

Washington, D.C. 20201

AUG 1 2 2008

TO:

Kerry Weems

Acting Administrator

Centers for Medicare & Medicaid Services

FROM:

Daniel R. Levinson Daniel R. Levinson

Inspector General

SUBJECT:

Memorandum Report: "Comparison of Fourth-Quarter 2007 Average Sales

Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2008," OEI-03-08-00340

This congressionally mandated review compares average sales prices (ASP) to average manufacturer prices (AMP) for Medicare Part B prescription drugs and identifies drugs with ASPs that exceeded AMPs by at least 5 percent during the fourth quarter of 2007. It also determines the impact of lowering reimbursement amounts for drugs that meet the 5-percent threshold.

This is the Office of Inspector General's (OIG) seventh report comparing ASPs to AMPs. However, it is OIG's first pricing comparison since the Centers for Medicare & Medicaid Services (CMS) implemented a revised ASP payment methodology recently mandated by statute. In December 2007, the Medicare, Medicaid, and SCHIP Extension Act of 2007, P.L. No. 110-173, amended section 1847A(b) of the Social Security Act (the Act) and changed the way in which CMS calculates volume-weighted ASPs, effective April 1, 2008.

Using CMS's revised ASP payment amount methodology, we identified 12 of 285 drug codes with ASPs that exceeded AMPs by at least 5 percent in the fourth quarter of 2007. If reimbursement amounts for all 12 codes had been based on 103 percent of the AMPs, we estimate that Medicare expenditures would have been reduced by \$20 million during the second quarter of 2008 alone.

BACKGROUND

Section 1847A(d)(2)(B) of the Act mandates that OIG compare ASPs to AMPs. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent), section 1847A(d)(3)(A) of the Act states that the Secretary of 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"

Medicare Part B Coverage of Prescription Drugs

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

Medicare Part B Payments for Prescription Drugs

CMS contracts with private companies, 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 about \$11 billion for Part B drugs in 2007. Although Medicare paid for more than 675 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 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. 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

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¹ 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.

rebate program.² 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.³

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.⁵

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 Medicare, Medicaid, and SCHIP Extension Act of 2007, P.L. No. 110-173, changed section 1847A(b)(6) 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.

Second-quarter 2008 Medicare allowances for most covered drug codes were based on fourth-quarter 2007 ASP submissions from manufacturers, which were volume-weighted using the revised methodology. Under the ASP pricing methodology, the Medicare

² Section 1847A(c)(3) of the Act.

³ 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.

⁴ Section 1847A(c)(2) of the Act.

⁵ Section 1927(b)(3) of the Act.

allowance for most Part B drugs is equal to 106 percent of the volume-weighted 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 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.⁶

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), P.L. No. 109-171, 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 discounts from their AMP calculations as of January 2007. In July 2007, CMS published a final rule (72 Fed. Reg. 39142) (July 17, 2007), which, among other things, implements section 6001(c)(1) of the DRA and clarifies the way in which the AMP must be calculated. Specifically, 42 CFR § 447.504 of the final regulation clarifies the manner in which the AMP is to be determined.⁸

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).

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 completed six reports comparing ASPs to AMPs. A list of these reports is provided in Appendix B.

Although CMS has acknowledged the Secretary's authority to adjust ASP payment limits based on the findings of these studies, the agency has yet to make any changes to Part B drug

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⁶ Section 6001(b)(1)(A) of the DRA 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.

⁷ Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 76, December 15, 2006.

⁸ 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.

reimbursement as a result of OIG's pricing comparisons. 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. 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.

METHODOLOGY

We obtained from CMS NDC-level ASP data from the fourth quarter of 2007, which were used to establish Part B drug reimbursement amounts for the second quarter of 2008. 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 current as of March 7, 2008. We also obtained AMP data from CMS for the fourth quarter of 2007, which were current as of February 6, 2008.

Analysis of Average Sales Price Data From the Fourth Quarter of 2007

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 NDCs that CMS opted to exclude from its calculation, nor did we verify the accuracy of CMS's crosswalk files.

As of March 2008, CMS had established prices for 525 HCPCS codes based on the revised ASP reimbursement methodology mandated by section 112(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007. Reimbursement amounts for the 525 HCPCS codes were based on ASP data for 3,378 NDCs.

Analysis of Average Manufacturer Price Data From the Fourth Quarter of 2007

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 3,378 NDCs that CMS used in its calculation of volume-weighted ASPs for the 525 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 237 HCPCS codes using this conservative approach.

⁹ OEI-03-07-00140, July 2007.

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

The remaining 288 HCPCS codes had AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs. These 288 HCPCS codes represented 1,127 NDCs.

We then multiplied the AMPs for these 1,127 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. For four NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These four NDCs were crosswalked to three HCPCS codes. We did not include these three HCPCS codes (24 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,103 NDCs, we then calculated a volume-weighted AMP for each of the codes, consistent with the revised methodology for calculating volume-weighted ASPs. We calculated volume-weighted AMPs for a total of 285 HCPCS codes. We did not verify the accuracy of manufacturer-reported ASP and AMP data.

Comparing Volume-Weighted ASPs to Volume-Weighted AMPs for the Fourth Quarter of 2007 Using the Revised ASP Payment Methodology

For each of the 285 HCPCS codes included in our study, we compared the volume-weighted ASPs and AMPs and identified codes with an ASP that exceeded the AMP by at least 5 percent.

For those HCPCS codes that met or exceeded the 5-percent threshold, we reviewed the associated NDCs to verify the accuracy of the billing unit information. According to our review, NDCs for 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 NDCs. Because volume-weighted ASPs and AMPs are calculated using this billing unit information, we could not be certain that the results for the two codes were correct. Therefore, we did not include these codes in our findings.

For the remaining HCPCS codes, we then estimated the monetary impact of lowering reimbursement to 103 percent of the AMP. The For each of the HCPCS codes that met the 5-percent threshold, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the second-quarter 2008 reimbursement amount for the HCPCS code, which is equal to 106 percent of the volume-weighted ASP. To estimate the financial effect for the second quarter of 2008, we then multiplied the difference by one-fourth of the number of services that were allowed by Medicare for each HCPCS code in 2007, as reported in

¹¹ 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 the authority to disregard the ASP 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.

CMS's Part B Extract and Summary System (BESS). This estimate assumes that the number of services that were allowed by Medicare in 2007 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2007 and 2008.

Limitations

This is the first comparison of ASPs to AMPs that OIG has conducted since CMS implemented its revised ASP payment methodology. Because pricing data in the fourth quarter of 2007 were volume-weighted differently than in previous quarters, the results of this current pricing comparison are not comparable to those of previous OIG pricing comparisons for the purpose of establishing trends over time. OIG is conducting follow-up work to identify the drug codes that would have met the 5-percent threshold if CMS's revised ASP payment methodology had been in effect throughout calendar year 2007.

Furthermore, the definition of AMP changed in January 2007, such that AMPs must now be determined without regard to customary prompt pay discounts. 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.

RESULTS

Under the Revised ASP Payment Methodology, Volume-Weighted ASPs for 12 of 285 Drug Codes Exceeded the Volume-Weighted AMPs 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. In the fourth quarter of 2007, 12 of the 285 HCPCS codes included in our review (4 percent) met this 5-percent threshold. A list of the 12 HCPCS codes, their descriptions, and their HCPCS dosage amounts is presented in Appendix C.

Table 1 on the next page describes the extent to which ASPs exceeded AMPs for the 12 HCPCS codes. ¹⁴ For over half of the 12 codes, volume-weighted ASPs exceeded volume-weighted AMPs by 20 percent or more. The ASPs for three of these codes were more than double the AMPs.

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¹² At the time of extraction, 2007 BESS data were 90 percent complete.

¹³ 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.

¹⁴ Because of the confidential nature of ASP data, the information in the table is presented in ranges.

Table 1: Extent to Which ASPs Exceeded AMPs for 12 HCPCS Codes

Percentage by Which ASP Exceeded AMP	Number of HCPCS Codes
5.00%-9.99%	4
10.00%–19.99%	1
20.00%–29.99%	2
30.00%-39.99%	1
40.00%-49.99%	1
50.00%-59.99%	0
60.00%–69.99%	0
70.00%–79.99%	0
80.00%-89.99%	0
90.00%-99.99%	0
100% and above	3
Total	12

Source: OIG analysis of fourth-quarter 2007 ASP and AMP data, 2008.

Lowering reimbursement amounts for the 12 HCPCS codes to 103 percent of the AMPs would have reduced Medicare allowances by an estimated \$20 million in the second quarter of 2008. Sections 1847A(d)(3)(A) and (B) of the Act provide that the Secretary may disregard the ASP pricing methodology for a drug with an ASP that exceeds the AMP by at least 5 percent. Pursuant to section 1847A(d)(3)(C) of the Act, "... the Secretary shall, effective as of the next quarter, substitute for the amount of payment ... the lesser of (i) the widely available market price ... (if any); or (ii) 103 percent of the average manufacturer price"

In this study, we identified 12 HCPCS codes that met the 5-percent threshold specified in the Act. If reimbursement amounts for these 12 codes had been based on 103 percent of the AMPs during the second quarter of 2008, we estimate that Medicare expenditures would have been reduced by \$20 million in that quarter alone. 16

Two of the twelve HCPCS codes accounted for almost 90 percent of the \$20 million. If the reimbursement amounts for codes J2505 and J3315 had been based on 103 percent of the AMP during the second quarter of 2008, Medicare expenditures would have been reduced by an estimated \$11 million and \$7 million, respectively.

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¹⁵ 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 estimates presented in this report would have been greater.

¹⁶ This savings estimate assumes that the number of services that were allowed by Medicare in 2007 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2007 and 2008.

CONCLUSION

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 and AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by at least 5 percent. This review is the seventh such comparison conducted by OIG. Using the revised ASP payment methodology recently implemented by CMS, we identified a total of 12 HCPCS codes in the fourth quarter of 2007 that met the threshold for price adjustment. To establish a more useful and consistent benchmark for comparisons of ASPs and AMPs over time, OIG is conducting follow-up work to identify the HCPCS codes that would have met the 5-percent threshold if CMS's revised ASP payment methodology had been in effect during every quarter of 2007.

Some of OIG's previous reports comparing ASPs and AMPs have contained recommendations. We are not making additional recommendations in this report and, as such, are issuing the report directly in final form. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-03-08-00340 in all correspondence.

APPENDIX A

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

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

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

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

APPENDIX B

Previous Office of Inspector General Reports Comparing Average Sales Prices and Average Manufacturer Prices

- "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices" (OEI-03-04-00430), April 2006.
- "Comparison of Fourth-Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2006" (OEI-03-06-00370), July 2006.
- "Comparison of Third-Quarter 2006 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007" (OEI-03-07-00140), July 2007.
- "Comparison of First-Quarter 2007 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2007" (OEI-03-07-00530), September 2007.
- "Comparison of Second-Quarter 2007 Average Sales Prices 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.

APPENDIX C

Twelve Healthcare Common Procedure Coding System Codes With Average Sales Prices That Exceeded Average Manufacturer Prices by at Least 5 Percent in the Fourth Quarter of 2007

HCPCS		
Code	Short Description	HCPCS Code Dosage
J0300	Amobarbital injection	125 mg
J1120	Acetazolamid sodium injection	500 mg
J1270	Doxercalciferol injection	1 mcg
J1364	Erythro lactobionate	500 mg
J1441	Filgrastim injection	480 mcg
J1626	Granisetron HCI injection	100 mcg
J2505	Pegfilgrastim injection	6 mg
J2690	Procainamide HCI injection	1 g
J2760	Phentolaine mesylate injection	5 mg
J3315	Triptorelin pamoate	3.75 mg
Q0168	Dronabinol oral	5 mg
Q0169	Promethazine HCl oral	12.5 mg

Source: Office of Inspector General analysis of fourth-quarter 2007 average sales price and average manufacturer price data, 2008.