

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**COMPARISON OF AVERAGE SALES  
PRICES AND AVERAGE  
MANUFACTURER PRICES:  
AN OVERVIEW OF 2007**



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Inspector General

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# *Office of Inspector General*

<http://oig.hhs.gov>

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## OBJECTIVE

1. To identify drugs with average sales prices (ASP) that would have exceeded average manufacturer prices (AMP) by at least 5 percent in any quarter of 2007 if the revised ASP payment methodology had been in effect during the entire year.
2. To examine the impact of missing or unavailable AMP data on mandated comparisons between ASPs and AMPs in 2007.

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## 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 drug codes is equal to 106 percent of the volume-weighted ASPs for the drug's NDCs.

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 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 the Department 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.

To date, OIG has issued seven quarterly reports comparing ASPs to AMPs. This current pricing comparison examines data throughout all four quarters of 2007 using a revised ASP payment methodology recently implemented by statute. In December 2007, the Medicare,

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Medicaid, and SCHIP Extension Act of 2007, P.L. No. 110-173, changed the way in which CMS calculates volume-weighted ASPs, effective April 1, 2008.

For this study, we obtained ASP and AMP data submitted by manufacturers for the first through fourth quarters of 2007. We calculated a volume-weighted ASP and AMP for each drug in each quarter using CMS's revised ASP payment methodology. We compared ASPs and AMPs for each quarter in 2007 and identified drug codes that would have met the 5-percent threshold if the revised payment methodology had been in effect throughout the year.

In addition, we identified the number of NDCs for which AMP data were missing or unavailable in 2007, as well as the number of drug codes that were removed from OIG's pricing comparisons because AMPs were missing or unavailable. For the purposes of this study, an AMP was considered "missing" if the manufacturer had a Medicaid rebate agreement in 2007 but did not submit a price for one or more quarters or "unavailable" if the manufacturer did not participate in the Medicaid drug rebate program and was therefore not required to submit AMP data to CMS.

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### FINDINGS

**If the revised payment methodology had been in effect throughout 2007, 71 drug codes would have met the 5-percent threshold in at least one quarter.** One-fourth of these drug codes (18 of 71) would have met the 5-percent threshold during multiple quarters of 2007. ASPs for three of these drug codes (J1364, J2690, and Q0169) would have exceeded the AMPs by at least 5 percent in every quarter of 2007.

**Additional codes may have met the 5-percent threshold in 2007; however, missing or unavailable AMPs prevented OIG from performing pricing comparisons on these codes.** A total of 1,185 NDCs had no AMP data during one or more quarters of 2007. Manufacturers for almost half of these drug products participated in the Medicaid drug rebate program in 2007 and were therefore generally required to submit AMP data for at least certain of their products. Because some NDCs had missing or unavailable AMPs, the number of pricing comparisons performed in 2007 was reduced by about 25 percent in each of the first and third quarters and by over 40 percent in each of the second and fourth quarters. In fact, OIG was unable to perform any

pricing comparisons on 106 drug codes in 2007 because of missing or unavailable AMP data.

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## RECOMMENDATIONS

This is OIG's eighth report comparing ASPs to AMPs. The law 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.

Missing or unavailable AMP data have prevented OIG from performing mandated pricing comparisons on some drug codes. Drug manufacturers that fail to provide required AMPs in a timely manner may be subject to administrative action, including civil monetary penalties.

Consistent with statutory requirements, we recommend that CMS:

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

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

**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.**

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation to develop a process for adjusting payment amounts based on the results of OIG's pricing comparisons. However, CMS did not specifically concur with our recommendation to lower Medicare reimbursement for drugs that meet the 5-percent threshold. Rather, CMS emphasized both the complexity of substituting payment amounts and the importance of proceeding cautiously as it seeks to understand the appropriate threshold percentage for pricing substitutions. In response to our final recommendation, CMS stated that it will continue its efforts to ensure that manufacturers are submitting required AMP data in a timely

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manner and that it supports adequate enforcement action against those that fail to comply with reporting requirements.

OIG acknowledges that CMS must make complex decisions regarding price substitutions for eligible drugs. However, consistent with statutory requirements, we continue to recommend that Medicare reimbursement amounts for eligible codes be lowered pursuant to section 1847A(d)(3) of the Act. 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.



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## OBJECTIVES

1. To identify drugs with average sales prices (ASP) that would have exceeded average manufacturer prices (AMP) by at least 5 percent in any quarter of 2007 if the revised ASP payment methodology had been in effect during the entire year.
2. To examine the impact of missing or unavailable AMP data on mandated comparisons between ASPs and AMPs in 2007.

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## BACKGROUND

Section 1847A(d)(2)(B) of the Social Security Act (the Act) mandates that the Office of Inspector General (OIG) compare ASPs with 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 the Department of Health and Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement amounts. 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 . . . .”

To date, OIG has issued seven quarterly comparisons of ASPs and AMPs, including one for each quarter of 2007. This current report examines data throughout all four quarters of 2007 using a revised ASP payment methodology recently implemented by the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Extension Act), P.L. No. 110-173.

### **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 carriers, 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 carriers 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 manufacturers or package sizes.

Medicare and its beneficiaries spent about \$11 billion for Part B drugs in 2007.<sup>1</sup> Although Medicare paid for more than 675 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 2007, 55 codes accounted for 90 percent of the expenditures for Part B drugs, with only 12 of these drugs representing half of the total Part B drug expenditures.

### **Reimbursement Methodology for Part B Drugs and Biologicals**

Since January 2005, Medicare Part B has been paying for most covered drugs using a reimbursement methodology based on ASPs.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4 5</sup>

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<sup>1</sup> Figure based on CMS's 2007 Part B Extract and Summary System data, which were 90 percent complete at the time of extraction (March 2008).

<sup>2</sup> In 2004, the reimbursement amount for most covered drugs was based on 85 percent of the average wholesale price as published in national pricing compendia, such as the "Red Book." Prior to 2004, Medicare Part B reimbursed for covered drugs based on the lower of either the billed amount or 95 percent of the average wholesale price.

<sup>3</sup> Section 1847A(c)(3) of the Act.

<sup>4</sup> 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.

<sup>5</sup> Section 1847A(c)(2) of the Act.

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

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 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.

Prior to April 2008, CMS calculated volume-weighted ASPs using the equation presented in Appendix A. However, section 112(a) of the Extension Act changed section 1847A(b) of the Act to require that CMS compute volume-weighted ASPs using a revised methodology, effective April 2008. This revised methodology was initially 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). 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

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<sup>6</sup> Section 1927(b)(3) of the Act.

for the HCPCS code.<sup>7</sup> However, there is a two-quarter lag 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 2007 were used to establish reimbursement amounts for the third quarter of 2007, and ASPs from the fourth quarter of 2007 were used to establish reimbursement for the second quarter of 2008.

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. In other words, CMS used more than one methodology to volume-weight ASP data submitted by manufacturers for 2007. The ASP submissions from the first through third quarters of 2007 were volume-weighted using the previous ASP payment methodology, whereas fourth-quarter ASP submissions were volume-weighted using the revised methodology.

#### **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.<sup>8</sup>

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. Prior to 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. In December 2006, CMS instructed manufacturers to exclude customary prompt pay

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<sup>7</sup> Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

<sup>8</sup> 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.

discounts from their AMP calculations as of January 2007.<sup>9</sup> In July 2007, CMS published a final rule that, among other things, implements section 6001(c)(1) of the DRA and clarifies the way in which the AMP must be calculated.<sup>10</sup> Specifically, 42 CFR § 447.504 of the final regulation clarifies the manner in which the AMP is to be determined.<sup>11</sup>

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 milligram, 1 milliliter, 1 tablet, 1 capsule).

If a manufacturer fails to provide AMP data in a timely manner, civil monetary penalties may be imposed.<sup>12</sup> In addition, pursuant to section 1927(b)(4)(B) of the Act, the Secretary may terminate a rebate agreement "for violation of the requirements of the agreement or other good cause shown." CMS has taken actions to terminate manufacturers for failure to report drug pricing data as required by section 1927 of the Act. CMS has also provided OIG with information about manufacturers that failed to submit drug pricing data for the purposes of evaluating potential civil monetary penalty actions.

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

Since the ASP reimbursement methodology for Part B prescription drugs was implemented in January 2005, OIG has issued seven reports comparing ASPs and AMPs. A list of the seven previously issued reports is provided in Appendix B.

Four of OIG's seven pricing comparisons used ASP and AMP data from 2007, with one report issued for each of the quarters in the calendar year.<sup>13</sup> Reports comparing first through third-quarter ASPs and AMPs

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<sup>9</sup> Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 76, December 15, 2006.

<sup>10</sup> 72 Fed. Reg. 39142 (July 17, 2007).

<sup>11</sup> In December 2007, the United States District Court for the District of Columbia preliminarily enjoined the implementation of the 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 and the DRA requirements. Again, those aspects are not relevant for the purposes of this report.

<sup>12</sup> Pursuant to section 1927(b)(3)(C) of the Act.

<sup>13</sup> OEI-03-07-00530, September 2007; OEI-03-08-00010, December 2007; OEI-03-08-00130, May 2008; and OEI-03-08-00340, August 2008.

used CMS's previous method for volume-weighting data. The report comparing fourth-quarter ASPs and AMPs used the revised method for volume-weighting data.

Although CMS has acknowledged the Secretary's authority to adjust ASP payment limits based on the findings of OIG's pricing comparisons, the agency has yet to make any changes to Part B drug reimbursement as a result of these studies. In commenting on one of OIG's reports, CMS expressed a desire to better understand fluctuating differences between ASPs and AMPs, with the intent of developing a process to adjust payment amounts based on the results of OIG's pricing comparisons.<sup>14</sup> 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 first annual overview of ASPs and AMPs, and it examines data across all four quarters of 2007 using a revised ASP payment methodology recently implemented by CMS.

OIG will continue to issue reports based on quarterly pricing comparisons, along with annual overviews to summarize findings across each calendar year.

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## METHODOLOGY

We obtained from CMS NDC-level ASP data from the first through fourth quarters of 2007, which were used to establish Part B drug reimbursement amounts for the third quarter of 2007 through the second quarter of 2008, respectively. In addition, we obtained the files that CMS used to crosswalk NDCs to their corresponding HCPCS codes. We also obtained AMP data from CMS for the first through fourth quarters of 2007.<sup>15</sup>

### **Comparing Volume-Weighted ASPs to Volume-Weighted AMPs for 2007 Using the Revised ASP Payment Methodology**

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

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<sup>14</sup> OEI-03-07-00140, July 2007.

<sup>15</sup> ASP data from the first through fourth quarters of 2007 were current as of June 2007, September 2007, December 2007, and March 2008, respectively. AMP data from the first through fourth quarters of 2007 were current as of May 2007, September 2007, November 2007, and February 2008, respectively.

uses ASP information submitted by manufacturers for each NDC to calculate a volume-weighted ASP for each covered HCPCS code.

Because pricing data in the fourth quarter of 2007 were volume-weighted differently than in the other three quarters of 2007, results of OIG's separate pricing comparisons from each of the four quarters could not be readily combined and summarized for this 2007 calendar year overview. To address this issue, and to establish a more useful and consistent benchmark for comparisons of ASPs and AMPs over time, OIG opted to conduct its yearend overview using only the revised payment methodology.<sup>16</sup> To that end, it was necessary to recalculate volume-weighted ASPs and AMPs for the first through third quarters of 2007 using the revised payment methodology. Therefore, the results presented in this 2007 overview may differ from the results presented in each of the separate quarterly reports previously published by OIG.

Appendix C provides a more detailed description of the methods we used to calculate volume-weighted ASPs and AMPs.

For each quarter of 2007, we compared the volume-weighted ASPs and AMPs calculated under the revised payment methodology and identified HCPCS codes with ASPs that exceeded the AMPs by at least 5 percent.

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 2007, we then merged the results of the pricing comparisons from all four quarters.

#### **Analysis of Average Manufacturer Price Data That Were Missing or Unavailable in 2007**

We examined the number of NDCs for which manufacturers submitted ASP data but not AMP data, both in each quarter and across all four

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<sup>16</sup>Although this report applies the revised methodology to all four quarters of 2007, CMS was not required by law to calculate reimbursement using the revised method until the second quarter of 2008. Because second-quarter 2008 reimbursement amounts were calculated using ASP data from the fourth quarter of 2007, CMS was only required to apply the new methodology to ASP data beginning with the fourth quarter of 2007.

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quarters of 2007. We also identified the number of drug codes that were removed from OIG's pricing comparisons because AMP data were either missing or unavailable. For the purposes of this study, an AMP was considered "missing" if the manufacturer had a Medicaid rebate agreement in 2007 but did not submit a price for one or more quarters. 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 2007, we consulted the list of participating drug companies posted on CMS's Web site.

### **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.

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.

Furthermore, the definition of AMP changed in January 2007, such that AMPs must now be determined without regard to customary prompt pay discounts.<sup>17</sup> Because manufacturers are still required to include customary prompt pay discounts in their ASP calculations, the dynamic between ASPs and AMPs may be different in this report as compared to that in OIG reports using prices submitted prior to 2007.

### **Standards**

This inspection was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

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<sup>17</sup> Section 1927(k)(1) of the Act (as amended by section 6001(c)(1) of the DRA) and Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 76, December 15, 2006.

## ► FINDINGS

### **If the revised payment methodology had been in effect throughout 2007, 71 drug codes would have met the 5-percent threshold in at least one quarter**

In April 2008, CMS began volume-weighting ASP data using a revised methodology mandated by section 112(a) of the Extension Act.<sup>18</sup> If this revised

payment methodology had been used to volume-weight pricing data from the first through fourth quarters of 2007, ASPs for 71 HCPCS codes would have exceeded the AMPs by at least 5 percent in at least one quarter.

Appendix D presents a list of the 71 HCPCS codes, along with the quarter(s) in which each would have met the 5-percent threshold under the revised payment methodology.

### **One-fourth of these drug codes (18 of 71) would have met the 5-percent threshold during multiple quarters of 2007**

If the revised payment methodology had been in effect for all of 2007, ASPs for three HCPCS codes (J1364, J2690, and Q0169) would have exceeded the AMPs by at least 5 percent in every quarter. An additional three HCPCS codes would have met the 5-percent threshold in three of the four quarters. For another 12 HCPCS codes, ASPs would have exceeded AMPs by at least 5 percent in two quarters.

### **Additional codes may have met the 5-percent threshold in 2007; however, missing or unavailable AMPs prevented OIG from performing pricing comparisons on these codes**

In comparing ASPs to AMPs, OIG typically examines only those HCPCS codes with AMP data for every NDC that was used to establish the Medicare reimbursement

amount. Therefore, 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. For the purposes of this study, an AMP was considered “missing” if the manufacturer had a Medicaid rebate agreement in 2007 but did not submit a price for one or more quarters. An AMP was considered “unavailable” for an NDC if the

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<sup>18</sup> There is a two-quarter lag between the sales period for which ASPs are reported and the effective date of reimbursement amounts based on those ASPs. Therefore, the methodological changes that went into effect in April 2008 were applied by CMS to ASP data from two quarters prior (i.e., the fourth quarter of 2007).



## F I N D I N G S

manufacturer did not participate in the Medicaid drug rebate program and was therefore not required to submit AMP data to CMS.

### **Almost half of NDCs without AMP data belonged to manufacturers with Medicaid drug rebate agreements**

A total of 1,185 NDCs had no AMP data during one or more quarters of 2007. Manufacturers for almost half of these NDCs (529 of 1,185) participated in the Medicaid drug rebate program in 2007 and were therefore generally required to submit AMP data.<sup>19</sup> For 14 percent of these NDCs (74 of 529), manufacturers did not submit AMP data for any quarter of 2007. The majority (52 percent) of the 529 NDCs with missing AMP data belonged to two manufacturers.

Manufacturers for the remaining 656 of 1,185 NDCs did not participate in the Medicaid drug rebate program in 2007 and therefore were not required to submit AMP data during that time.

### **As a result of NDCs without AMP data, the number of pricing comparisons performed in 2007 was reduced by at least 25 percent**

In 2007, the number of NDCs with ASPs but no AMPs fluctuated from quarter to quarter, with the second and fourth quarters having more NDCs without AMPs. In the first and third quarters of 2007, about one-fourth of HCPCS codes were excluded from OIG's pricing comparisons because AMP data were missing or unavailable for one or more of the associated NDCs.<sup>20</sup> In the second and fourth quarters of 2007, over 40 percent of HCPCS codes were excluded from OIG's pricing comparisons because AMP data were missing or unavailable. Table 1 on the next page lists the number of NDCs without AMP data in each quarter, as well as the number and percentage of HCPCS codes that were excluded from our analysis as a result of NDCs without AMPs.

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<sup>19</sup> 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.

<sup>20</sup> Relative to the total number of HCPCS codes in each quarter with Medicare reimbursement amounts based on the ASP payment methodology.

F I N D I N G S

**Table 1. Impact of NDCs Without AMP Data on Quarterly Comparisons of ASPs to AMPs**

Quarter in 2007	Number of NDCs With ASP Data but No AMP Data	Number of HCPCS Codes Excluded Because of NDCs Without AMP Data	Percentage of HCPCS Codes Excluded Because of NDCs Without AMP Data
<b>First Quarter</b>	<b>653</b>	<b>141</b>	<b>27%</b>
<i>Missing</i>	102		
<i>Unavailable</i>	551		
<b>Second Quarter</b>	<b>880</b>	<b>211</b>	<b>41%</b>
<i>Missing</i>	355		
<i>Unavailable</i>	525		
<b>Third Quarter</b>	<b>603</b>	<b>138</b>	<b>26%</b>
<i>Missing</i>	100		
<i>Unavailable</i>	503		
<b>Fourth Quarter</b>	<b>1051</b>	<b>237</b>	<b>45%</b>
<i>Missing</i>	487		
<i>Unavailable</i>	564		

Source: OIG analysis of ASP and AMP data from the first through fourth quarters of 2007.

**As a result of NDCs without AMP data, no pricing comparisons were performed on over 100 drug codes in 2007**

Because of NDCs without AMP data, a total of 268 different HCPCS codes were excluded from OIG’s pricing comparisons during one or more quarters of 2007. For 106 of these codes, we were unable to perform any pricing comparisons for the entire year because AMPs were missing or unavailable for one or more of the associated NDCs.



## R E C O M M E N D A T I O N S

This is OIG's eighth report comparing ASPs to AMPs since the ASP reimbursement methodology for Part B prescription drugs took effect in January 2005. 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. 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. In addition, CMS has not specified the process by which it will make reimbursement adjustments for drugs that meet the 5-percent threshold.

This current study, which summarizes data across all four quarters of 2007, identifies 71 drug codes that would have been eligible for price adjustment if CMS's revised ASP payment methodology had been in effect throughout 2007. One-fourth of the 71 drug codes would have met the 5-percent threshold during multiple quarters of 2007.

Additional codes may have been eligible for price adjustments based on data from 2007; however, missing and unavailable AMPs prevented OIG from performing pricing comparisons on at least 25 percent of codes in each quarter. Manufacturers for almost half of the NDCs without AMPs participated in the Medicaid drug rebate program in 2007 and were therefore generally expected to submit AMP data.

Consistent with statutory requirements, we recommend that CMS:

### **Develop a Process To Adjust Payment Amounts Based on the Results of OIG's Pricing Comparisons**

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 will remain in effect.

### **Subsequently 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, would have 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**

CMS should continue to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data. 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.

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**AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

CMS concurred with our recommendation to develop a process for adjusting payment amounts based on the results of OIG's pricing comparisons. However, CMS did not specifically concur with our recommendation to lower Medicare reimbursement for drugs that meet the 5-percent threshold specified in section 1847A(d)(3) of the Act. Rather, CMS emphasized both the complexity of substituting payment amounts and the importance of proceeding cautiously as it seeks to understand the appropriate threshold percentage for pricing substitutions. CMS expressed a desire to better understand differences between ASPs and AMPs, as well as to engage stakeholders (particularly drug manufacturers affected by potential price substitutions) and provide adequate notice when developing its pricing substitution policies. In response to our final recommendation, CMS stated that it will continue its efforts to ensure that manufacturers are submitting required AMP data in a timely manner and that it supports adequate enforcement action against those that fail to comply with reporting requirements.

OIG acknowledges that CMS must make complex decisions regarding price substitutions for eligible drugs, including the circumstances under which substitutions will be made, the effective date of such substitutions, and the time period for which the substitutions will remain in effect. However, consistent with statutory requirements, we continue to recommend that Medicare reimbursement amounts for eligible codes be lowered pursuant to section 1847A(d)(3) of the Act, particularly for codes that meet the threshold percentage in multiple quarters. OIG will continue to assist CMS, both in developing a timely

## R E C O M M E N D A T I O N S

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 E.

**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**

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

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

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

**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 to 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 to 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 to Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2008” (OEI-03-08-00340), August 2008.

## **Detailed Methodology for Calculating Volume-Weighted Average Sales Prices and Average Manufacturer Prices for 2007**

Before computing quarterly volume-weighted average sales prices (ASP) and average manufacturer prices (AMP) for 2007, it was necessary to identify the national drug codes (NDC) that should be included in each quarter's calculations and convert AMPs so that they would be comparable to ASPs.

### **Analysis of 2007 ASPs**

When calculating volume-weighted ASPs under the revised ASP payment methodology, we included only those NDCs that the Centers for Medicare & Medicaid Services (CMS) deemed valid in each quarter of 2007. We did not examine NDCs that CMS opted to exclude from its own calculation of volume-weighted ASPs each quarter, nor did we verify the accuracy of CMS's crosswalk files.

### **Analysis of 2007 AMPs**

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.

In making these conversions, we examined AMPs only for those NDCs that CMS used in its calculation of volume-weighted ASPs for a given quarter. If AMP data were not available for one or more of these NDCs, we excluded the corresponding Healthcare Common Procedure Coding System (HCPCS) code from our analysis of that quarter's data.

For each quarter, we then multiplied the AMPs for the remaining NDCs 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. We will refer to the resulting amounts as converted AMPs. If we could not successfully identify the amount of the drug reflected by the ASP in a given quarter and therefore could not calculate a converted AMP, we excluded the corresponding HCPCS codes from our analysis of that quarter.



## A P P E N D I X ~ C

Using the converted AMPs for the remaining NDCs, we then calculated the quarterly volume-weighted AMP for each of the codes, consistent with the revised methodology for calculating volume-weighted ASPs.

**Seventy-one Healthcare Common Procedure Coding System Codes With Average Sales Prices That Exceeded Average Manufacturer Prices by at Least 5 Percent in 2007 Under the Revised Payment Methodology**


HCPCS 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
J2690	X	X	X	X
Q0169	X	X	X	X
J2800	X	X	X	
J7505	X	X	X	
J1120		X	X	X
J1457	X	X		
J1756	X	X		
J1790	X	X		
J2321	X	X		
J2440	X	X		
J9065	X		X	
J9250	X		X	
J9260	X		X	
J0476		X	X	
J2370		X	X	
J3315	X			X
J2760		X		X
J0456	X			
J0770	X			
J0780	X			
J1940	X			
J2545	X			
J3230	X			
J3410	X			
J3475	X			
J7608	X			
J8530	X			
J8560	X			
J9060	X			
J9062	X			
J9360	X			
Q0171	X			
Q0172	X			
J0280		X		
J0637		X		
J2060		X		

A P P E N D I X ~ D

Quarter(s) in Which the Codes Met the 5-Percent Threshold				
HCPCS Code	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
J3070		X		
J3465		X		
J9175		X		
J9340		X		
J0210			X	
J0636			X	
J0800			X	
J1240			X	
J1580			X	
J1800			X	
J1840			X	
J1850			X	
J2150			X	
J2430			X	
J2560			X	
J2675			X	
J2700			X	
J2730			X	
J3000			X	
J7500			X	
J7620			X	
J7631			X	
J7669			X	
J9050			X	
J9190			X	
J9208			X	
Q0175			X	
Q0176			X	
J0300				X
J1270				X
J1441				X
J1626				X
J2505				X
Q0168				X

Source: Office of Inspector General's analysis of ASP and AMP data from the first through fourth quarters of 2007.

**Agency Comments**



DEPARTMENT OF HEALTH & HUMAN SERVICES

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*Administrator*  
Washington, DC 20201

Centers for Medicare & Medicaid Services

**DATE:** OCT 31 2008

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Kerry Weems   
Acting Administrator

**SUBJECT:** Office of Inspector General's (OIG) Draft Report: "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007" (OEI-03-08-00450)

Thank you for the opportunity to review and comment on the OIG draft report entitled, "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007." 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 during 2007. This report differs from prior reports of similar focus in that it applies the volume-weighting methodology specified by the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) to each quarter of 2007. The findings, however, are generally consistent with previous report findings. The OIG found that 71 drug codes would have met the 5 percent threshold in at least 1 quarter during 2007. Notably, the number of drug codes exceeding the 5 percent threshold is substantially lower in the fourth quarter than in the other three quarters reviewed for this report.

Medicare first applied the MMSEA volume-weighting methodology to data from the fourth quarter 2007 to calculate payment amounts effective April 2008. Thus, the OIG's findings for the first three quarters of 2007 are instructive to the extent they may predict results of future OIG price comparison studies. However, the findings for the fourth quarter are more informative as they represent a true comparison of payment limits calculated using the same methodology.

To better understand the OIG's findings and to consider potential program implications, we requested and received a supporting data table from OIG for the 71 drugs identified in the report. Our review of the OIG supporting data table indicated the following results:

- A few single source drug codes account for most of the potential impact from the price comparisons;

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- Sixty-four percent of the total annual potential program impact, as identified by OIG, arise from the price comparisons for the fourth quarter alone;
- Three single source drug codes account for nearly 98 percent of the potential impact for the fourth quarter;
  - Two of these three drug codes did not exceed the threshold in the other three quarters reviewed;
- Another single source drug code exceeded the threshold in the third quarter and accounts for 72 percent of the potential impact for that quarter and over 20 percent of potential impact of price substitutions identified for the year;
- For drug codes that exceeded the threshold for two or more quarters, nearly 94 percent of the potential impact is attributed to one single source drug code that exceeded the threshold in the first and fourth quarters; and,
- For the remaining 17 drug codes identified in this report that exceeded the threshold in 2 or more quarters, the potential program impact would be approximately \$500,000 for all of 2007.

The Centers for Medicare & Medicaid Services (CMS) believes these findings 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**

The CMS recognizes that complex operational issues, both within CMS and externally, could have an impact on potential payment rate substitutions. 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. 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, particularly manufacturers of drugs impacted by potential

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price substitutions, with adequate notice of our intention regarding price substitutions and allowing for the opportunity for input with regards 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**

The CMS has been and continues to identify 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 data 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 have 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.



## A C K N O W L E D G M E N T S

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.