG, making price substitutions could have a significant negative impact on both providers and beneficiaries. CMS expressed a desire to better understand differences between ASPs and AMPs, engage stakeholders affected by potential price substitutions, and provide adequate notice when developing price substitution policies. With respect to the threshold percentage for price substitutions, CMS noted that it does not have sufficient data to suggest a more appropriate level and will therefore continue the 5-percent threshold into 2010.

Finally, CMS concurred with our third recommendation to ensure that manufacturers submit timely AMP data and outlined several steps that it already takes to address this issue, including prompting noncompliant manufacturers to report outstanding prices and referring noncompliant manufacturers to OIG. CMS stated that it will continue to work with OIG and supports appropriate enforcement action against manufacturers that fail to comply with reporting requirements.

Beginning with its comments on OIG's July 2007 pricing comparison, CMS has repeatedly emphasized the complexity of substituting payment amounts and expressed a desire to better understand differences between ASPs and AMPs with the intent of developing a price substitution policy. Although OIG has issued 14 reports demonstrating differences between ASPs and AMPs over the past 5 years, CMS has yet to use our data to propose or evaluate any concrete strategies for making price substitutions.

OIG acknowledges that CMS must make complex decisions regarding price substitutions and that ASPs and AMPs will inevitably fluctuate to some extent; however, OIG has not identified significant volatility in the ASPs and AMPs for 33 of the 80 HCPCS codes identified in this report. Rather, these codes have repeatedly been identified as having ASPs at or above the 5-percent threshold. Therefore, consistent with statutory requirements, we continue to recommend that Medicare reimbursement amounts for eligible codes be lowered, particularly for codes that meet

the threshold percentage in multiple quarters. OIG will continue to assist CMS, both in developing a timely and effective price substitution policy and in taking appropriate action against manufacturers that fail to comply with AMP-reporting requirements.

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

APPENDIX ~ A

Equations Used by the Centers for Medicare & Medicaid Services To Calculate Volume-Weighted Average Sales Prices

In the following equations, a "billing unit" is defined as the number of Healthcare Common Procedure Coding System (HCPCS) code units that are contained in a national drug code (NDC).

1. The Revised Equation Used by the Centers for Medicare & Medicaid Services (CMS) To Calculate Volume-Weighted Average Sales Prices (ASP) Beginning April 1, 2008

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

2. The Equation Used by CMS To Calculate Volume-Weighted ASPs Before April 1, 2008

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

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

APPENDIX ~ B

- *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

APPENDIX ~ C

Detailed Methodology for Calculating Volume-Weighted Average Manufacturer Prices for 2008

Before computing quarterly volume-weighted average manufacturer prices (AMP) for 2008, it was necessary to identify the national drug codes (NDC) that should be included in each quarter's calculations. Prior to 2008, the Office of Inspector General (OIG) performed pricing comparisons for only those Healthcare Common Procedure Coding System (HCPCS) codes with complete AMP data (i.e., AMP data for every NDC used by CMS to calculate the Medicare reimbursement amount). As of the first quarter of 2008, we began additionally examining HCPCS codes with only partial AMP data (i.e., HCPCS codes with AMP data for some, but not all, of the NDCs used to establish Medicare reimbursement).[26]

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, 1 tablet, 1 capsule). In contrast, an ASP is reported for the entire amount of the drug contained in the NDC (e.g., for 50 milliliters, for 100 tablets). To ensure that 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 CMS crosswalk file, manufacturer Web sites, the "Red Book," and the Food and Drug Administration's NDC directory.

For some NDCs, we could not successfully 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.

[26] We excluded NDCs without AMPs when calculating volume-weighted AMPs for HCPCS codes with partial AMP data; however, 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.

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, then 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 then 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 Met the 5-Percent Threshold in 2008

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 2008, we estimated the savings associated with lowering reimbursement for that code to 103 percent of the AMP.

There is a two-quarter lag 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 met the 5-percent threshold during the first through fourth quarters of 2008 were applied to the third quarter of 2008 through the second quarter of 2009, respectively. We estimated savings only for the time period(s) during which a HCPCS code met the 5-percent threshold.

For each of the HCPCS codes that met the 5-percent threshold in a given quarter of 2008, 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 then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2008, as reported in CMS's Part B Analytics and Reports (PBAR).[27] This estimate assumes that the number of services that were allowed by Medicare in 2008 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2008 and 2009.

[27] The PBAR data for 2008 were downloaded on July 8, 2009.

APPENDIX ~ E

Eighty Drug Codes With Average Sales Prices That Exceeded Average Manufacturer Prices by at Least 5 Percent in 2008

Drug Code	Quarter(s) in Which the Codes Met the 5-Percent Threshold			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
J1364	X	X	X	X
Q0169	X	X	X	X
J0560	X*	X*	X*	X*
J1190	X*	X*	X*	X*
J2310	X*	X*	X*	X*
J9260	X*	X	X*	
J0670	X*	X*	X*	
J2690	X	X		X
J2760	X	X		X
J2792	X		X	X
J0170	X*		X*	X*
J8515		X	X	X
J9225		X	X	X
J1642		X*	X*	X*
J9185		X*	X*	X
J2700	X	X*		
J9250	X*	X		
J1626	X*	X*		
J9000	X*	X*		
J1020	X		X	
J0278	X		X*	
J9060	X*		X*	
J9062	X*		X*	
J7506		X*	X*	
J9040		X*	X	
J9370		X*	X	
J9375		X*	X	
J9380		X*	X	
J9340		X		X
J2765			X	X
Q0179			X*	X*
Q9965			X*	X*
Q9966			X*	X*
J0300	X			
J1457	X			

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Eighty Drug Codes With Average Sales Prices That Exceeded Average Manufacturer Prices by at Least 5 Percent in 2008

	Quarter(s) in Which the Codes Met the 5-Percent Threshold			
Drug Code	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
J1955	X			
J3315	X			
J7310	X			
J9202	X			
J9320	X			
Q0166	X			
J0610	X*			
J1631	X*			
J1940	X*			
J2430	X*			
J2680	X*			
J2790	X*			
J3370	X*			
J3410	X*			
J3475	X*			
J9027	X*			
J9181	X*			
J9182	X*			
J9293	X*			
Q0164	X*			
Q0168		X		
90376		X*		
J0500		X*		
J7509		X*		
J9130		X*		
J9150		X*		
Q0175		X*		
Q0176		X*		
J0330			X	
J0720			X	
J7500			X	
J7631			X	
J0640			X*	
J3250			X*	
J7612			X*	

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Eighty Drug Codes With Average Sales Prices That Exceeded Average Manufacturer Prices by at Least 5 Percent in 2008

Drug Code	Quarter(s) in Which the Codes Met the 5-Percent Threshold			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
J7614			X*	
J9045			X*	
J9390			X*	
J0475				X
J2597				X
J2820				X
J7501				X
J7611				X*
J7644				X*
Q9967				X*

* These codes met the 5-percent threshold during the specified quarter based on partial AMP data.
Source: Office of Inspector General's analysis of ASP and AMP data from 2008.

APPENDIX ~ F

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: DEC 1 1 2009

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera /S/
Acting Administrator

SUBJECT: Office of Inspector General's Draft Report: "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2008" (OEI-03-09-00350)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2008." We appreciate the OIG's continuing efforts to examine payment made under the Average Sales Price (ASP) methodology. The OIG report presents findings from a comparison of Medicare payment amounts to an OIG-calculated Average Manufacturer Price (AMP) payment amount for certain drugs throughout 2008.

The OIG is completing this report pursuant to Section 1847A(d) of the Social Security Act (the Act), which requires a comparison of ASP to AMP and (if any) Widely Available Market Price (WAMP) to determine whether ASP exceeds AMP by more than a specified threshold percentage, currently set at 5 percent.

A basic analysis of the OIG's findings is useful when considering the potential program implications. Reviewing the data contained in the OIG report, we note the following:

- Of the 80 Healthcare Common Procedure Coding System (HCPCS) codes for which ASP exceeded AMP by the 5 percent threshold in 2008:
  - 5 codes (6 percent) exceeded the threshold in all four quarters;
  - 10 (13 percent) codes exceeded the threshold in three of the four quarters;
  - 18 (23 percent) codes exceeded the threshold in two of the four quarters; and,
  - 47 (59 percent) codes exceeded the threshold in one of the four quarters.
- Of the 33 codes that exceeded the 5 percent threshold for two or more quarters in 2008:
  - None had total allowed charges greater than $16 million;
  - None are among the top 50 Part B paid physician-administered drugs, as determined by 2008 Medicare allowed charges;
  - Total spending on these 33 HCPCS codes was slightly more than $70 million, or about 7 percent of all Part B physician-administered drug spending.

It is difficult to identify a causal relationship to explain why a particular HCPCS code's ASP would exceed the AMP by 5 percent or more. Market conditions affecting any one drug product can affect the overall calculation of ASP for the multiple source HCPCS code. The 77 percent of HCPCS codes that exceeded the corresponding AMP by the 5 percent threshold in 3 or fewer quarters, we believe that the ASP system properly corrected for changing market conditions and that making price adjustments outside of the normal ASP quarterly update process would have been unnecessary and could have contributed to market instability.

The CMS believes the OIG report and the CMS analysis demonstrate the complexity of making price substitutions. Data from a few single source drug manufacturers and data from certain quarters can strongly influence the potential impacts. Because making price substitutions is a complicated endeavor, CMS believes it should be undertaken with great care to avoid creating unintended consequences.

OIG Recommendation:

The CMS should develop a process to adjust payment amounts based on the results of OIG's pricing comparisons.

CMS Response:

We concur and look forward to working with the OIG on this issue.

OIG Recommendation:

The CMS should lower the Medicare reimbursement amounts for drugs with ASPs that meet the 5 percent threshold specified in Section 1847A(d)(3) of the Act.

CMS Response:

Currently, we do not concur. The CMS recognizes that complex operational issues, both within CMS and externally, could have an impact on potential payment rate substitutions. In particular, CMS is concerned that making payment substitutions, in light of the volatility of drug prices OIG has identified, could have a significant negative effect on providers' ability to purchase drugs and make those drugs available to Medicare beneficiaries.

We continue to believe that it is important to proceed cautiously while we seek to further understand the appropriate applicable threshold percentage for price substitutions. Each year, CMS undertakes notice and comment rulemaking to establish the threshold for ASP to AMP comparisons. As noted in the 2010 Medicare Physician Fee Schedule Notice of Proposed Rulemaking (74 Fed. Reg. 33,623), at this time we do not have sufficient data to suggest that another level is more appropriate, and we have continued the 5 percent threshold into 2010.

We believe further analysis of the differences between ASP and AMP and the quality of some of the reported data are important next steps for developing the price substitution policies and a process for adjusting payment amounts. CMS is committed to engaging stakeholders, including manufacturers and providers of drugs affected by potential price substitutions, with adequate notice of our intention regarding price substitutions and allowing for the opportunity for input with regard to the process for making such substitutions.

OIG Recommendation:

The CMS should continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with OIG about administrative remedies for noncompliance.

CMS Response:

We concur. The CMS has been and continues to identify to the OIG drug manufacturers that have failed to submit required pricing data (AMP) timely for two or more quarters in a four-quarter period. We contact these drug manufacturers to remind them of their responsibilities and to request that they submit their data immediately. In some cases CMS has received missing data as a result of contacting manufacturers who did not timely reported data; however, other manufacturers have not submitted missing data. CMS will continue to work with the OIG and is in support of appropriate enforcement action against manufacturers who fail to comply with applicable requirements.

Again, we appreciate the opportunity to review and comment on this draft report.

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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