DEC 13 2007

TO: Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: Daniel R. Levinson
Inspector General

SUBJECT: Memorandum Report: "Comparison of Second-Quarter 2007 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2007," OEI-03-08-00010

This memorandum report compares average sales prices (ASP) and 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 second 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) fifth report comparing ASPs and AMPs.[1]

We identified 22 of 292 drug codes with ASPs that exceeded AMPs by at least 5 percent in the second quarter of 2007. Of these 22 codes, 16 also met the threshold for price adjustments in at least one of the prior OIG studies comparing ASPs and AMPs. If reimbursement amounts for all 22 codes were based on 103 percent of AMP, we estimate that Medicare expenditures would be reduced by $8 million during the fourth quarter of 2007 alone.

BACKGROUND

Section 1847A(d)(2)(B) of the Social Security Act (the Act) mandates that 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 (i) the widely available market price . . . (if any); or (ii) 103 percent of the average manufacturer price . . . . "

[1]Since the ASP reimbursement methodology for Part B prescription drugs was implemented in January 2005, OIG has completed four other reports comparing ASPs to AMPs: OEI-03-04-00430, April 2006; OEI-03-06-00370, July 2006; OEI-03-07-00140, July 2007; and OEI-03-07-00530, September 2007.

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 about $11 billion for Part B drugs in 2006. Although Medicare paid for more than 650 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 2006, 56 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.[2] 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.[3] Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program.[4] [5]

[2] 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.
[3] Section 1847A(c)(3) of the Act.
[4] Pursuant to section 1927(c)(1)(C)(i) of the Act, "best price" is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, with certain exceptions.
[5] Section 1847A(c)(2) of the Act.

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.[6]

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

Second-quarter 2007 ASP submissions from manufacturers served as the basis for fourth-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 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.[7]

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. 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.[8] In July 2007, CMS published a final rule (72 FR 39241; 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.

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

[7] Pursuant to section 6001(b)(1)(A) of the DRA, manufacturers must 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.

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

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 four reports comparing ASPs and AMPs. A description of each report is provided in Appendix A.

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 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.[9] 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 second quarter of 2007, which were used to establish Part B drug reimbursement amounts for the fourth 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 September 2007. We also obtained AMP data from CMS for the second quarter of 2007.

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

As of September 2007, CMS had established prices for 515 HCPCS codes based on the ASP reimbursement methodology.[10] Reimbursement amounts for the 515 HCPCS codes were based on ASP data for 3,176 NDCs.

To calculate the volume-weighted ASPs for these 515 codes, CMS used an equation that involves the following variables: the ASP for the NDC as reported by the manufacturer, the

[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.

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 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 B.

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 3,176 NDCs that CMS used in its calculation of volume-weighted ASPs for the 515 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 211 HCPCS codes using this conservative approach. The remaining 304 HCPCS codes had AMP data for every NDC that CMS used in its calculation of volume-weighted ASPs. These 304 HCPCS codes represented 1,224 NDCs.

We then multiplied the AMPs for these 1,224 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 five NDCs, we could not successfully identify the amount of the drug reflected by the ASP and therefore could not calculate a converted AMP. These five NDCs were crosswalked to 12 HCPCS codes. We did not include these 12 HCPCS codes (50 NDCs) in our final analysis.

Using the converted AMPs for the remaining 1,174 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 292 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 292 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 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 result for these 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.[11] First, we calculated 103 percent of the volume-weighted AMP and subtracted this amount from the fourth-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 fourth 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).[12] 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.

Limitations

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

OIG maintains 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 amount methodology set forth in section 1847A(b)(3) of the Act. However, to be consistent with the payment amount methodology currently used by CMS, OIG has opted to use CMS's calculation method when comparing ASPs and AMPs.

We also note that the definition of AMP changed in January 2007, such that AMPs must now be determined without regard to customary prompt pay discounts.[13] Because manufacturers are still required to include customary prompt pay discounts in their ASP calculations, the

[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 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.

[12] At the time of extraction, 2006 BESS data were 99 percent complete.

[13] Section 6001(c)(1) of the DRA and Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Release No. 76, December 15, 2006.

dynamic between ASPs and AMPs may be different in this report as compared to previous OIG reports monitoring 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.

RESULTS

For 22 of 292 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 and AMPs to identify instances in which the ASP for a particular drug exceeded the AMP by a threshold of 5 percent. In the second quarter of 2007, 22 of the 292 HCPCS codes included in our review (8 percent) met or surpassed this 5-percent threshold. A list of the 22 HCPCS codes, their descriptions, and their HCPCS dosage amounts is presented in Appendix C.

Table 1 below describes the extent to which ASPs exceeded AMPs for the 22 HCPCS codes.[14] For 6 of the 22 codes, volume-weighted ASPs exceeded volume-weighted AMPs by 20 percent or more. The ASPs for two of these codes were more than double the AMPs.

Table 1: Extent to Which ASPs Exceeded AMPs for 22 HCPCS Codes

Percentage Difference Between ASP and AMP	Number of HCPCS Codes
5.00%–9.99%	8
10.00%–19.99%	8
20.00%–29.99%	1
30.00%–39.99%	1
40.00%–49.99%	2
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	2
Total	**22**

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

Sixteen of the twenty-two HCPCS codes were previously identified by OIG as having ASPs that exceeded the AMPs by at least 5 percent. ASPs for four HCPCS codes (J7620, J9000,

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

J9214, and J2690) exceeded AMPs by at least 5 percent in four of OIG's five reports comparing ASPs and AMPs, dating back almost 3 years. An additional three HCPCS codes met the 5-percent threshold in three of OIG's five pricing comparisons. Table 2 below presents a breakdown of the 16 HCPCS codes that previously met the threshold for price adjustments.

Table 2: Sixteen HCPCS Codes That Met the 5-Percent Threshold in Second Quarter 2007 as Well as Previous Quarters

HCPCS Code	OIG Comparisons of ASPs and AMPs				
	Second Quarter 2007	First Quarter 2007	Third Quarter 2006	Fourth Quarter 2005	Third Quarter 2004
J7620	X	X	X	X	
J9000	X	X	X	X	
J9214	X	X	X	X	
J2690	X	X		X	X
J2321	X	X	X		
J7608	X	X	X		
J1790	X	X	X		
Q0169	X	X			
J2800	X	X			
J1457	X	X			
J8530	X	X			
J2060	X	X			
J7505	X	X			
J0280	X	X			
J0637	X		X		
J9340	X			X	

Source: OIG analysis of ASP and AMP data from second quarter 2007, first quarter 2007, third quarter 2006, fourth quarter 2005, and third quarter 2004.

In each of OIG's four previous pricing comparisons, which used data from the first quarter of 2007, the third quarter of 2006, the fourth quarter of 2005, and the third quarter of 2004, respectively, we identified three other HCPCS codes (J2545, J3410, and J9360) with ASPs that exceeded AMPs by at least 5 percent. However, the three HCPCS codes could not be included in this current study because second-quarter 2007 AMP data were not available for one or more of the NDCs associated with each HCPCS code.

Lowering reimbursement amounts for the 22 HCPCS codes to 103 percent of the AMPs would reduce Medicare allowances by an estimated $8 million in the fourth 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 (i) the widely available

market price . . . (if any); or (ii) 103 percent of the average manufacturer price . . . . "[15] In this study, we identified 22 HCPCS codes that met or exceeded the 5-percent threshold specified in the Act. If reimbursement amounts for these 22 codes were based on 103 percent of the AMPs during the fourth quarter of 2007, we estimate that Medicare expenditures would be reduced by $8 million in that quarter alone.[16]

One of the twenty-two HCPCS codes, J7620, accounted for 85 percent of the $8 million. If the reimbursement amount for this one code were based on 103 percent of the AMP during the fourth quarter of 2007, Medicare expenditures would have been reduced by an estimated $7 million. Furthermore, the ASP for this code exceeded the AMP by at least 5 percent in three previous OIG reports, which compared prices from the first quarter of 2007, the third quarter of 2006, and the fourth quarter of 2005, respectively. As in this current review, the estimated savings for HCPCS code J7620 accounted for the largest single share of the total savings identified in each of the three other OIG pricing comparisons. In those reports, OIG estimated that lowering reimbursement for J7620 to 103 percent of AMP would have reduced Medicare expenditures by $7 million in the third quarter of 2007, $8 million in the first quarter of 2007, and $6 million in the second quarter of 2006.

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 a threshold of 5 percent. This review is the fifth such comparison conducted by OIG, and we identified 22 HCPCS codes that meet the threshold for price adjustment established by section 1847A(d)(3)(B) of the Act. Of these 22 codes, 16 were previously identified by OIG as having ASPs that exceeded the AMPs by at least 5 percent. ASPs for 4 of the 16 HCPCS codes (J7620, J9000, J9214, and J2690) exceeded AMPs by at least 5 percent in four of OIG's five reports comparing ASPs and AMPs, dating back almost 3 years. Three additional HCPCS codes met the 5-percent threshold in all of OIG's previous reports comparing ASPs and AMPs but could not be included in this current review because AMP data were unavailable for one or more of the NDCs associated with each HCPCS code.

This report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-03-08-00010 in all correspondence.

[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 estimate presented in this report would have been greater.

[16] This savings estimate is based on one-fourth of the number of estimated services allowed by Medicare for each HCPCS code in 2006.

APPENDIX A

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

In April 2006, the Office of Inspector General (OIG) released the first of its reports comparing average sales prices (ASP) to average manufacturer prices (AMP). 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 Healthcare Common Procedure Coding System (HCPCS) codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004. Because OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology, the Centers for Medicare & Medicaid Services (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.

In July 2007, OIG released its third comparison between ASPs and AMPs, entitled "Comparison of Third-Quarter 2006 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2007" (OEI-03-07-00140). This report identified 39 of 326 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2006. Of these 39 codes, 4 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. OIG recommended that CMS adjust Medicare reimbursement amounts for the 39 codes meeting the 5-percent threshold in the third quarter of 2006.

OIG released its fourth pricing comparison 2 months later, entitled "Comparison of First-Quarter 2007 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2007" (OEI-03-07-00530). According to this report, ASPs for 34 of 371 drug codes exceeded AMPs by at least 5 percent in the first quarter of 2007. Of these 34 codes, 20 also met the threshold for price adjustments in at least one of the prior OIG studies comparing ASPs and AMPs.

APPENDIX B

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 national drug code (NDC):

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

The Centers for Medicare & Medicaid's (CMS) calculation of volume-weighted average sales prices (ASP) is discussed in greater detail in the Office of Inspector General (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.

APPENDIX C

Twenty-Two Healthcare Common Procedure Coding System Codes With Average Sales Prices That Exceeded Average Manufacturer Prices by at Least 5 Percent

HCPCS Code	Short Description	HCPCS Code Dosage
J0280	Aminophyllin 250 mg injection	250 mg
J0476	Baclofen intrathecal trial	50 mcg
J0637	Caspofungin acetate	5 mg
J1120	Acetazolamid sodium injection	500 mg
J1457	Gallium nitrate injection	1 mg
J1756	Iron sucrose injection	1 mg
J1790	Droperidol injection	5 mg
J2060	Lorazepam injection	2 mg
J2321	Nandrolone decanoate 100 mg	100 mg
J2690	Procainamide HCl injection	1 g
J2760	Phentolaine mesylate injection	5 mg
J2800	Methocarbamol injection	10 mL
J3465	Voriconazole injection	10 mg
J7505	Monoclonal antibodies	5 mg
J7608	Acetylcysteine inhalation solution unit dose	1 g
J7620	Albuterol and ipratropium bromide non-compounded	2.5 mg/0.5 mg
J8530	Cyclophosphamide oral 25 mg	25 mg
J9000	Doxorubic HCl 10 mg vial chemo	10 mg
J9175	Elliotts b solution per ml	1 mL
J9214	Interferon alfa-2b injection	1 million units
J9340	Thiotepa injection	15 mg
Q0169	Promethazine HCl oral	12.5 mg

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