

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**COMPARISON OF THIRD-QUARTER  
2006 AVERAGE SALES PRICES TO  
AVERAGE MANUFACTURER PRICES:  
IMPACT ON MEDICARE  
REIMBURSEMENT FOR FIRST  
QUARTER 2007**



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Inspector General

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## OBJECTIVE

1. To determine whether average sales prices (ASP) for individual Medicare Part B prescription drugs exceeded average manufacturer prices (AMP) by at least 5 percent during the third quarter of 2006.
2. To determine the impact of lowering reimbursement amounts for drugs that meet the 5-percent threshold.

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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. Section 1847A(c) of the Social Security Act (the Act) 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. 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.

Although manufacturers submit ASP data by NDCs, CMS does not reimburse Medicare providers for drugs using NDCs. Instead, CMS uses Healthcare Common Procedure Coding System (HCPCS) codes. More than one NDC may meet the definition of a particular HCPCS code; therefore, CMS uses NDC-level information submitted by the manufacturers to calculate an ASP for each covered HCPCS code. When CMS calculates payment amounts for HCPCS codes, it must weight ASPs at the NDC level by the amount of the drug sold during the quarter. Under the ASP pricing methodology, Medicare's allowance for most Part B drug codes is equal to 106 percent of the volume-weighted ASPs for those HCPCS codes.

Section 1847A(d)(2)(B) of the Act mandates that the Office of Inspector General (OIG) compare ASPs with AMPs. As defined in section 1927(k)(1) of the Act during the time period covered by our review, an AMP was 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, minus customary prompt pay discounts. As part of the Medicaid drug rebate program, manufacturers must provide CMS with the AMP for each of their NDCs on a quarterly basis, pursuant to section 1927(b)(3) of the Act. If OIG finds that the ASP for

a drug exceeds the AMP by a certain threshold (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. Section 1847A(d)(3)(C) goes on to state “. . . 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 the (i) widely available market price . . . (if any); or (ii) 103 percent of the average manufacturer price . . . .”

For this study, we obtained CMS’s ASP data from the third quarter of 2006, which were used to establish volume-weighted ASPs and reimbursement amounts for the first quarter of 2007. We also obtained CMS’s AMP data from the third quarter of 2006. We used these AMP data to calculate volume-weighted AMPs using the same method that CMS uses to calculate volume-weighted ASPs. Ultimately, we compared volume-weighted ASPs to volume-weighted AMPs for 326 HCPCS codes and identified codes for which ASPs exceeded AMPs by at least 5 percent.

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## FINDINGS

**For 39 of 326 HCPCS codes reviewed, the volume-weighted ASP exceeded the volume-weighted AMP by at least 5 percent.** Based on our analysis of data from the third quarter of 2006, 39 of the 326 HCPCS codes included in our review had an ASP that exceeded the AMP by at least 5 percent. Of these 39 HCPCS codes, 12 were also identified in a previous OIG report as having ASPs that exceeded AMPs by at least 5 percent in the fourth quarter of 2005. Four of the twelve also met the 5-percent threshold in OIG’s initial comparison of ASPs and AMPs, which used data from the third quarter of 2004. In other words, ASPs for these four drugs have exceeded AMPs by at least 5 percent in each of our three reports, dating back more than 2 years.

If reimbursement amounts for these 39 codes had been based on 103 percent of the AMP during the first quarter of 2007, we estimate that Medicare expenditures would have been reduced by \$13 million. One of the thirty-nine HCPCS codes (J7620) accounted for over 60 percent of the \$13 million. The ASP for this code also exceeded the AMP by at least 5 percent in a previous OIG report comparing prices from the fourth quarter of 2005.

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## RECOMMENDATION

This is OIG's third review comparing ASPs and AMPs, and we identified 39 HCPCS codes that are eligible for price adjustments under authority of the Secretary. Of these 39 codes, 4 have met the threshold for price adjustments in all three of OIG's studies comparing ASPs and AMPs. An additional eight HCPCS codes were previously eligible for price adjustments as a result of OIG's second report, which used data from the fourth quarter of 2005.

**We therefore recommend that CMS adjust Medicare reimbursement amounts for drugs that meet the 5-percent threshold specified in section 1847A(d)(3) of the Act. CMS may want to specifically focus on those drugs that, according to the three OIG reports, have ASPs that consistently meet this threshold.**

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS expressed a desire to better understand the sources of 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. CMS would like to collaborate with OIG to minimize the time lag between OIG analysis and the implementation of quarterly ASP prices. To help ensure that ASP submissions are correct, CMS suggests that OIG focus its activities on manufacturers of drugs whose ASPs consistently differ from AMPs. CMS did not specify what 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.

OIG acknowledges that manufacturers' drug prices will inevitably fluctuate to some extent. However, the difference between ASPs and AMPs has not fluctuated considerably for 12 of the 39 HCPCS codes identified in this report. Rather, these codes have been consistently identified as having ASPs at or above the 5-percent threshold. OIG continues to recommend that the Medicare reimbursement amounts for these 12 codes, as well as the other codes identified in the report, be adjusted pursuant to section 1847A(d)(3) of the Act. As in the past, OIG will work with CMS to ensure that pricing comparison data are available to the Agency in a timely manner. In addition, we will consider CMS's suggestion to focus our activities on manufacturers of drugs whose ASPs consistently differ from AMPs.

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## OBJECTIVE

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2. To determine the impact of lowering reimbursement amounts for drugs that meet the 5-percent threshold.

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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 threshold (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. Section 1847A(d)(3)(C) of the Act goes on to state “. . . 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 the (i) 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 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 manufacturer or package size information.

Medicare and its beneficiaries spent almost \$10 billion for Part B drugs in 2005.<sup>1</sup> Although Medicare paid for almost 550 outpatient prescription drug HCPCS codes that year, the majority of spending for Part B drugs was concentrated on a relatively small subset of those codes. In 2005, 53 codes represented 90 percent of the expenditures for Part B drugs, with only 11 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, Public Law 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>

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

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<sup>1</sup> At the time of this report, information regarding complete 2006 Part B drug expenditures was not yet available. Therefore, we used total expenditures from 2005.

<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.

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.

Third-quarter 2006 ASP submissions from manufacturers served as the basis for first-quarter 2007 Medicare allowances for most covered drug codes. Under the ASP pricing methodology, the Medicare allowance for most Part B drugs is equal to 106 percent of the ASP for the HCPCS code. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

#### **The Medicaid Drug Rebate Program and AMP**

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>7</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 Deficit Reduction Act of 2005 (DRA), Public Law 109-171, manufacturers were required to deduct customary prompt pay discounts when calculating AMPs.<sup>8</sup> However, section 6001(c)(1) of the DRA amended section 1927(k)(1) of the Act and the AMP is now determined without regard to customary prompt pay

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

<sup>7</sup> Pursuant to section 6001(b)(1)(A) of the DRA, manufacturers are also required to report AMPs on a monthly basis as of January 2007. Drug manufacturers will continue to report quarterly AMP data in addition to their monthly submissions.

<sup>8</sup> Section 1927(k)(1) of the Act.

discounts. CMS has instructed manufacturers to exclude customary prompt pay discounts from their AMP calculations as of January 2007.<sup>9</sup>

The AMP is 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).

#### **Office of Inspector General's Monitoring of ASP and AMP**

In April 2006, OIG released the first of its reports comparing ASPs to AMPs. That report, entitled "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices" (OEI-03-04-00430), identified 51 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004. Given that OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology, CMS opted not to take action in response to OIG's findings.

Three months later, OIG released a second report comparing ASPs to AMPs, entitled "Comparison of Fourth Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2006" (OEI-03-06-00370). According to this follow-up study, which used data from the fourth quarter of 2005, 46 of 341 HCPCS codes had ASPs that exceeded AMPs by at least 5 percent. Twenty of these forty-six codes had also met the 5-percent threshold in OIG's initial pricing comparison of third-quarter 2004 ASPs and AMPs.

To date, CMS has not made any adjustments to Part B drug reimbursement as a result of the two OIG reports comparing ASPs and AMPs. In commenting on OIG's initial report, CMS acknowledged the Secretary's authority to adjust ASP payment limits when certain conditions are met. However, CMS stated that other issues should be considered before making any price reductions, including the timing and frequency of pricing comparisons, stabilization of ASP reporting, the effective date and duration of rate substitution, and the accuracy of ASP and AMP data.

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

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## METHODOLOGY

We obtained from CMS NDC-level ASP data from the third quarter of 2006, which were used to establish Part B drug reimbursement amounts for the first quarter of 2007. In addition, we obtained the file that CMS used to crosswalk NDCs to their corresponding HCPCS codes. Both the ASP data and the crosswalk file were updated as of December 2006. We also obtained AMP data from CMS for the third quarter of 2006. During the third quarter of 2006, manufacturers were required to deduct customary prompt pay discounts when calculating both ASPs and AMPs.

### **Calculation of Volume-Weighted Average Sales Price**

As mentioned previously, Medicare does not base reimbursement for covered drugs on NDCs; instead, it uses HCPCS codes. Therefore, CMS uses ASP information submitted by manufacturers for each NDC to calculate a volume-weighted ASP for each covered HCPCS code. When calculating these volume-weighted ASPs, CMS includes only NDCs with ASP submissions that are deemed valid. We did not examine the NDCs that CMS opted to exclude from its calculation, nor did we verify the accuracy of CMS's crosswalk files.

As of December 2006, CMS had established prices for 514 HCPCS codes based on the ASP reimbursement methodology.<sup>10</sup> Reimbursement amounts for the 514 HCPCS codes were based on ASP data for 3,160 NDCs.

To calculate the volume-weighted ASPs for these 514 codes, CMS used an equation that involves the following variables: the ASP for the 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

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<sup>10</sup> Several Part B drugs, including certain vaccines and blood products, are not paid under the ASP methodology.

11-digit NDC when developing its crosswalk files. A more detailed description of CMS's method of calculating volume-weighted ASPs is provided in Appendix A.

#### **Analysis of Average Manufacturer Price Data**

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 the AMP would be comparable to the ASP, it was necessary to convert the AMP for each NDC so that it represented the total amount of the drug contained in that NDC.

In making these conversions, we examined AMPs only for those 3,160 NDCs that CMS used in its calculation of volume-weighted ASPs for the 514 codes. If AMP data were not available for one or more of these NDCs, we excluded the corresponding HCPCS code from our analysis. We excluded a total of 174 HCPCS codes using this conservative approach. The remaining 340 HCPCS codes had AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs. These 340 HCPCS codes represented 1,639 NDCs.

We then multiplied the AMPs for these 1,639 NDCs by the total amount of the drug contained in each NDC, as identified by sources such as the CMS crosswalk file, the "Red Book," manufacturer Web sites, and the Food and Drug Administration's NDC directory. We will refer to the resulting amounts as converted AMPs. For 19 NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These 19 NDCs were crosswalked to 14 HCPCS codes. We did not include these 14 HCPCS codes (161 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,478 NDCs, we then calculated volume-weighted AMPs for each of the codes using the same method that CMS uses to calculate volume-weighted ASPs. We calculated volume-weighted AMPs for a total of 326 HCPCS codes. We did not independently verify the accuracy of manufacturer-reported ASP and AMP data.

#### **Comparing Volume-Weighted ASPs to Volume-Weighted AMPs**

For each of the 326 HCPCS codes included in our study, we then compared the volume-weighted ASPs and AMPs and identified codes with ASPs that exceeded 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 units information. According to our review, two of the codes that met the 5-percent threshold had associated NDCs with potentially inaccurate billing units.<sup>11</sup> Given that volume-weighted ASPs and AMPs were calculated using this billing unit information, we could not be certain that the results for these two codes were correct. Therefore, we did not include these two codes in our findings.

For the remaining HCPCS codes, we then estimated the monetary impact of lowering reimbursement to 103 percent of the AMP.<sup>12</sup> First, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the first-quarter 2007 reimbursement amount for the HCPCS code, which is equal to 106 percent of the volume-weighted ASP. To estimate the financial effect for the first quarter of 2007, we then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2006, as reported in CMS's Part B Extract and Summary System (BESS).<sup>13</sup> This estimate assumes that the number of services that were allowed by Medicare in 2006 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2006 and 2007.

### **Limitation**

In a February 2006 report entitled "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310), OIG stated that CMS's method for calculating the volume-weighted ASP is incorrect because CMS does not use billing units consistently throughout its equation. As a result of this finding, OIG recommended that CMS change its calculation of volume-weighted

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<sup>11</sup> NDCs for these two codes had billing unit information in CMS's crosswalk file that may not have accurately reflected the number of billing units actually contained in the NDC.

<sup>12</sup> Pursuant to section 1847A(d)(3) of the Act, if the ASP for a drug exceeds the AMP by at least 5 percent, the Secretary has authority to disregard the ASP pricing methodology for that drug and replace the payment amount for the drug code 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.

<sup>13</sup> At the time of extraction, 2006 BESS data were only 66 percent complete. Therefore, to estimate the number of services that would have been provided during the entirety of 2006, we multiplied the number of allowed services currently reported in BESS by 1.515.

## I N T R O D U C T I O N

ASPs. Although CMS indicated that it may consider altering the ASP methodology, it has yet to do so.

OIG continues to believe that CMS calculates volume-weighted ASPs incorrectly and that this incorrect calculation results in reimbursement amounts that are inaccurate and inconsistent with the ASP payment methodology set forth in section 1847A(b)(3) of the Act. However, to be consistent with the payment methodology currently used by CMS, OIG has opted to use CMS's calculation method when comparing ASPs and AMPs.

### **Standards**

This study 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.

► F I N D I N G

**For 39 of 326 HCPCS codes reviewed, the volume-weighted ASP exceeded the volume-weighted AMP by at least 5 percent**

Consistent with sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act, OIG compared ASPs to AMPs to identify instances in which the ASP for a particular drug exceeded the AMP

by a threshold of 5 percent. Thirty-nine of the three hundred and twenty-six HCPCS codes (12 percent) included in our review met or surpassed this 5-percent threshold in the third quarter of 2006. Of these 39 HCPCS codes, 12 were also identified in a previous OIG report as having ASPs that exceeded AMPs by at least 5 percent in the fourth quarter of 2005.<sup>14</sup> Four of the twelve also met the 5-percent threshold in OIG’s initial comparison of ASPs and AMPs, which used data from the third quarter of 2004.<sup>15</sup> In other words, the ASPs for these four drugs have exceeded the AMP by at least 5 percent in each of our three reports, dating back more than 2 years. A list of all 39 HCPCS codes is presented in Appendix B.

The table below describes the extent to which ASPs exceeded AMPs for the 39 HCPCS codes. For 17 of the 39 codes, volume-weighted ASPs exceeded volume-weighted AMPs by 20 percent or more, with ASPs for 6 of these exceeding AMPs by more than 60 percent.<sup>16</sup>

**Table: Extent to Which ASPs Exceeded AMPs for 39 HCPCS Codes**

| Percentage Difference Between ASP and AMP | Number of HCPCS Codes |
|---|-----------------------|
| 5%–9%                                     | 12                    |
| 10%–19%                                   | 10                    |
| 20%–29%                                   | 7                     |
| 30%–39%                                   | 2                     |
| 40%–49%                                   | 2                     |
| 50%–59%                                   | 0                     |
| 60%–69%                                   | 2                     |
| 70%–79%                                   | 0                     |
| 80%–89%                                   | 1                     |
| 90%–99%                                   | 2                     |
| 100% and above                            | 1                     |
| <b>Total</b>                              | <b>39</b>             |

Source: OIG analysis of fourth-quarter 2006 ASP and AMP data, 2006.

<sup>14</sup> “Comparison of Fourth-Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Second-Quarter 2006” (OEI-03-06-00370).

<sup>15</sup> “Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Price to Average Manufacturer Price” (OEI-03-04-00430).

<sup>16</sup> Because of the confidential nature of ASP data, OIG is not publicly providing the exact percentages for each of the 39 HCPCS codes.

**Lowering reimbursement amounts for these 39 HCPCS codes to 103 percent of the average manufacturer price would have reduced Medicare allowances by an estimated \$13 million in the first quarter of 2007**

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 the (i) widely available market price . . . (if any); or (ii) 103 percent of the average manufacturer price . . . .”<sup>17</sup> In this study, we identified 39 HCPCS codes that met or exceeded the 5-percent threshold specified in the Act. If reimbursement amounts for these 39 codes were based on 103 percent of the AMP during the first quarter of 2007, we estimate that Medicare expenditures would be reduced by \$13 million in that quarter.<sup>18</sup>

One of the thirty-nine HCPCS codes, J7620, accounted for over 60 percent of the \$13 million. If the reimbursement amount for this one code were based on 103 percent of the AMP during the first quarter of 2007, Medicare expenditures would be reduced by an estimated \$8 million. The ASP for this code also exceeded the AMP by at least 5 percent in a previous OIG report comparing prices from the fourth quarter of 2005. Given that fourth-quarter 2005 ASPs were used to establish second-quarter 2006 reimbursement amounts, the previous report estimated that lowering reimbursement for J7620 to 103 percent of AMP for the second quarter of 2006 would have reduced Medicare expenditures by \$6 million. As in this report, the estimated savings for HCPCS code J7620 accounted for the largest single share of the total savings for that quarter.

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<sup>17</sup> 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.

<sup>18</sup> This savings estimate is based on one-fourth of the number of estimated services allowed by Medicare for each HCPCS code in 2006. One HCPCS code, J8560, did not have any allowances in 2006 according to the BESS data. Therefore, there were no estimated savings for this code.

## ► R E C O M M E N D A T I O N

For the purpose of monitoring Medicare reimbursement amounts based on ASPs and 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. This review is the third such comparison conducted by OIG, and we identified 39 HCPCS codes that are eligible for price adjustments under authority of the Secretary. Of these 39 codes, 4 have met the threshold for price adjustments in all three of OIG's studies comparing ASPs and AMPs. An additional eight HCPCS codes were also previously eligible for price adjustments as a result of OIG's second report, which used data from the fourth quarter of 2005.

**We therefore recommend that CMS adjust Medicare reimbursement amounts for drugs that meet the 5-percent threshold specified in section 1847A(d)(3) of the Act. CMS may want to specifically focus on those drugs that, according to the three OIG reports, have ASPs that consistently meet this threshold.** In addition, we note that the results of our review are based on data from the third quarter of 2006. However, the definition of AMP changed in January 2007, such that AMPs are determined without regard to customary prompt pay discounts. CMS should consider taking this change into account when adjusting Medicare reimbursement amounts.

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### AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

According to CMS, the results of this report imply that some fluctuation in the difference between ASPs and AMPs is to be expected. CMS expressed a desire to better understand the sources of such fluctuations, with the intent of developing a process to adjust payment amounts based on the results of OIG's pricing comparisons. CMS would like to collaborate with OIG to minimize the time lag between OIG analysis and the implementation of quarterly ASP prices. To help ensure that ASP submissions are correct, CMS suggests that OIG focus its activities on manufacturers of drugs whose ASPs consistently differ from AMPs. CMS did not specify what 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. See Appendix C for the full text of CMS's comments.

Since the ASP pricing methodology was implemented in January 2005, OIG has completed three studies comparing ASPs and AMPs, as

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

mandated by sections 1847A(d)(2)(B) and 1847A(d)(3) of the Act. To date, CMS has made no payment reductions for HCPCS codes with ASPs that meet the 5-percent threshold.

OIG acknowledges that manufacturers' drug prices will inevitably fluctuate to some extent. However, the difference between ASPs and AMPs has not fluctuated considerably for 12 of the 39 HCPCS codes identified in this report. Rather, these codes have been consistently identified as having ASPs at or above the 5-percent threshold. OIG continues to recommend that the Medicare reimbursement amounts for these 12 codes, as well as the other codes identified in the report, be adjusted pursuant to section 1847A(d)(3) of the Act. As in the past, OIG will work with CMS to ensure that pricing comparison data are available to the Agency in a timely manner. In addition, we will consider CMS's suggestion to focus our activities on manufacturers of drugs whose ASPs consistently differ from AMPs.

**Equation Used by the Centers for Medicare & Medicaid Services to Calculate Volume-Weighted Average Sales Prices**

In the following equation, a “unit” is defined as the entire amount of the drug contained in the NDC:

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

CMS’s calculation of volume-weighted ASPs is discussed in greater detail in the OIG report, “Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs” (OEI-03-05-00310). This report found that CMS’s method for calculating volume-weighted ASPs is incorrect because CMS does not use billing units consistently throughout its equation. Therefore, OIG recommended that CMS adopt an alternate method for calculating volume-weighted ASPs. Although CMS indicated that it may consider altering the ASP methodology, it has yet to do so.

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**Thirty-nine HCPCS Codes With an ASP That Exceeded the AMP by at Least 5 Percent**

| HCPCS Code | Short Description            | HCPCS Code Dosage |
|------------|------------------------------|-------------------|
| J0256      | Alpha 1 proteinase inhibitor | 10 MG             |
| J0360**    | Hydralazine hcl injection    | 20 MG             |
| J0456      | Azithromycin                 | 500 MG            |
| J0610*     | Calcium gluconate injection  | 10 ML             |
| J0636      | Inj calcitriol               | 0.1 MCG           |
| J0637      | Caspofungin acetate          | 5 MG              |
| J0640*     | Leucovorin calcium injection | 50 MG             |
| J0694*     | Cefoxitin sodium injection   | 1 GM              |
| J1110      | Inj dihydroergotamine mesylt | 1 MG              |
| J1260      | Dolasetron mesylate          | 10 MG             |
| J1364      | Erythro lactobionate         | 500 MG            |
| J1752      | Iron dextran 267 injection   | 50 MG             |
| J1790      | Droperidol injection         | 5 MG              |
| J1940      | Furosemide injection         | 20 MG             |
| J1955      | Inj levocarnitine            | 1 GM              |
| J2320      | Nandrolone decanoate         | 50 MG             |
| J2321      | Nandrolone decanoate         | 100 MG            |
| J2322      | Nandrolone decanoate         | 200 MG            |
| J2545**    | Pentamidine isethionte       | 300 MG            |
| J2680      | Fluphenazine decanoate       | 25 MG             |
| J2700      | Oxacillin sodium injection   | 250 MG            |
| J2792      | Rho(D) immune globulin h, sd | 100 IU            |
| J3010      | Fentanyl citrate injection   | 0.1 MG            |
| J3230      | Chlorpromazine hcl injection | 50 MG             |
| J3410**    | Hydroxyzine hcl injection    | 25 MG             |
| J3470      | Hyaluronidase injection      | 150 UNITS         |
| J3472      | Ovine                        | 1000 USP UNITS    |
| J3475*     | Inj magnesium sulfate        | 500 MG            |
| J7500      | Azathioprine oral            | 50 MG             |
| J7501*     | Azathioprine parenteral      | 100 MG            |
| J7608      | Acetylcysteine inh sol u d   | 1 GM              |
| J7620*     | Albuterol ipratrop non-comp1 | 2.5 MG/0.5 MG     |

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| HCPCS Code | Short Description           | HCPCS Code Dosage |
|------------|-----------------------------|-------------------|
| J7631      | Cromolyn sodium inh sol u d | 10 MG             |
| J8560      | Etoposide oral              | 50 MG             |
| J9000*     | Doxorubic hcl vl chemo      | 10 MG             |
| J9065      | Inj cladribine              | 1 MG              |
| J9200      | Floxuridine injection       | 500 MG            |
| J9214*     | Interferon alfa-2b inj      | 1 MIL UNITS       |
| J9360**    | Vinblastine sulfate inj     | 1 MG              |

\* Codes were also identified in a previous OIG report as having ASPs that exceeded AMPs by at least 5 percent in the fourth quarter of 2005.

\*\* Codes were also identified in two previous OIG reports as having ASPs that exceeded AMPs by at least 5 percent in both the fourth quarter of 2005 and the third quarter of 2004.

Source: OIG analysis of third-quarter 2006 ASP and AMP data, 2006.

**Agency Comments**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW  
Washington, DC 20201

**DATE:** JUN - 6 2007

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

**FROM:** Leslie V. Norwalk, Esq.  
Acting Administrator *LN*

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "Comparison of Third-Quarter 2006 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007," (OEI-03-07-00140)

Thank you for the opportunity to review and comment on the OIG draft report entitled, "Comparison of Third-Quarter 2006 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007." We appreciate the OIG's efforts in examining this issue.

The OIG report compares manufacturers' reported drug prices under the Medicare and Medicaid programs for the third calendar quarter of 2006 to identify drug billing codes for which the volume weighted average sale price (ASP) exceeds the volume weighted average manufacturer price (AMP) by at least 5 percent. The OIG found that for a number of billing codes the ASP payment limit exceeds the volume weighted AMP by 5 percent or more. The OIG estimates that Medicare expenditures could have been reduced by nearly \$13 million by basing reimbursement on 103 percent of the AMP.

**OIG Recommendation**

The OIG recommends that CMS adjust Medicare reimbursement amounts for drugs that meet the 5 percent threshold and that CMS may want to specifically focus on those drugs that consistently meet the threshold.

**CMS Response**

The Centers for Medicare & Medicaid Services (CMS) note that of the 39 codes identified by the OIG, only 11 (28 percent) were identified in a previous report as having exceeded the AMP while only 4 (10 percent) were identified in 2 previous reports. This seems to imply that some fluctuation in the difference between ASP and AMP is to be expected. We are interested in better understanding the sources of these fluctuations as we work towards developing a process to make adjustments to payment amounts under

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**ASP for the particular drugs and time periods where the OIG finds that the ASP exceeded the threshold. One important part of the process will be working in collaboration with the OIG to minimize the time lag between the OIG analysis and the implementation of the quarterly ASP prices. We also believe that consistent differences between the ASP and AMP for a manufacturer's drug may be one factor for the OIG to consider in its ASP audit activities to help ensure that manufacturers are correctly submitting their ASP data.**

**We thank OIG for their work on this report.**



## 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 Linda Boone Abbott.