DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

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SUBJECT: Memorandum Report: *Comparison of Average Sales Prices to Widely Available Market Prices for Selected Drugs*, OEI-03-10-00280

This review was conducted in accordance with the statutory mandate for the Office of Inspector General (OIG) to compare average sales prices (ASP) to widely available market prices (WAMP) for Medicare Part B prescription drugs and to identify ASPs that exceed WAMPs by at least 5 percent.

SUMMARY

Federal law requires OIG to conduct studies that compare ASPs to WAMPs and average manufacturer prices (AMP). If OIG finds that the ASP of a drug exceeds either the WAMP or AMP by a certain threshold (currently 5 percent), the Secretary of Health and Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement amounts. Since the implementation of the ASP reimbursement methodology, OIG has issued 27 reports comparing ASPs to WAMPs and AMPs (2 comparing ASPs to WAMPs, 25 comparing ASPs to AMPs).

The purpose of this review was to compare ASPs to WAMPs for 14 drugs that have been identified in previous OIG reports as repeatedly exceeding the 5-percent ASP-AMP threshold. However, limitations and irregularities in the sales data provided by the distributors and manufacturers of the 14 drugs called into question the data's accuracy and reliability, and prevented us from measuring WAMPs against the threshold.

- All of the manufacturers that reported direct sales to providers included data on their discounts and rebates for those sales. However, two distributors (which sold over half of all the units reported to us) were not able to determine the discounts and rebates they provided, meaning that the WAMPs we calculated most likely did not reflect the actual prices paid in the marketplace. In the past, OIG has had

difficulty obtaining data on discounts and rebates from distributors, but in those instances, the missing data did not have the same impact on our results.

- Furthermore, the total number of units sold reported to us by distributors and manufacturers differed substantially from the number reported to the Centers for Medicare & Medicaid Services (CMS) through quarterly ASP submissions, potentially resulting in our data reflecting an inaccurate number of sales.

- Most likely because of these issues, the WAMPs we calculated varied widely from other pricing points; several drugs had WAMPs that were substantially higher than the associated ASPs and AMPs.

We plan to continue to fulfill our statutory mandate to conduct WAMP studies, and these issues will need to be addressed before any future efforts can be made to compare ASPs to WAMPs. We will consider alternative methodologies that will allow us to conduct pricing comparisons, including directly surveying providers to obtain accurate and complete sales data.

BACKGROUND

Medicare Part B Coverage of Prescription Drugs

Although Medicare Part D covers most outpatient prescription drugs, CMS continues to cover a limited number of outpatient prescription drugs and biologicals (hereinafter referred to as drugs) under its Part B benefit. 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. Part B and its beneficiaries spent $12 billion for more than 600 outpatient prescription drugs in 2010.

Medicare Part B Payment for Prescription Drugs

To obtain Medicare payment for Part B-covered drugs, physicians and suppliers submit claims using the Healthcare Common Procedure Coding System (HCPCS) codes. In the case of prescription drugs, each HCPCS code defines the drug ingredient name and billing unit size but does not specify the manufacturer or package size.

Part B pays for most covered drugs using a methodology based on ASPs. Manufacturers report ASPs for their covered drugs to CMS on a quarterly basis. The ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter (net of most discounts) divided by the total number of units of the drug sold by

the manufacturer in that same quarter.[1] This includes sales to distributors and wholesalers (distributors) and direct sales to providers. Manufacturers report ASPs for Part B-covered drugs by national drug codes (NDC), which are 11-digit numeric codes divided into three segments identifying (1) the firm that manufactures, distributes, or repackages the drug product (i.e., the labeler code); (2) the specific strength, dosage form, and formulation of the product; and (3) the product's package size.[2]

Because 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 (the ASP background file[3]) that "crosswalks" manufacturers' NDCs to HCPCS codes. CMS uses information in this file to calculate volume-weighted ASPs for covered HCPCS codes based on the data from the relevant NDCs. The Medicare payment amount for most Part B drugs is equal to 106 percent of the volume-weighted ASP for the HCPCS code. Medicare beneficiaries are generally responsible for 20 percent of this amount in the form of coinsurance.

OIG's Monitoring of ASPs, AMPs, and WAMPs

Federal law requires OIG to conduct studies that compare ASPs to WAMPs and AMPs.[4, 5] If OIG finds that the ASP of a drug exceeds either the WAMP or AMP by a certain threshold (currently 5 percent), the Act states that the Secretary may disregard the ASP for the drug when setting reimbursement amounts,[6, 7] and 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

[1] Section 1847A(c) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173. Pursuant to § 1847A(c) of the Act, 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. 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.

[2] Pursuant to §§ 1927(a)(1) and (b)(1) of the Act, for Federal payment to be available for covered outpatient drugs provided under Medicaid, drug manufacturers must enter into rebate agreements with the Secretary. Manufacturers with Medicaid drug rebate agreements in effect must, among other things, provide CMS with pricing information, including the ASP for each of their Part B-covered drugs and the AMP for each of their applicable Medicaid-covered drugs.

[3] CMS provides OIG with the ASP background file each quarter. This file contains ASP data (including the ASP itself and the number of units sold in the quarter) for all NDCs (grouped by their corresponding HCPCS codes) that were reported in that quarter.

[4] Section 1847A(d)(2) of the Act.

[5] Section 1927(k)(1) of the Act, as amended by section 2503(a)(2) of the Affordable Care Act, P.L. 111-148, defines AMP as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer, with certain exclusions.

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

[7] Section 1847A(d)(3)(B)(ii) of the Act provided the Secretary with authority to adjust the applicable threshold percentage in 2006 and subsequent years; however, the threshold percentage has been maintained at 5 percent.

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…."[8] The Act defines WAMP as the price that a prudent physician or supplier would pay for the drug, and states that "[i]n determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals."[9]

Since 2006, OIG has issued 27 reports (2 comparing ASPs to WAMPs, 25 comparing ASPs to AMPs), and has repeatedly identified certain drugs with ASPs that exceeded the 5-percent threshold in one or more quarters. For example, a 2010 OIG report comparing ASPs to AMPs found that 26 drugs exceeded the 5-percent threshold in the third quarter of 2009.[10] Lowering reimbursement amounts for the 26 drugs to 103 percent of the AMP would have reduced Medicare expenditures by $2.7 million in the first quarter of 2010. Fourteen of the drugs that exceeded the 5-percent threshold in the third quarter of 2009 also exceeded the threshold in at least one of the previous four quarters.

Although CMS has yet to make changes to Part B reimbursement as a result of OIG's pricing comparisons, in November 2011 CMS issued a Notice of Final Rulemaking that applies price substitutions beginning in 2012 to certain drugs that repeatedly exceed the 5-percent AMP threshold.[11] CMS stated that it is excluding WAMP from the price substitutions because of the lack of data regarding comparisons between ASPs and WAMPs; however, the agency will reconsider proposing a policy for price substitutions based on ASP and WAMP comparisons at a later date.[12] Furthermore, in its comments on another OIG pricing comparison, CMS also stated that additional analysis of pricing data is an important next step in developing a price substitution policy.[13] This current study, which focused on drugs that have repeatedly exceeded the 5-percent AMP threshold, was intended to provide further analysis to assist CMS in its efforts to develop a price substitution policy.

[8] Section 1847A(d)(3)(C) of the Act.
[9] Section 1847A(d)(5)(A) of the Act.
[10] OIG, *Comparison of Third-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010* (OEI-03-10-00150), April 2010.
[11] 76 Fed. Reg. 73026, 73293 (Nov. 28, 2011). Specifically, CMS will substitute prices for drugs that exceed the 5-percent AMP threshold in two consecutive quarters, or three of four quarters. Price substitutions will only apply to drugs with complete AMP data, and will remain in effect for one quarter.
[12] Ibid., at 73287.
[13] OIG, *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2008* (OEI-03-09-00350), February 2010.

METHODOLOGY

In an April 2010 report comparing ASPs and AMPs, we identified 14 HCPCS codes that exceeded the 5-percent threshold in the third quarter of 2009 and at least one of the previous four quarters (see Table 1). Eight of the 14 drugs exceeded the threshold based on complete AMP data, and 6 exceeded the threshold based on partial AMP data.[14]

Table 1: Fourteen HCPCS Codes That Exceeded the 5-Percent ASP-AMP Threshold in the Third Quarter of 2009 and at Least One of the Four Previous Quarters

HCPCS Code	Drug Name
J0560*	Penicillin g benzathine inj., 600,000 units
J1190	Dexrazoxane HCl inj., 250 mg
J1364	Erythro lactobionate, 500 mg
J2597	Desmopressin acetate inj., 1 mcg
J2765	Metoclopramide HCl inj., 10 mg
J2792*	Rho(D) immune globulin h, sd, 100 units
J2993*	Reteplase inj., 18.1 mg
J3470*	Hyaluronidase inj., 150 units
J7506	Prednisone oral, 5 mg
J7509	Methylprednisolone oral, 4 mg
J9340	Thiotepa inj., 15 mg
Q0163	Diphenhydramine HCl, 50 mg
Q9965*	Low osmolar contrast material, 100–199 mg/mL iodine, 1 mL
Q9966*	Low osmolar contrast material, 200–299 mg/mL iodine, 1 mL

mg=milligram, mcg=microgram, and mL=milliliter
Source: OIG, *Comparison of Third-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010* (OEI-03-10-00150), April 2010.
* Indicates the drug is only available in brand-name form.

We surveyed each of the 23 manufacturers with NDCs in CMS's ASP background file that were associated with any of the 14 HCPCS codes listed in Table 1. We asked each manufacturer to provide pricing data for any direct purchases by suppliers or physicians in third-quarter 2009, fourth-quarter 2009, and first-quarter 2010. Because WAMP is defined as being net of any discounts and rebates,[15] we asked the manufacturers to provide data on discounts and rebates. Because many providers purchase drugs from distributors rather than directly from manufacturers, the manufacturer-reported sales data alone would not reflect all sales to providers. Therefore, we also asked each

[14] A HCPCS code with complete AMP data is one with AMP data for every NDC that CMS used in its calculation of the HCPCS code's volume-weighted ASP.
[15] Section 1847A(d)(5)(A) of the Act.

manufacturer to provide the contact information for all distributors to which it sold any of the drugs during the quarters under review. The 23 manufacturers reported selling these drugs to 127 distributors. We then surveyed all 127 distributors, and asked for data on their sales to providers for any NDCs that met the description of any of the 14 drugs in third-quarter 2009, fourth-quarter 2009, and first-quarter 2010. We asked the distributors to break down the data by class of trade, and to provide data on discounts and rebates.

We received responses from every manufacturer and distributor.[16] We compiled the sales data reported by the 23 manufacturers and 127 distributors for each drug in each of the three quarters. We excluded data on sales made to "institutional" classes of trade and on sales of NDCs not included in CMS's calculation of ASPs. We calculated the volume-weighted WAMP for each of the 14 HCPCS codes in each of the three quarters by using the NDC-level pricing data provided by the distributors and direct sales data provided by the manufacturers. When available, we included all discounts and rebates. We then obtained volume-weighted ASPs for each of the three quarters from CMS, and compared these figures to the volume-weighted WAMP in each quarter.

Limitations
We did not verify the accuracy or completeness of CMS's ASP data or the sales data provided to us by the manufacturers and distributors.

Standards
This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

Limitations and irregularities in the sales data prevented an accurate determination of whether any of the 14 drugs exceeded the ASP-WAMP threshold

Because of limitations in the distributor-reported data, most of the sales data we received did not reflect discounts and rebates that were passed on to providers. Because WAMP is statutorily defined as being net of any routinely available price concessions, we asked the manufacturers and distributors to include data on discounts and rebates along with their sales data. All of the manufacturers that reported direct sales included data on their discounts and rebates. However, two large distributors reported that they calculate discounts and rebates based on each customer's total purchases for a variety of drugs, rather than individual sales transactions for each drug, and therefore they were unable to determine the amount of discounts and rebates provided for each NDC. In other words, although these distributors responded to our request and provided their total sales data, they could not calculate the net price for each drug.

[16] In some cases, respondents reported that they had no sales of the drugs to providers in the quarters under review.

These two distributors accounted for 58 percent of all units sold during the three quarters under review, meaning that more than half of the sales data we received for each quarter did not include any information on the discounts and rebates received by providers. For example, for the third quarter of 2009, we were provided data on discounts and rebates for only 42 percent of all units sold.[17] Among the individual drugs, the proportion of sales data that included discounts and rebates in that quarter ranged from 4 to 51 percent.

Because of the incomplete data on discounts and rebates, the WAMPs we calculated most likely did not reflect the actual prices paid in the marketplace, and therefore could not appropriately be compared to the 5-percent threshold. In addition, because the price concessions offered by these two large distributors may have differed substantially from the average price concessions, it is not possible to estimate discounts and rebates for these sales.

The total number of units sold reported to us through the WAMP survey differed substantially from those reported to CMS through manufacturers' ASP submissions, with the possible implication that our data represented an inaccurate number of sales. Because manufacturers are required to report all sales of a drug when submitting quarterly ASP data to CMS, and our survey requested all direct sales data from every manufacturer and distributor of each drug, the total units sold reported to CMS would be expected to resemble those reported through our survey. However, for 11 of the 14 drugs, ASP units reported to CMS differed by more than 10 percent from the WAMP units reported to us for third-quarter 2009.[18, 19] ASP units were greater than WAMP units for eight drugs, and WAMP units were greater than ASP units for six drugs. In three cases, manufacturers reported over twice as many units sold in CMS's ASP background file than were reported to us. See Table 2 for a comparison of the total units reported to CMS through ASP submissions and the total units submitted in response to our WAMP survey.

[17] We were provided discount and rebate data for 40 percent of units sold in fourth-quarter 2009 and 44 percent of units sold in first-quarter 2010.

[18] For the purposes of this analysis, we included only units reported to us through the WAMP survey for NDCs used in CMS's calculation of ASPs. These included units sold to institutional classes of trade.

[19] These figures were similar in the remaining two quarters: 12 of the 14 drugs had units that differed by more than 10 percent in fourth-quarter 2009, and 11 of 13 drugs had units that differed by more than 10 percent in first-quarter 2010. One drug in this quarter had no sales reported to us or sales reported in CMS's ASP background file.

Table 2: Units Reported to CMS and OIG, Third-Quarter 2009

HCPCS Code[1]	Units Reported to CMS	Units Reported to OIG	Percentage Difference[2]
1	14,387,315	6,582,136	118.58%
2	38,581,894	17,891,338	115.65%
3	15,737,251	7,133,905	120.60%
4	7,442	12,140	-38.70%
5	1,117,331	1,174,360	-4.86%
6	70,780	94,284	-24.93%
7	2,062,877	1,579,540	30.60%
8	30,286	29,370	3.12%
9	6,425,800	6,350,280	1.19%
10	502,080	600,655	-16.41%
11	65,170	56,093	16.18%
12	3,014	5,314	-43.28%
13	13,476	17,977	-25.04%
14	82,037,410	55,509,110	47.79%
Total	**161,042,126**	**97,036,502**	**65.96%**

Sources: OIG analysis of manufacturer- and distributor-reported sales data and CMS's ASP data, 2010–2011.
[1] HCPCS codes are in random order. Because of the data's proprietary status, we could not identify individual HCPCS codes.
[2] Figures are shown for only third-quarter 2009; however, the other two quarters under review showed similar results.

Some distributors may have sold products in a different quarter than when they purchased them, slightly altering the number of units reported to us as compared to the number of manufacturer-reported ASP units for each quarter. However, this is unlikely to account for the large disparities in units reported to OIG and CMS. Rather, it appears likely that the data we received were not an accurate representation of the number of sales that occurred in the marketplace. This is evident by the fact that the total number of units reported to CMS for all 14 drugs was 66 percent greater than the number of units reported to us for those same drugs in that timeframe.

Based on the data we received, it appears that certain manufacturers failed to report ASPs to CMS. The distributors and manufacturers we surveyed reported their sales data by NDC. In those data, we identified many NDCs that were not included in CMS's ASP background file. For example, for the third quarter of 2009, the manufacturers and distributors reported sales data to us for 108 unique NDCs that did not have ASPs reported to CMS. These data represented:

- 10 of the 14 drugs under review,
- sold by 44 unique manufacturers, and

- totaling $538,000 in sales in third-quarter 2009.

Of the 108 NDCs not included in CMS's ASP background file that quarter, 83 NDCs (77 percent) were sold by manufacturers with Medicaid Rebate Agreements in effect, thereby requiring them to report ASP data to CMS. Sales reported to us for these 83 NDCs totaled $470,000 in third-quarter 2009.[20]

Any NDC for which a manufacturer has ever provided ASP data to CMS is included in the ASP background file. Therefore, the absence of these NDCs in the ASP background file indicates that there is no record (at least for the purposes of calculating the Medicare payment amounts) of these products being sold in the marketplace, despite our survey results' demonstrating otherwise. Because CMS uses ASP data to calculate Medicare payment amounts, the failure of manufacturers to report these data may result in payment amounts that are inaccurate and not reflective of all Part B-covered drug sales.

Most likely because of the issues previously described, the WAMPs we calculated varied widely from other pricing points, and therefore we could not accurately determine whether any of the drugs exceeded the ASP-WAMP threshold. As Table 3 shows, ASPs for the 14 drugs ranged from 42 percent below the WAMPs to 51 percent above the WAMPs in the third quarter of 2009.[21] Four of the drugs had ASPs that were more than 20 percent below the WAMPs we calculated for that quarter. This particularly calls the WAMP data's integrity into question, as WAMPs that are substantially higher than ASPs (and AMPs) would likely be indications of widespread provider underreimbursement. However, although these drugs consistently appeared in OIG's quarterly pricing comparisons as candidates for price reductions, as far as we know, no providers have claimed that they are being underreimbursed for the particular products. These factors indicate that our WAMP data (rather than CMS's ASP data) are the most likely cause of the ASP-WAMP comparison irregularities, and as a result, our confidence in our WAMP calculations has been further eroded.

[20] We will refer these manufacturers to CMS and work with it to take appropriate action.

[21] ASPs for the 14 drugs ranged from 36 percent below the WAMPs to 47 percent above the WAMPs in fourth-quarter 2009, and from 43 percent below the WAMPs to 49 percent above the WAMPs in first-quarter 2010.

Table 3: ASP-WAMP and ASP-AMP Comparisons, Third-Quarter 2009

HCPCS Code	Percentage Difference Between ASP and WAMP[1]	Percentage Difference Between ASP and AMP
1*	-41.74%	9.68%
2*	-24.27%	5.29%
3*	-23.13%	7.04%
4*	-21.38%	64.14%
5	-10.54%	22.43%
6	-8.08%	7.32%
7*	-5.80%	449.97%
8	-2.92%	9.52%
9	2.08%	6.54%
10	4.18%	6.76%
11	7.05%	6.71%
12	7.87%	66.92%
13	7.94%	9.74%
14*	51.20%	48.32%

Sources: OEI-03-10-00150; OIG analysis of manufacturer- and distributor-reported sales data and CMS's ASP data, 2010–2011.
[1] Comparisons are shown for only third-quarter 2009; however, the other two quarters under review showed similar results.
* Denotes HCPCS codes with partial AMP data.

CONCLUSION

CMS recently stated that additional analysis of pricing data is an important next step for developing a price substitution policy. The purpose of this review was to assist CMS in that effort by comparing ASPs to WAMPs for 14 drugs that have been identified in previous OIG reports as repeatedly exceeding the 5-percent ASP-AMP threshold. However, limitations and irregularities in the sales data we received prevented us from conducting accurate comparisons between ASPs and WAMPs, and as a result, we were unable to determine whether any of the drugs exceeded the ASP-WAMP threshold.

The data issues we identified in this report will need to be addressed in any future OIG efforts to compare ASPs to WAMPs. In the past, OIG has collected sales data from distributors for studies involving drug pricing in both Medicare and Medicaid. Discount and rebate data have been difficult to obtain from certain respondents, but the lack of data on discounts and rebates previously had little influence on our results. For example, in one recent report, OIG was not comparing prices against a set threshold for individual drugs. Rather, we were using the distributor sales data to evaluate an overall pricing

policy (i.e., Medicaid Federal upper limits) that resulted in hundreds of millions of dollars in excessive payments for more than 550 drugs.[22] Because the difference between Federal upper limit amounts and acquisition costs was very large (an average of more than 300 percent), our pricing comparisons were not inhibited by the lack of data on discounts and rebates (and, in fact, additional data on discounts and rebates would have widened the spread between acquisition costs and Medicaid payments). Therefore, in that instance, calculating estimated sales prices (rather than exact prices) was appropriate, and we noted the lack of price concession data as a limitation. However, the objectives of our WAMP comparisons require more precise estimates of provider acquisition costs, and the lack of data on discounts and rebates prevented us from accurately measuring WAMPs against the statutory threshold. In the future, we plan to continue to fulfill our statutory mandate to conduct WAMP studies, and we will consider alternative methodologies that will allow us to do so, including directly surveying providers to obtain accurate and complete sales data.

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-03-10-00280 in all correspondence.

[22] OIG, *A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices* (OEI-03-08-00490), August 2009.