

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**A COMPARISON OF AVERAGE
SALES PRICES TO WIDELY
AVAILABLE MARKET PRICES:
FOURTH QUARTER 2005**



Daniel R. Levinson
Inspector General

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Office of Inspector General

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OBJECTIVE

To determine whether the volume-weighted average sales prices (ASP) for a select group of Medicare Part B prescription drugs exceed their widely available market prices by at least 5 percent.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a new prescription drug benefit available to all Medicare beneficiaries under Medicare Part D. However, a limited number of outpatient prescription drugs are still covered under Medicare Part B. These 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.

Expenditures for Part B drugs totaled more than \$9 billion in calendar year 2005. Although Medicare covers more than 500 outpatient prescription procedure codes, the majority of spending for Part B drugs is concentrated on a relatively small subset of those codes.

Medicare's reimbursement amount for covered outpatient drugs is generally equal to 106 percent of the volume-weighted ASP. The Centers for Medicare & Medicaid Services (CMS) uses ASP information submitted by manufacturers for each drug to calculate a volume-weighted ASP for each covered procedure code. The MMA defines ASP as a manufacturer's sales of a drug to all nonexempt 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, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those paid under the Medicaid drug rebate program.

Sections 1847A(d)(1) and 1847A(d)(2)(A) of the Social Security Act (the Act) mandate that the Office of Inspector General (OIG) conduct surveys to determine widely available market prices and compare ASPs with these widely available market prices. Section 1847A(d)(5)(A) defines widely available market price to be the price that a prudent physician or supplier would pay for the drug, net of any routinely available price concessions. Pursuant to Section 1847A(d)(3)(C), if OIG determines that the ASP for a drug exceeds the widely available market prices by

5 percent and so informs the Secretary of the Department of Health and Human Services, the Secretary shall substitute the payment amount for that drug with the lesser of the widely available market price, or 103 percent of the average manufacturer price (AMP) as reported for Medicaid drug rebate purposes.

We selected a sample of procedure codes based on the results of a September 2005 OIG report that calculated physicians' estimated purchase prices for oncology drugs. For the nine procedure codes in our sample, we compared second-quarter 2005 volume-weighted ASPs (the basis of fourth-quarter 2005 Medicare reimbursement amounts) to fourth-quarter 2005 widely available market prices, and identified codes for which the ASP exceeded the widely available market price by at least 5 percent. We estimated the amount that Medicare would save by lowering reimbursement to the widely available market price for any procedure codes that met or exceeded the 5-percent threshold.

FINDINGS

For 5 of the 9 procedure codes under review, the volume-weighted ASP exceeded the widely available market price by at least 5 percent. Five of the nine procedure codes included in our study met or surpassed the 5-percent threshold defined by the Act. For these 5 codes, the difference between the ASPs and the widely available market prices calculated by OIG ranged from 17 to 185 percent. We estimate that Medicare expenditures would be reduced by as much as \$67 million in 2006 if reimbursement amounts were lowered to the widely available market price for these 5 codes.

The widely available market prices for these drugs may be even lower than the amounts we found, as all five specialty distributors offered price discounts to physician customers that were not reflected in our calculation. We did not take discounts into account when determining widely available market prices because these discounts were not routinely available to all physician customers.

The most common type of price discount offered to physician customers was a percentage off the list or net price when a customer pays his/her balance within a certain time period (i.e., a "prompt pay" discount). In general, the more quickly payment is made, the higher the discount the customer receives. Three of the five companies that responded to our request offered this type of incentive, with percentage discounts ranging from 1 to 3 percent, depending on the time of payment. Anywhere from

10 to 90 percent of physician customers of these companies take advantage of prompt pay discounts. A fourth company offered a prompt pay discount for only one of the drugs it sold. This discount ranged from 1 to 4 percent.

In addition, companies also offered other types of discounts to group purchasing organizations and members of State oncology associations.

SUMMARY

Section 1847A(d)(2)(A) of the Act mandates that OIG perform comparisons between ASPs and widely available market prices to identify drugs for which ASP exceeds widely available market prices by 5 percent. This study is the first of these comparisons. Based on our analysis, we have identified five procedure codes that met the criterion for a price adjustment. Pursuant to the Act, the Secretary shall reduce the reimbursement for these 5 codes to the lesser of the widely available market price, or 103 percent of the AMP. We estimate that lowering the reimbursement to the widely available market price would reduce Medicare expenditures by as much as \$67 million in 2006. If 103 percent of AMP is lower than the widely available market price for any of these 5 codes, then Medicare expenditures would be reduced even further.

Agency Comments and Office of Inspector General Response

CMS shares OIG's concern that Medicare pay appropriately for Part B drugs, and states that our findings are helpful to its ongoing efforts to enhance implementation of the ASP methodology. However, CMS notes that because OIG's analysis focuses on fourth-quarter 2005 reimbursement amounts, the report does not reflect the downward trend in drug prices and Medicare reimbursement that has occurred for some drugs since our analysis. CMS believes that Medicare savings would be substantially less than the amount estimated in the report.

Based on CMS's comments, it is unclear what, if any, specific steps the agency plans to take to further reduce Medicare reimbursement amounts for the drugs identified in this report. OIG recognizes the fact that the ASPs and the resulting Medicare reimbursement amounts for some of the drugs in our review have decreased since our analysis was completed. However, even with these recent reductions, widely available market prices for 4 out of the 5 procedure codes still meet the 5-percent threshold when compared to fourth-quarter 2005 ASPs (the basis of second-quarter 2006 reimbursement amounts).

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OBJECTIVE

To determine whether the volume-weighted average sales prices (ASP) for a select group of Medicare Part B prescription drugs exceed their widely available market prices by at least 5 percent.

BACKGROUND

Medicare Coverage of Prescription Drugs

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a new prescription drug benefit available to all Medicare beneficiaries under Medicare Part D. However, a limited number of outpatient prescription drugs are still covered under Medicare Part B. These 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 claims for most prescription drugs are processed and paid for by carriers. Claims for drugs that are used with medical equipment are typically processed and paid by one of four durable medical equipment regional carriers (DMERCs). To obtain Medicare reimbursement for covered outpatient prescription drugs, physicians and suppliers submit claims using procedure codes. Procedure codes define the type of drug and, in most cases, a dosage amount. In contrast, manufacturers and distributors identify prescription drugs using an 11-digit National Drug Code (NDC) that indicates the manufacturer of the drug, the product dosage form, and the package size. One or more NDCs may meet the definition of a particular procedure code.

Medicare Part B Payments for Prescription Drugs

Expenditures for Part B drugs totaled over \$9 billion in calendar year 2005. Although Medicare covers more than 500 outpatient prescription drug procedure codes, the majority of spending for Part B drugs is concentrated on a relatively small subset of those codes.

Medicare Drug Reimbursement Methodologies

Reimbursement methodologies prior to and during 2004. Prior to 2004, Medicare Part B reimbursed covered drugs based on the lower of either the billed amount or 95 percent of the average wholesale price (AWP) as published in national pricing compendia such as the “Red Book.”

However, numerous reports by the Office of Inspector General (OIG)¹ and the Government Accountability Office (GAO)² indicated that Medicare reimbursement amounts were significantly higher than the prices that drug manufacturers, wholesalers, and other similar entities actually charge the physicians and suppliers who purchase these drugs. The MMA made significant changes to the way Medicare Part B reimburses for covered drugs. The MMA specified that the reimbursement rate for most outpatient prescription drugs furnished on or after January 1, 2004, must be set at 85 percent of the AWP until a new methodology could be implemented in 2005.

Current reimbursement methodology. In 2005, Medicare began paying for most Part B drugs using an entirely new methodology based on the ASP rather than the AWP. The MMA defines ASP as a manufacturer's sales of a drug to all nonexempt 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, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those paid under 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" for Medicaid drug rebate purposes, which is the lowest price paid by any purchaser with certain exceptions.

Manufacturers must provide the Centers for Medicare & Medicaid Services (CMS) with the ASP and volume of sales for each NDC on a quarterly basis, with submissions due 30 days after the close of the quarter. Manufacturers were required to submit their initial quarterly ASP data by April 30, 2004. If ASPs were not available during the initial quarter, manufacturers were required to report the wholesale acquisition cost (WAC) of the drug, which is defined in section 1847A(c)(6) of the Social Security Act (the Act) to be the manufacturer's list price to wholesalers or direct purchasers in the United States, excluding price concessions as reported in publications of pricing data.

¹ For example, see "Excessive Medicare Reimbursement for Ipratropium Bromide," OEI-03-01-00411, and "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310.

² For example, see "Medicare: Payments for Covered Outpatient Exceed Providers' Costs," GAO-01-1118, and "Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements," GAO-02-53.

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

As set forth in Section 1847A(b) of the Act, as of January 1, 2005, Medicare's allowance for covered outpatient drugs became equal to 106 percent of one of the following:

- If a drug is available only in brand form (i.e., is a single-source drug), the lesser of either the volume-weighted ASPs for that drug or the volume-weighted WACs for that drug; or
- If a drug is available in both brand and generic forms (i.e., is a multiple-source drug), the volume-weighted average of the ASPs reported for that drug.

Second-quarter 2005 ASP submissions from manufacturers serve as the basis for fourth-quarter 2005 Medicare allowances for most covered procedure codes.

Collection of Widely Available Market Prices

Sections 1847A(d)(1) and 1847A(d)(2)(A) of the Act mandate that OIG conduct surveys to determine widely available market prices and compare ASPs with these widely available market prices. Section 1847A(d)(5)(A) of the Act defines widely available market price to be the price that a prudent physician or supplier would pay for the drug, net of any routinely available price concessions. Pursuant to section 1847A(d)(5)(b) of the Act, OIG should consider information from one or more of the following sources:

- Manufacturers
- Wholesalers
- Distributors
- Physician supply houses
- Specialty pharmacies
- Group purchasing arrangements
- Surveys of physicians
- Surveys of suppliers

- o Insurers
- o Private health plans

If OIG determines that the ASP for a drug exceeds widely available market prices by 5 percent, OIG shall inform the Secretary of the Department of Health and Human Services (Secretary). Under Section 1847A(d)(3)(C):

. . . the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—

- (i) the widely available market price for the drug or biological (if any); or
- (ii) 103 percent of the average manufacturer price.³

Related Work by the Office of Inspector General

The MMA mandated that OIG conduct a study on the ability of physician practices of different sizes in the specialties of hematology, hematology/oncology, and medical oncology to obtain drugs and biologicals at 106 percent of the ASP. OIG completed this study in September 2005.⁴ OIG’s review focused on purchases made by physician practices in these three specialties during the first quarter of 2005 (January through March). For the analysis, OIG selected 40 procedure codes that represented more than 94 percent of the \$4.5 billion in total 2004 Medicare expenditures for drugs administered by physician practices in the 3 mandated specialties. These 40 codes accounted for 63 percent of the \$9.4 billion in overall Part B spending for prescription drugs in 2004.

OIG requested copies of all drug purchase invoices for the sampled practice/months⁵ from the sampled physician practices. OIG calculated

³ For covered outpatient drugs to be eligible for reimbursement by Medicaid, sections 1927(a)(1) and 1927(b)(2) of the Act mandate that drug manufacturers enter into rebate agreements with the Secretary and pay quarterly rebates to State Medicaid agencies. Under section 1927(b)(3) and the rebate agreements, manufacturers must provide the Secretary with average manufacturer prices (AMP) for each of their NDCs on a quarterly basis. As defined in section 1927(k)(1) of the Act, the AMP is the average unit 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.

⁴ “Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients,” A-06-05-00024.

⁵ A practice/month represents a month in the first quarter of 2005 in which a physician practice could have purchased a drug.

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the average price for each practice/month (net of rebates and other price concessions, not including prompt-pay discounts) for drugs associated with each procedure code and used the calculated average prices for the estimates. OIG then compared these average price estimates with reimbursement amounts published by CMS on May 12, 2005, for the first quarter of 2005.

OIG concluded that physician practices in the three specialties could generally purchase drugs for the treatment of cancer patients at less than the MMA-established reimbursement rates, i.e., 106 percent of the ASP. Overall, the report found that the average prices paid for drugs associated with 35 of the 39⁶ procedure codes were less than the Medicare reimbursement amounts based on ASP. OIG also estimated that for 35 of the 39 codes, physician practices could purchase drugs at less than the reimbursement amounts for at least half of the practice/months.

⁶ OIG did not receive enough responses for one code to reliably estimate the average purchase price or the number of practice/months for which physician practices were able to purchase drugs at less than the reimbursement amount.

METHODOLOGY

We reviewed the estimated purchase prices for the 40 procedure codes identified in the September 2005 OIG report described earlier in this report. Additional analysis performed by our office found that second-quarter 2005 volume-weighted ASPs exceeded the estimated purchase prices physicians paid for the drugs included in the study by at least 5 percent for 9 of the 40 procedure codes. These nine procedure codes, listed in Table 1 below, form the sample of this current study. Table 1 also shows the estimated purchase prices in the first quarter of 2005, the second-quarter 2005 volume-weighted ASPs, and the percentage difference between the two amounts for each of the nine procedure codes. We used second-quarter 2005 volume-weighted ASPs in this comparison to account for any changes in the volume-weighted ASPs after the publication of the earlier OIG report.

Table 1. Nine Procedure Codes With Volume-Weighted ASPs That Exceeded Estimated Purchase Prices to Physicians by at Least 5 Percent

Procedure Code	Short Description	Estimated Purchase Price*	Second-Quarter 2005 ASP**	Percentage Difference
J1100	Dexamethasone sodium phosphate	\$0.05	\$0.103	106.4%
J9045	Carboplatin	\$16.24	\$33.259	104.8%
J1260	Dolasetron mesylate	\$4.04	\$6.147	52.2%
J9390	Vinorelbine tartrate	\$35.71	\$40.410	13.2%
J9060	Cisplatin	\$2.05	\$2.239	9.2%
J0640	Leucovorine calcium	\$1.16	\$1.248	7.6%
J1441	Filgrastim G-CSF	\$245.46	\$263.743	7.4%
J9370	Vincristine sulfate	\$3.18	\$3.399	6.9%
J1626	Granisetron HCl	\$6.39	\$6.735	5.4%

*Source: Office of Inspector General, Office of Audit Services, First Quarter 2005.

**Source: CMS's crosswalk file updated December 8, 2005.

Note: All figures in the table have been rounded.

Average Sales Prices

We contacted CMS to obtain volume-weighted ASPs for the nine procedure codes for the second quarter of 2005. These ASPs serve as the basis of fourth-quarter 2005 reimbursement amounts. In addition, we obtained the file that CMS uses to crosswalk NDCs to their corresponding procedure codes. Both the volume-weighted ASPs and the crosswalk file were updated as of December 8, 2005. As mentioned

previously, Medicare does not base reimbursement for covered drugs on NDCs; instead, it uses procedure codes. Therefore, CMS uses ASP information submitted by manufacturers for each NDC to calculate a volume-weighted ASP for each covered procedure code. When calculating these volume-weighted ASPs, CMS only includes NDCs with ASP submissions that are deemed valid.

To calculate the volume-weighted ASPs for procedure codes, CMS uses an equation that involves the following factors: 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 procedure code that providers use to bill Medicare. Therefore, the number of billing units in an NDC describes the number of procedure code units that are in that NDC. CMS calculates the number of billing units in each NDC when developing its crosswalk files. We did not systematically verify the accuracy of the billing unit information.⁷

Widely Available Market Prices

Although the Act names numerous entities from which OIG may obtain data, we believed that it would be most effective to collect pricing information from the sources from which physicians were most likely to have purchased the drugs under review. Based on information from the drug industry and our own analysis, we identified five specialty distributors that provide a majority of the oncology pharmaceuticals purchased by oncology practices: Oncology Therapeutic Network, Oncology Supply, Cardinal Specialty Distribution, Priority Healthcare, and Florida Infusion. We contacted each of these distributors by mail to request fourth-quarter 2005 prices for any NDCs that correspond to the nine procedure codes in our study. We asked the companies to include all prices charged to different types of customers (e.g., physicians, hospitals, pharmacies, etc.). In addition, for each of the drugs, we asked

⁷ In a recent OIG report entitled “Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs” (OEI-03-05-00310), OIG stated that CMS’s calculation of volume-weighted ASP is incorrect because CMS does not use billing units consistently throughout its equation. As a result, many procedure codes have reimbursement amounts that are higher or lower than the amounts that would have been calculated if billing units were used consistently. In the above-referenced report, OIG proposed an alternative methodology that we believe uses billing units correctly. However, for the purposes of this study we used the volume-weighted ASPs that CMS calculates using its equation.

for a description of any types of discounts they offer to customers, the amounts of those discounts, and the percentage of customers that receive those discounts.

All five companies responded to our request. Companies may have had multiple sales prices for each NDC. Two companies submitted an average of their selling prices for each NDC, weighted by the number of units sold at each price. Another company provided all of its prices for each NDC and the number of units sold at each price, allowing us to calculate our own weighted average. The final two companies provided only their list prices for each NDC. For these two companies, to be conservative, we used the highest list prices for each NDC in our analysis.

We only included sales prices to physicians in our analysis. Although we asked the specialty distributors to provide information regarding discounts offered to physicians, we did not take these discounts into account when analyzing prices because these discounts were not routinely available to all physician customers.

To ensure that the market prices would be comparable to the volume-weighted ASP for the procedure code, it was necessary to divide the price per NDC by the number of billing units in that NDC as listed on CMS's crosswalk file. This price represented a price for the amount of drug defined by the procedure code. If a company submitted prices for NDCs that were not included on CMS's crosswalk file, we calculated the billing units by using data from manufacturers' Web sites. Our final step was to calculate a median price for each of the nine procedure codes. For the purposes of this report, widely available market prices refer to the median market price we calculated for each of the nine procedure codes.⁸

Comparing Widely Available Market Prices to Average Sales Prices

We determined the percentage difference between the second-quarter 2005 volume-weighted ASPs and the fourth-quarter 2005 widely available market prices for each of the nine procedure codes. We determined the percentage difference in prices by subtracting the widely available market price from the volume-weighted ASP and then dividing this number by the widely available market price. We

⁸ Given the available data, we believed that the median was the most appropriate measure of the amount a "prudent physician" would pay for the drug.

identified any procedure codes for which the volume-weighted ASP exceeded the widely available market price by 5 percent.

Calculating Potential Medicare Savings

For the procedure codes that met the 5-percent threshold, we estimated the monetary impact of lowering the reimbursement amount to the widely available market price as found in this report. We subtracted the widely available market price from the fourth-quarter 2005 reimbursement amount for the procedure code (equal to 106 percent of the volume-weighted ASP). We then multiplied the difference by the number of services that were allowed by Medicare for each procedure code in 2005, as reported in CMS's Part B Extract and Summary System⁹. This estimate assumes that 2006 utilization for each procedure code will be similar to 2005 utilization and the volume-weighted ASP for each procedure code will remain consistent throughout 2006.

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.

⁹ At the time of extraction, CMS's Part B Extract and Summary System data were 90 percent complete for procedure codes processed by local carriers and DMERCs.

For 5 of the 9 procedure codes under review, the volume-weighted ASP exceeded the widely available market price by at least 5 percent

Five of the nine procedure codes included in our study met or surpassed the 5-percent threshold specified in Section 1847A(d)(3)(B) of the Act.¹⁰ Pursuant to Section

1847A(d)(3)(C), OIG shall notify the Secretary if the ASP for a particular drug exceeds the widely available market price by a threshold of 5 percent. The difference between ASP and widely available market price calculated by OIG for these 5 procedure codes ranged from 17 to 185 percent. A list of these five procedure codes is presented in the table below.

Table 2. Five Procedure Codes With Volume-Weighted ASPs That Exceeded Widely Available Market Prices by at Least 5 Percent

Procedure Code	Short Description	Widely Available Market Price*	Second-Quarter 2005 ASP**	Percentage Difference
J9045	Carboplatin	\$11.667	\$33.259	185.1%
J1100	Dexamethasone sodium phosphate	\$0.062	\$0.103	65.2%
J1260	Dolasetron mesylate	\$3.926	\$6.147	56.6%
J9390	Vinorelbine tartrate	\$31.000	\$40.410	30.4%
J1626	Granisetron HCl	\$5.738	\$6.735	17.4%

*Source: Office of Inspector General, Office of Evaluation and Inspections, fourth quarter 2005.

**Source: CMS's crosswalk file updated December 8, 2005.

Note: All figures in the table have been rounded.

The widely available market prices for these drugs may be even lower than the prices we found, as all five specialty distributors offered price discounts to physician customers that were not reflected in our calculation. We did not take discounts into account when determining widely available market prices because these discounts were not routinely available to all physician customers.

The most common type of price discount offered to physician customers was a percentage off the list or net price when a customer pays his/her balance within a certain time period (i.e., a “prompt pay” discount).

¹⁰ For this report we compared fourth-quarter 2005 market prices to second-quarter 2005 volume-weighted ASPs (the basis of fourth-quarter 2005 reimbursement amounts). The same 5 procedure codes met the 5-percent threshold when we compared widely available market prices to third-quarter 2005 volume-weighted ASPs (the basis of first-quarter 2006 reimbursement amounts).

Three of the five companies that responded to our request offered this type of incentive, with discounts ranging from 1 to 3 percent depending on the time of payment. According to the companies, anywhere from 10 to 90 percent of physician customers take advantage of prompt pay discounts. A fourth company offered a prompt pay discount for only one of the drugs it sold. This discount ranged from 1 to 4 percent.

In addition to prompt pay discounts, one company offered a 2-percent discount for one drug to all physician customers at the time of purchase. This company also offers a “retrospective rebate” to group purchasing organizations (GPO). These rebates are paid retrospectively, approximately 30 days after the close of each quarter. However, the company is not aware of what portion, if any, of the rebates is passed on to individual physicians. Depending on the drug, these rebates ranged from 0.25 to 7.5 percent.

Another company offered discounts to members of a GPO and to members of the State oncology association, which functions like a GPO. The discounts offered to members of the GPO and State oncology association were 2 and 0.25 percent, respectively.

Lowering reimbursement amounts for these five codes to the widely available market price would reduce Medicare expenditures by \$67 million in 2006

Section 1847A(d)(3)(C) of the Act states that OIG shall inform the Secretary if OIG finds that the ASP for a drug or biological exceeds such widely available market price for drugs by 5 percent. If this criterion is met, the lesser of 103 percent of the AMP for the drug or the widely available market price for the drug shall be substituted for the ASP-based payment amount. In this study, we identified 5 codes that met or exceeded the 5-percent threshold specified in the Act. Based on the number of allowed services in 2005, we estimate that Medicare expenditures would be reduced by \$67 million in 2006 if reimbursement amounts for these five codes were lowered to the widely available market price.¹¹ If 103 percent of AMP is lower than the widely available market price for any of these 5 codes, then Medicare expenditures would be reduced even further.¹²

¹¹ Medicare expenditures for these five codes totaled \$315 million in 2005.

¹² Data needed to calculate fourth-quarter 2005 AMPs for the 5 codes were unavailable at the time of analysis.

Section 1847A(d)(2)(A) of the Act mandates that OIG perform comparisons between ASP and widely available market prices to identify drugs for which ASP exceeds widely available market prices by 5 percent. This study is the first of these comparisons. Based on our analysis, we have identified five procedure codes that met the criteria for a price adjustment. Pursuant to the Act, the Secretary shall reduce the reimbursement for these 5 codes to the lesser of the widely available market price or 103 percent of the AMP. We estimate that lowering the reimbursement to the widely available market price would reduce Medicare expenditures by as much as \$67 million in 2006. If 103 percent of AMP is lower than the widely available market price for any of these 5 codes, then Medicare expenditures would be reduced even further.

AGENCY COMMENTS

CMS shares OIG's concern that Medicare pay appropriately for Part B drugs, and states that our findings are helpful to its ongoing efforts to enhance implementation of the ASP methodology. However, CMS notes that because OIG's analysis focuses on fourth-quarter 2005 reimbursement amounts, the report does not reflect the downward trend in drug prices and Medicare reimbursement that has occurred for some drugs since our analysis.

According to CMS, although drug prices appear to have stabilized over the last few quarters, prices for some drugs (particularly generics) continue to decline. CMS specifically cites carboplatin (the drug for which OIG found the largest discrepancy between ASP and widely available market price) as a prime example of this downward trend. CMS concludes that based on the price reductions for carboplatin and other drugs since the time of our analysis, Medicare savings would be substantially less than the amount estimated in the report.

The full text of CMS's comments can be found in Appendix A.

OFFICE OF INSPECTOR GENERAL RESPONSE

OIG acknowledges CMS's efforts in reducing Medicare reimbursement for Part B drugs. However, based on CMS's comments, it is unclear what, if any, specific steps the agency plans to take to further reduce Medicare reimbursement amounts for the drugs identified in this report.

We recognize that the ASPs and the resulting Medicare reimbursement amounts for some of the drugs in our review have decreased since our analysis was completed. However, even with these recent reductions, widely available market prices for 4 out of the 5 procedure codes still meet the 5-percent threshold when compared to fourth-quarter 2005 ASPs (the basis of second-quarter 2006 reimbursement amounts).

For example, CMS is correct that the ASP for carboplatin has declined substantially since the time of our analysis, from \$33.26 in the second quarter of 2005 to \$13.08 in the fourth quarter of that year. Despite this significant reduction, the ASP for carboplatin still exceeds the widely available market price by 12 percent. Therefore, while the potential savings caused by any price reductions for carboplatin and the other drugs would now be lower than the amount calculated in our report, four of the five drug products still meet the criteria specified in MMA.




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAY 12 2006

TO: Daniel R. Levinson
Inspector General

FROM: Mark B. McClellan, M.D., Ph.D. 
Administrator

SUBJECT: Office of Inspector General's (OIG) Draft Report: "A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005," (OEI-03-05-00430)

Thank you for the opportunity to review and comment on the OIG draft report entitled, "A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005." In accord with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medicare pays for most Part B covered drugs based on 106 percent of the average sales price (ASP). The MMA provides that the OIG conduct studies comparing the ASP to the widely available market price (WAMP) and to the average manufacturer price (AMP). The statute further provides that the Secretary substitute a lower payment amount for a drug if the OIG finds and informs the Secretary at such times, as the Secretary may specify that the ASP exceeds the WAMP or AMP by more than 5 percent.

In this report, the OIG collected data on the market price offered by five specialty distributors in fourth quarter 2005 for a sample of nine drugs, and compared it with the ASP for second quarter 2005 (the basis of the fourth quarter 2005 payment rates). The OIG report concluded that for five of the nine drugs, the ASP exceeded the WAMP by more than five percent, and that Medicare would realize as much as \$67 million in savings in 2006 by lowering reimbursement for these drugs. However, we note that because the OIG report focuses on Medicare payment rates in fourth quarter 2005, the report does not reflect the downward trend in drug prices and Medicare reimbursement that has occurred for some drugs in the period since the OIG analysis. We share the OIG's concern that Medicare pay appropriately for Part B covered drugs. The ASP system, which is based on market prices, has led to lower Medicare payment rates for many drugs and generated substantial savings for beneficiaries. Over the last few quarters, drug prices generally appear to be stabilizing, although prices for some drugs, particularly new generic drugs, continue to decline. For example, the Medicare payment rate for Carboplatin (the drug OIG found had the largest difference between the ASP and the median market price) has declined 60 percent in the two quarters since it was examined by OIG. Due to this downward trend in Medicare payment rates for some drugs in the period since the OIG analysis, Medicare savings from substituting the price Medicare pays for the five drugs

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would be substantially less than originally estimated by the OIG report. With the marketplace still evolving in response to the new payment system, the report's findings are very helpful to our ongoing efforts to enhance implementation of the new ASP methodology.

We thank the OIG for their work on this report, and appreciate their commitment to ensuring that Medicare pays appropriately for Medicare Part B covered drugs.



A C K N O W L E D G E 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 Tawes, Director, Medicare and Medicaid Prescription Drug Unit. Other principal Office of Evaluation and Inspections staff who contributed include:

Tanaz Dutia, *Project Leader*

Linda Boone Abbott, *Program Specialist*

Tricia Davis, *Director, Medicare and Medicaid Branch*