

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE PAYMENT FOR
IRINOTECAN**



Daniel R. Levinson
Inspector General

August 2008
OEI-03-08-00310

Office of Inspector General

<http://oig.hhs.gov>

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E X E C U T I V E S U M M A R Y

OBJECTIVE

To compare the first-quarter 2008 Medicare payment amount to manufacturer prices for irinotecan hydrochloride in March 2008.

BACKGROUND

Irinotecan hydrochloride (hereinafter referred to as irinotecan) is an injectable drug used to treat patients with colorectal cancer. The Food and Drug Administration approved the first generic version of irinotecan on February 20, 2008. This study examines the difference between the Medicare payment amount and manufacturer-reported sales prices during March 2008. At that time, generic versions of irinotecan were available for purchase, but not yet factored into the calculation of the Medicare payment amount because of the two-quarter lag between the time when sales occur and the time when these sales become the basis for Medicare payment.

Sections 1847A(d)(1) and (2) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, direct the Office of Inspector General (OIG) to undertake studies that compare average sales prices (ASP) to widely available market prices and average manufacturer prices (AMP). If OIG finds that the ASP for a drug exceeds the widely available market price by a certain threshold (currently 5 percent), section 1847A(d)(3) 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. After being so informed by OIG, the Secretary shall substitute, effective as of the next quarter, the payment amount for that drug with the lesser of the widely available market price, or 103 percent of the AMP.

We collected pricing and other information (e.g., sales volume and discounts) from seven manufacturers of irinotecan (one brand-name manufacturer and six generic manufacturers). To calculate the average manufacturer sales price, we divided total sales (net of discounts, where available) for March 2008 by the total number of units sold during that month. We compared the first-quarter 2008 Medicare payment amount to the March 2008 average manufacturer sales price calculated by OIG. We also estimated the amount that Medicare would have saved in

March 2008 if reimbursement had been based on average manufacturer sales prices.

FINDING

In March 2008, the Medicare payment amount for irinotecan was more than double the OIG-calculated average manufacturer sales price. The Medicare payment amount for irinotecan (\$126.31) exceeded the OIG-calculated average manufacturer sales price (\$51.59) by 145 percent in March 2008. Lower priced generic versions accounted for the vast majority (86 percent) of irinotecan sales in March 2008. The average manufacturer sales price for generic irinotecan was \$40.66; the average manufacturer sales price for the brand-name product was nearly three times greater.

Further, we estimate that had the Medicare payment amount for irinotecan been based on the average manufacturer sales price in March 2008, Medicare expenditures for this drug would have been reduced by \$6.5 million in that month alone.

RECOMMENDATION

Because of the two-quarter lag in CMS's standard process for establishing Medicare payment amounts, the underlying pricing issues identified in this report are not limited to irinotecan. Absent a change in the standard process, Medicare payment amounts for drugs with new generic versions will continue to be temporarily higher than manufacturer sales prices, sometimes substantially.

We therefore recommend that CMS explore options to expedite the process to ensure that Medicare payment amounts for drugs with newly available generic versions accurately reflect market prices. The Secretary has the authority to lower Medicare payment amounts based on the results of OIG studies comparing ASPs to AMPs and widely available market prices; however, CMS has yet to make any changes as a result of OIG's pricing comparisons. Further, the effectiveness of using this authority to address the disparities between Medicare payment amounts and market prices for drugs with newly available generics is limited by timing issues. In addition to the time needed to collect data on widely available market prices, pricing changes based on these data would not take effect until the quarter after OIG provides the pricing data to CMS. Therefore, CMS should explore alternative

options to address pricing discrepancies arising from newly available generic drugs, which may include seeking a legislative change.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS concurred with our recommendation. CMS expressed its commitment to ensuring accurate payments for drug products under the ASP methodology and will review any specific suggestions OIG may have to further this goal. CMS noted that the third-quarter 2008 Medicare payment amount for irinotecan is \$74.75, representing a 40-percent decrease from the previous quarter (\$126.24). CMS also noted that this decrease results in a payment differential per unit for the third quarter that is substantially lower than the differential for March 2008, demonstrating that the ASP methodology reflects market-based prices over time.

OIG's recommendation focuses on exploring options to reduce the time it takes for ASP to reflect market-based prices. The third-quarter payment amount is still substantially higher than the average manufacturer sales price OIG found for March 2008 (\$51.59), further illustrating the effects of the two-quarter lag. The first full quarter of generic sales data for irinotecan will not be reflected in the Medicare payment amount until October 2008—almost 8 months after the first generic versions reached the market.

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Medicare Part B Payment for Irinotecan

Medicare Part B covers a limited number of outpatient prescription drugs, including drugs used in conjunction with durable medical equipment; injectable drugs administered by a physician (such as irinotecan); certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; and some vaccines.¹ To obtain Medicare payment for Part B-covered drugs like irinotecan, physicians submit claims using codes established by the Centers for Medicare & Medicaid Services (CMS) as part of the Healthcare Common Procedure Coding System (HCPCS).² The HCPCS codes 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 paid \$132 million for irinotecan in 2007.³

Medicare payment methodology. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. 108-173,

¹ For the purpose of this report, the term “Part B-covered drugs” refers to outpatient prescription drugs covered by Medicare Part B. Part B-covered drugs do not refer to drugs billed under Part A but paid with Part B funds, such as drugs administered in a dialysis setting.

² CMS contracts with private companies, known as carriers, to process and pay Medicare Part B claims.

³ Medicare Part B Extract and Summary System, updated through March 2008 (98 percent of claims reported), accessed on May 15, 2008.

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changed the basis of payment for most Part B-covered drugs to average sales price (ASP) effective January 1, 2005. Prior to 2005, Medicare generally paid for these drugs based on the average wholesale price (AWP).⁴ Previous reports by the Office of Inspector General (OIG) and the Government Accountability Office found that the AWP-based reimbursements were often significantly higher for Part B-covered drugs than the prices that drug manufacturers, wholesalers, and similar entities actually charged the physicians and suppliers that purchased these drugs.⁵

Section 1847A(c) of the Social Security Act (the Act), as added by the MMA, defines the 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 includes all sales (e.g., sales to pharmacies that are reimbursed by Medicaid or private insurance plans), not just sales reimbursed by Medicare Part B. 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 obtained through the Medicaid drug rebate program.⁶ 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.^{7 8}

Manufacturers report ASPs by national drug codes (NDC), which are 11-digit identifiers that indicate the drug name, the manufacturer of the drug, the product dosage form, and the package size. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a

⁴ In 2004, the reimbursement amount for most covered drugs was based on either 80 or 85 percent of the AWP 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 AWP.

⁵ OEI-03-00-00310, January 2001; OEI-03-97-00290, December 1997; GAO-01-1118, September 2001.

⁶ Section 1847A(c)(3) of the Act.

⁷ 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.

⁸ Section 1847A(c)(2) of the Act.

quarterly basis, with submissions due 30 days after the close of the quarter.⁹

Because Medicare payment for Part B-covered 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 the crosswalk to calculate volume-weighted ASPs for covered HCPCS codes.

Because Medicare payment amounts are based on ASPs reported by manufacturers within 30 days after the end of the applicable calendar quarter, there is a two-quarter lag between the time when sales reflected in the ASP occur and the time when these sales become the basis for Medicare payment amounts. For example, third-quarter 2007 ASP data from manufacturers served as the basis for first-quarter 2008 Medicare payment amounts for most Part B-covered drug codes, including irinotecan. Effective January 1, 2005, Medicare payment amounts for most Part B-covered prescription drugs are equal to 106 percent of the volume-weighted ASPs for the HCPCS codes. Medicare beneficiaries are responsible for 20 percent of this amount in the form of coinsurance.

Generic Versions of Irinotecan

On February 20, 2008, FDA approved the first generic versions of irinotecan. As of May 2008, nine manufacturers had received FDA approval to market the drug. The generic versions of irinotecan are identical, or bioequivalent, to the brand-name version in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, according to FDA. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.¹⁰ However, because of the two-quarter lag, the Medicare payment amount for brand-name and generic irinotecan will be based on only brand-name ASPs and will not include the ASPs for generic irinotecan until the third quarter of 2008 (beginning July 1, 2008). In addition, because the generic versions were not sold until the middle of the first quarter, the full impact of generic irinotecan will not be realized in

⁹ Section 1927(b)(3) of the Act.

¹⁰ FDA. “Office of Generic Drugs.” Available online at <http://www.fda.gov/cder/ogd/>. Accessed on May 5, 2008.

July 2008; i.e., the first full quarter of sales will be for the period from April 1 to June 30, 2008, which then are reflected in the Medicare payment amount starting October 1, 2008.

Office of Inspector General Authority to Conduct Medicare Drug Pricing Studies

Sections 1847A(d)(1) and (2) of the Act, as added by the MMA, direct OIG to undertake studies that compare ASPs to widely available market prices and average manufacturer prices (AMP).^{11 12} Related to this requirement, OIG has completed six reports comparing ASPs to AMPs and one report comparing ASPs to widely available market prices.¹³ In determining widely available market prices, OIG is authorized to consider information from sources including (but not limited to) manufacturers, wholesalers, distributors, physicians, and suppliers.¹⁴

If OIG finds that the ASP exceeds the widely available market price or AMP by a certain threshold (currently 5 percent), the Secretary of the Department of Health and Human Services (the Secretary) may disregard the ASP for the drug when setting reimbursement.¹⁵ After being so informed by OIG, the Secretary shall substitute, effective as of the next quarter, the payment amount for that drug with the lesser of the widely available market price, or 103 percent of the AMP.¹⁶ Although CMS 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 the fluctuating differences between ASPs and AMPs, with the intent of developing a process to adjust payment

¹¹ Section 1927(k)(1) of the Act generally defines AMP as the average price paid to the manufacturer by wholesalers in the United States for drugs distributed to the retail pharmacy class of trade.

¹² Section 1847A(d)(5) 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.

¹³ OEI-03-04-00430, April 2006; OEI-03-05-00430, June 2006; OEI-03-06-00370, July 2006; OEI-03-07-00140, July 2007; OEI-03-07-00530, September 2007; OEI-03-08-00010, December 2007; and OEI-03-08-00130, May 2008.

¹⁴ Section 1847A(d)(5)(B) of the Act.

¹⁵ Section 1847A(d)(3)(A) of the Act.

¹⁶ Section 1847A(d)(3)(C) of the Act.

amounts based on the results of OIG's comparisons.¹⁷ However, CMS has not specified what, if any, steps it will take to adjust Medicare payment amounts.

METHODOLOGY

Scope and Data Collection

Scope. We compared the Medicare payment amount from the first and second quarters of 2008 to manufacturer sales prices from March 2008. We obtained Medicare payment data from CMS and manufacturer sales data from irinotecan manufacturers.

Manufacturer sales data. In April 2008, we sent surveys to seven manufacturers that have FDA approval to produce and market brand-name and generic irinotecan (one brand-name manufacturer and six generic manufacturers).¹⁸ The surveys requested that the manufacturers provide total irinotecan sales and sales volume for March 2008 by NDC.^{19 20} We also asked manufacturers to include any discounts and rebates that they offered to their customers. All seven manufacturers responded to our survey; six manufacturers provided us with irinotecan sales data.²¹

CMS data. We obtained the Medicare payment amount for irinotecan from CMS for the first and second quarters of 2008 (based on volume-weighted ASPs from the third and fourth quarters of 2007, respectively).

Data Analysis

To calculate the average manufacturer sales price, we summarized the total irinotecan sales (including brand-name and generic irinotecan) for

¹⁷ OEI-03-07-00140, July 2007.

¹⁸ Two additional manufacturers received approval to produce irinotecan; however, we excluded these manufacturers from our analysis. One manufacturer received FDA approval to market irinotecan after we began data collection; the other manufacturer is not based in the United States. Additionally, the manufacturer of brand-name irinotecan also produces a generic version through a subsidiary company; we consider the data for both products to be from the same respondent.

¹⁹ Several manufacturers stated that the data were the same as the ASP data they would report to CMS.

²⁰ One manufacturer provided data that included sales from February 28 through March 31, 2008.

²¹ The manufacturer that did not provide sales data responded that it did not have any irinotecan sales for the period under review (March 2008).

March 2008 to all customers, net of discounts, where available, and divided that number by the total number of units sold during that month.²² This figure is hereinafter referred to as the average manufacturer sales price.

Comparing Medicare payment amount to manufacturer sales prices. We compared the first-quarter 2008 Medicare payment amount for irinotecan to the average manufacturer sales prices from March 2008. We calculated the percentage difference between the average manufacturer sales price and the Medicare payment amount for irinotecan.

Brand-name and generic product sales. The average manufacturer sales prices include prices for both generic and brand-name products; the Medicare payment amount from the first quarter of 2008 includes only ASPs for brand-name products. We also calculated separate average manufacturer sales prices for brand-name and generic versions of irinotecan and determined the percentage of manufacturer sales in March 2008 for both versions.

Monetary impact. We estimated what the monetary impact would have been in March 2008 if Medicare had based payment for irinotecan on the average manufacturer sales price calculated for this report. We subtracted the March 2008 average manufacturer sales price from the first-quarter 2008 Medicare payment amount for irinotecan. To estimate the financial impact for March 2008, we multiplied the difference by one-twelfth of the number of services allowed by Medicare for irinotecan in 2007, as reported in CMS's Part B Extract and Summary System.²³ This estimate assumes that the number of services allowed by Medicare in 2007 remained consistent from 1 month to the next and that there were no significant changes in utilization between 2007 and 2008. We also estimated what the financial impact would have been if Medicare had based payment for irinotecan on the average manufacturer sales price during the time the Medicare payment amount included brand-name prices only, i.e., March to June 2008.

Limitations

This study compares 1 month of manufacturer sales data to one quarter of Medicare payment data; we were unable to collect a full quarter of

²² The unit values are based on the Medicare payment amount for irinotecan. Medicare payment for irinotecan is calculated per 20 milligrams.

²³ As of May 15, 2008, CMS's 2007 Medicare Part B Extract and Summary System was 98 percent complete.

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manufacturer sales data because manufacturers did not receive approval to market generic versions of irinotecan until February 20, 2008. We did not verify the accuracy of the sales data provided by the manufacturers.

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.

► FINDING

In March 2008, the Medicare payment amount for irinotecan was more than double the OIG-calculated average manufacturer sales price

The Medicare payment amount for irinotecan (\$126.31) exceeded the OIG-calculated average manufacturer sales price (\$51.59) by 145 percent in March 2008. (See Table 1.)

Table 1. Volume-Weighted ASP and Manufacturer Sales Price for Irinotecan

HCPCS Code	Short Description	March 2008 Average Manufacturer Sales Price*	First-Quarter 2008 Medicare Payment Amount**	Percentage Difference
J9206	Irinotecan injection, 20 milligrams	\$51.59	\$126.31	145%

*Source: OIG analysis of March 2008 manufacturer sales prices for irinotecan. The average manufacturer sales price includes both brand-name and generic irinotecan.
 **Source: CMS's first-quarter 2008 ASP file (based on volume-weighted ASPs from the third quarter of 2007).

Generic irinotecan made up the majority of manufacturer sales and had substantially lower prices in March 2008

Lower priced generic versions accounted for the vast majority (86 percent) of irinotecan sales in March 2008. According to manufacturer sales prices and sales volume in March 2008, the average price for generic irinotecan was \$40.66; the average price for the brand-name product was nearly three times greater.²⁴ Therefore, any purchaser acquiring generic irinotecan in March 2008 received Medicare payment that was approximately \$85 more than the average manufacturer sales price. In addition, because the Medicare payment amount changed minimally in the second quarter of 2008, manufacturer sales prices are likely to continue to be substantially lower than the Medicare payment amount during that period as well.^{25 26}

²⁴ We are not publishing the brand-name average manufacturer sales price because of the proprietary nature of the manufacturer sales data.

²⁵ The Medicare payment amount for irinotecan in the second quarter of 2008 was \$126.24 per 20 milligrams.

²⁶ The Medicare payment amount for irinotecan in the third quarter of 2008 (\$74.75) is 41 percent lower than it was for the previous quarter. This reduction is because of the inclusion of approximately 6 weeks of generic sales (generic irinotecan did not enter the market until the middle of the first quarter). The first full quarter of generic sales will be for the period from April 1 to June 30, 2008, which then will be reflected in the Medicare payment amount starting October 1, 2008. It is likely that the Medicare payment amount will undergo another reduction at that time.

F I N D I N G

Medicare expenditures would have been reduced by \$6.5 million in March 2008 had the Medicare payment amount for irinotecan been based on the average manufacturer sales price

We estimate that had the Medicare payment amount for irinotecan been based on the calculated manufacturer prices in March 2008, Medicare expenditures for this drug would have been reduced by \$6.5 million in that month alone.

Further, because of the two-quarter lag, the lower generic sales prices for irinotecan are not reflected in the second-quarter 2008 reimbursement amount. As a result, we estimate that Medicare expenditures could be reduced by a total of \$26 million during the period between the initial approval of generic irinotecan and the time when the lower prices are included in the ASP calculation (i.e., March to June 2008).²⁷

²⁷ This assumes that expenditures would have been reduced by \$6.5 million per month for the 4 full months before generic prices were included in the Medicare payment amount (March–June 2008).

► R E C O M M E N D A T I O N

OIG compared the Medicare payment amount to manufacturer prices and found that the Medicare payment amount for irinotecan (\$126.31) was more than double the average manufacturer sales price (\$51.59) in March 2008. Further, Medicare and its beneficiaries would have saved an estimated \$6.5 million in March 2008 had Medicare payment amounts been based on the average manufacturer sales price. The recent approval of lower priced generic irinotecan, which accounted for 86 percent of irinotecan manufacturer sales in March 2008, led to this substantial difference.

Because of the two-quarter lag in the ASP system, the Medicare payment amount will not reflect any sales of lower priced generic irinotecan until the third quarter of 2008. Further, because the generic versions were not sold until the middle of the quarter, the full impact of generic irinotecan will not be realized until the quarter beginning on October 1, 2008. The results of this report indicate that the two-quarter lag in the ASP system leads to Medicare payment amounts that are substantially higher than manufacturer prices when generic products first become available.

The underlying pricing issues identified in this report are not limited to irinotecan because of the two-quarter lag in CMS's standard process for establishing Medicare payment amounts. Absent a change in the standard process, Medicare payment amounts for drugs with new generic versions will continue to be temporarily higher than manufacturer sales prices, sometimes substantially.

We therefore recommend that CMS explore options to expedite the process to ensure that Medicare payment amounts for drugs with newly available generic versions accurately reflect market prices.

The Secretary has the authority to lower Medicare payment amounts based on the results of OIG studies comparing ASPs to AMPs and widely available market prices; however, CMS has yet to make any changes as a result of OIG's pricing comparisons. Further, the effectiveness of using this authority to address the disparities between Medicare payment amounts and market prices for drugs with newly available generics is limited by timing issues. In addition to the time needed to collect data on widely available market prices, pricing changes based on these data would not take effect until the quarter after OIG provides the pricing data to CMS. Therefore, CMS

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

should explore alternative options to address pricing discrepancies arising from newly available generic drugs, which may include seeking a legislative change.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, CMS concurred with our recommendation. CMS expressed its commitment to ensuring accurate payments for drug products under the ASP methodology and will review any specific suggestions OIG may have to further this goal. To that end, CMS stated that it continuously looks for ways to improve the methods it uses to collect data. CMS noted that the third-quarter 2008 Medicare payment amount for irinotecan is \$74.75, representing a 40-percent decrease from the previous quarter (\$126.24). CMS also noted that this decrease results in a payment differential per unit for the third quarter that is substantially lower than the differential for March 2008, demonstrating that the ASP methodology reflects market-based prices over time.

OIG's recommendation focuses on exploring options to reduce the time it takes for ASP to reflect market-based prices. The third-quarter payment amount is still substantially higher than the average manufacturer sales price OIG found for March 2008 (\$51.59), further illustrating the effects of the two-quarter lag. The first full quarter of generic sales data for irinotecan will not be reflected in the Medicare payment amount until October 2008—almost 8 months after the first generic versions reached the market.

The full text of CMS's comments is provided in the Appendix.

▶ A P P E N D I X

Agency Comments

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Centers for Medicare & Medicaid Services
		Office of the Administrator Washington, DC 20201

DATE: JUL 25 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General's (OIG) Draft Report: "Medicare Payment for Irinotecan" (OEI-03-08-00310)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and respond to the OIG draft report entitled, "Medicare Payment for Irinotecan." We appreciate the OIG's continuing efforts to examine payment made under the Average Sales Price (ASP) methodology.

The OIG report presents findings from a comparison of the Medicare payment amounts for irinotecan to the OIG-calculated average manufacturer sales price (AMP). The OIG study found that the ASP for J9206, the billing and payment code used to describe irinotecan, that was in effect in March 2008, considerably exceeded the OIG-calculated AMP, calculated using sales data from March 2008. The OIG acknowledges that this differential is the direct result of the entrance of generic products. The OIG also notes that the 2-quarter lag, inherent with the statutory ASP methodology, is a contributing factor to this payment differential.

In accordance with section 1847(A) of the Social Security Act (the Act), the payment amount for most drugs not paid on a cost or prospective payment system is made using the ASP methodology. This methodology relies on sales data submitted quarterly by manufacturers to serve as the basis for a volume weighted ASP applicable to all drugs within a billing and payment code. CMS receives manufacturers' ASP data no later than 30 days after the end of the calendar quarter in which the sale(s) occurred, as specified in section 1927(b)(3)(A)(iii) of the Act. The payment limits are updated using these data at the first opportunity after receipt of the data, which is the calendar quarter after receipt or 2 quarters after the sale(s) occurred.

In the 4 months since the OIG collected the study data and performed their pricing calculations, the ASP-based payment limits have fallen. The July 2008 ASP for J9206 is \$74.753, representing a 40 percent decrease in Medicare payments from the previous quarter. The July ASP is based on sales made between January and March 2008. Comparing the July ASP to the OIG's AMP shows a payment differential per unit substantially lower than the differential found

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by the OIG. This decline demonstrates that the ASP methodology reflects market-based prices over time.

OIG Recommendation

The OIG recommends that CMS explore options to expedite the process to ensure the Medicare payment amounts for drugs with newly available generic versions accurately reflect market prices.

CMS Response

We concur and look forward to working with the OIG on this issue. It is important to note that while the 2-quarter ASP lag can result in Medicare paying higher prices that do not reflect the current market for products with generic entrants, it also means that Medicare is paying less than market prices when market prices increase. However, recognizing that price increases are not automatically reflected in ASP, some manufacturers approach price increase in a measured fashion, electing to take monthly or quarterly, rather than annual, price increases in order to protect customers from financial risk.

The CMS remains committed to ensuring accurate payments for drug products under the ASP methodology and continuously looks for ways to refine and improve the methods we use to collect and array the data we use. We will review any specific suggestions OIG may have to further this goal. Thank you again for the opportunity to review this report. We look forward to continuing to work with you on these issues in the future.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director, Prescription Drug Pricing Unit.

Edward K. Burley served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Kevin McAloon; other central office staff who contributed include Kevin Manley.