Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

A COMPARISON OF AVERAGE SALES PRICES TO WIDELY AVAILABLE MARKET PRICES FOR INHALATION DRUGS

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EXECUTIVE SUMMARY

OBJECTIVE

To determine whether the volume-weighted average sales price (ASP) exceeded the widely available market price by at least 5 percent for any of the five inhalation drugs under review.

BACKGROUND

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 pricing studies that compare ASPs 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 the payment amount for that drug (typically 106 percent of the ASP) with the lesser of the widely available market price, or 103 percent of the AMP pursuant to section 1847A(d)(3)(C) of the Act. Section 1847A(d)(5)(A) of the Act defines widely available market price as the price that a prudent physician or supplier would pay for the drug, net of any routinely available price concessions.

We collected pricing and sales data for the top five inhalation drug codes (according to 2006 utilization data) from 24 distributors. To calculate the widely available market prices, we divided the total sales (net of discounts, where available) for the second quarter of 2007, i.e., April 1 through June 30, 2007, by the total number of units sold during the same quarter. For the five drug codes under review, we compared fourth-quarter 2006 volume-weighted ASPs (the basis of second-quarter 2007 Medicare payment amounts) to second-quarter 2007 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 have saved by lowering reimbursement to the widely available market price for any codes that met or exceeded the 5-percent threshold.

After data collection began, the Centers for Medicare & Medicaid Services (CMS) changed the way in which it pays for two of the

inhalation drugs under review (albuterol and levalbuterol). As explained in a May 2007 coding announcement, CMS reestablished a single drug code for albuterol and levalbuterol effective July 1, 2007. Payment for the new code was based on a combination of ASPs for both drugs.

The application of a provision in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Extension Act) effectively required separate payment amounts for albuterol and levalbuterol beginning in April 2008. After we completed our analysis, but before we issued a draft report, CMS established separate payment amounts for albuterol and levalbuterol, as required by the Extension Act.

FINDINGS

The volume-weighted average sales price for two of the five inhalation drugs under review exceeded the widely available market price by at least 5 percent in the second quarter of 2007. In the second quarter of 2007, two of the five codes included in this analysis surpassed the threshold specified in section 1847A(d)(3)(B) of the Act. For albuterol, the volume-weighted ASP exceeded the widely available market price by 85 percent; for levalbuterol, the volume-weighted ASP exceeded the widely available market price by 19 percent. Had Medicare payment amounts for albuterol and levalbuterol been based on widely available market prices in the second quarter of 2007, we estimate that Medicare expenditures would have been reduced by $27 million.

Because of CMS's May 2007 coding change, the Medicare payment amount for albuterol in the third quarter of 2007 may have been 13 times greater than its widely available market price. As reflected in the May 2007 coding announcement, CMS reestablished a single drug code for albuterol and levalbuterol and based Medicare payment for these drugs on the ASPs of both products effective July 1, 2007. From the second to the third quarter of 2007, this coding change resulted in a 650-percent increase in the Medicare payment amount for albuterol and a 66-percent decrease in the Medicare payment amount for levalbuterol. Assuming that the market prices did not change substantially in subsequent quarters, the new payment amount was 13 times greater than the widely available market price for albuterol and 57 percent less than the widely available market price for levalbuterol in the third quarter of 2007.

SUMMARY

OIG compared ASPs to widely available market prices to identify instances in which the volume-weighted ASPs for five inhalation drugs exceeded the widely available market price by a threshold of 5 percent. We identified two drugs (albuterol and levalbuterol) that exceeded the 5-percent threshold in the second quarter of 2007. However, CMS established a single payment code and amount for albuterol and levalbuterol effective July 1, 2007. As a result of this change, the Medicare payment amount for albuterol in the third quarter of 2007 may have been 13 times greater than the widely available market price in the previous quarter. In contrast, the Medicare payment amount for levalbuterol in the third quarter of 2007 was 57 percent below the widely available market price in the previous quarter.

After we completed our analysis, but before we issued a draft report, CMS separated albuterol and levalbuterol back into two codes, thereby establishing separate payment amounts for the two drugs. As of April 1, 2008, the new Medicare payment amount for albuterol is $0.044 per milligram, an amount very close to the widely available market price ($0.041) we calculated for the second quarter of 2007. The new Medicare payment amount for levalbuterol under the new calculation method required by the Extension Act is $0.280 per 0.5 milligrams, which is substantially lower than the widely available market price of $1.218 from the second quarter of 2007. In future studies, OIG will continue to monitor the utilization of and payment for inhalation drugs.

AGENCY COMMENTS

CMS states that the Extension Act not only established a special payment rule for certain inhalation drugs included in this study but also revised the volume-weighting methodology for determining payments based on the ASP. As a result, CMS believes that there are limitations to this study's methodology and findings directly related to the calculation of the volume-weighted ASP. In addition, CMS notes that because levalbuterol is required to be treated as a multiple-source drug for payment purposes, the agency is concerned that OIG's pricing comparison for the drug may not be accurate.

OFFICE OF INSPECTOR GENERAL RESPONSE

OIG notes that, unlike the methodology for determining the ASP, the methodology for determining the widely available market price is not explicitly defined in statute. Rather, the statute indicates that OIG's determination of this price should reflect what a prudent physician or supplier would pay for a drug based on data collected from any number of specified sources taking into account price concessions. In meeting this requirement, we calculated the widely available market price in a manner (total sales divided by total units sold) consistent with the ASP calculation as defined by the Extension Act, rather than CMS's now discontinued methodology.

Furthermore, we understand that provisions of the Act require levalbuterol to be classified as a multiple-source drug for payment purposes. However, the widely available market price that we calculated illustrates how the Medicare payment amount determined under the method required by the Extension Act compares to the actual price of the drug in the marketplace.

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INTRODUCTION

OBJECTIVE

To determine whether the volume-weighted average sales price (ASP) exceeded the widely available market price by at least 5 percent for any of the five inhalation drugs under review.

BACKGROUND

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 (MMA), P.L. No. 108-173, direct the Office of Inspector General (OIG) to undertake pricing studies that compare ASPs to widely available market prices and average manufacturer prices (AMP). If the ASP for a drug exceeds the widely available market price 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, pursuant to section 1847A(d)(3) of the Act. Section 1847A(d)(3)(C) of the Act goes on to state that " . . . the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment . . . the lesser of (i) widely available market price . . . (if any); or (ii) 103 percent of the AMP. . . ."[1]

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. 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.[2]

Medicare Part B Coverage of Inhalation Drugs

Medicare Part B currently covers only a limited number of outpatient prescription drugs, including drugs used in conjunction with durable medical equipment (DME); injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer

[1] Section 1927(k)(1) of the Act 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. Pursuant to section 6001(c)(1) of the Deficit Reduction Act of 2005, the AMP will be determined without regard to customary prompt pay discounts beginning January 1, 2007.

[2] Section 1847A(d)(5)(B) of the Act.

drugs and immunosuppressive drugs; and some vaccines.[3] Inhalation drugs used in conjunction with a nebulizer are covered by Medicare Part B under the DME provisions.[4] These drugs treat and prevent symptoms brought on by lung diseases, such as asthma and chronic obstructive pulmonary disorder.

Medicare Part B Payments for Inhalation Drugs

Suppliers (e.g., home care companies, mail order pharmacies, and retail pharmacies) typically provide the inhalation drugs prescribed by physicians to Medicare beneficiaries. Suppliers can purchase the drugs through several sources, including wholesalers, distributors, and manufacturers.

To obtain Medicare payment for inhalation drugs, suppliers submit claims using codes established by the Centers for Medicare & Medicaid Services (CMS) as part of the Healthcare Common Procedure Coding System (HCPCS).[5] 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.[6]

Medicare and its beneficiaries paid over $900 million for inhalation drugs in 2006, with five HCPCS codes representing 97 percent of Medicare expenditures for inhalation drugs.[7] [8] The five HCPCS codes for inhalation drugs with the highest Medicare expenditures in 2006 are listed in Table 1 on the following page.

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[3] 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.

[4] 70 Fed. Reg. 10746, 10747 (Mar. 4, 2005).

[5] CMS contracts with private companies, known as carriers, to process and pay Medicare Part B claims, including those for inhalation drugs.

[6] Typically, HCPCS codes correspond to a single drug distributed by one or more manufacturers. However, in some cases, HCPCS codes may represent several different drugs.

[7] Medicare and its beneficiaries paid over $11 billion for all Part B-covered prescription drugs in 2006.

[8] Medicare Part B Extract and Summary System (99 percent of claims reported). Accessed July 30, 2007.

Table 1. HCPCS Codes for Inhalation Drugs With the Highest Medicare Expenditures in 2006

HCPCS Code	Short Description	2006 Expenditures
J7614*	Levalbuterol inhalation solution (unit dose), 0.5 mg	$366,421,299
J7620*	Albuterol, up to 2.5 mg, and ipratropium bromide, up to 0.5 mg, noncompounded	$246,224,526
J7626*	Budesonide inhalation solution (unit dose), up to 0.5 mg	$214,217,163
J7613**	Albuterol inhalation solution (unit dose), 1 mg	$41,358,006
J7644**	Ipratropium bromide inhalation solution (unit dose), 1 mg	$16,143,862

* Levalbuterol, the combination of albuterol and ipratropium bromide, and budesonide are single-source drugs that do not have generic versions and are supplied by a single manufacturer.

** Albuterol and ipratropium bromide are multiple-source drugs that have numerous generic versions and are supplied by multiple manufacturers.

Source: CMS's Part B Extract and Summary System data (99 percent complete). Accessed July 30, 2007.

Medicare Part B Payment Methodology for Inhalation Drugs

The MMA changed the basis of payment for most Part B-covered drugs, including inhalation drugs, to ASP, effective January 1, 2005. Prior to 2005, Medicare generally paid for these drugs based on the average wholesale price (AWP).[9] Numerous reports by 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 purchase these drugs.

Section 1847A(c) of the Act, as added by the MMA, defines 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

[9] In 2004, the reimbursement amount for most covered drugs was based on either 80 percent 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.

(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.[10] 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.[11] [12]

Manufacturers report ASPs by national drug code (NDC), which is an 11-digit identifier that indicates 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 quarterly basis, with submissions due 30 days after the close of the quarter.[13]

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.

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, fourth-quarter 2006 ASP submissions from manufacturers served as the basis for second-quarter 2007 Medicare payment for most Part B-covered drug codes. As of 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.

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[10] Section 1847A(c)(3) of the Act.

[11] 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.

[12] Section 1847A(c)(2) of the Act.

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

Changes to Medicare Payment for Inhalation Drugs

The way Medicare pays for two inhalation drugs (albuterol and levalbuterol) has undergone several changes since 2003.

- In 2003, albuterol and levalbuterol were included in the same HCPCS code (J7619) and had the same Medicare payment amount.[14]
- Effective January 1, 2005, CMS created separate HCPCS codes and Medicare payment amounts for both albuterol (J7613) and levalbuterol (J7614).
- However, as reflected in a May 2007 coding announcement, CMS reestablished a single HCPCS code (Q4094) for albuterol and levalbuterol effective July 1, 2007.[15] Payment for the new code was based on a combination of the ASPs for both drugs.[16]
- A provision in the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Extension Act) provides flexibility in payment determinations designed to yield the lowest payment amount for certain drugs including those studied for this report. After we completed our analysis, but before we issued a draft report, CMS once again established separate HCPCS codes and payment amounts for albuterol (J7613) and levalbuterol (J7614), as required by the Extension Act, effective April 1, 2008.[17] [18]

For a more detailed discussion of recent changes to Medicare payment for albuterol and levalbuterol, please refer to Appendix A.

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[14] For the purpose of this review, albuterol and levalbuterol refer to the unit-dose forms of these drugs; this review does not include the concentrated forms. Levalbuterol is produced by one manufacturer (Sepracor) under the brand name of Xopenex, has its own patent, and contains only a therapeutically active single isomer (molecule). Albuterol is a two-isomer (molecule) inhalation drug with numerous generic versions and is supplied by multiple manufacturers. According to the Food and Drug Administration, levalbuterol and albuterol are not therapeutically equivalent.

[15] CMS Coding Announcement. Available online at http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf. Accessed on May 22, 2007.

[16] For the third quarter of 2007, the Medicare payment amount increased nearly 650 percent for albuterol (from $0.081 per milligram to $0.525 per milligram) and decreased by 66 percent for levalbuterol (from $1.535 per half milligram to $0.525 per half-milligram).

[17] Section 112(b)(2) of the Extension Act.

[18] For the second quarter of 2008, the Medicare payment amount for albuterol is $0.044 per milligram and for levalbuterol is $0.280 per half milligram.

Related Work by the Office of Inspector General

A June 2006 report entitled "A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005" (OEI-03-05-00430) was the first OIG review to compare ASPs to widely available market prices. For that review, OIG compared second-quarter 2005 volume-weighted ASPs (the basis of fourth-quarter 2005 Medicare payment amounts) to fourth-quarter 2005 widely available market prices for nine HCPCS codes identified by a previous OIG study for which ASPs exceeded widely available market prices by at least 5 percent.[19] OIG found that for five of nine HCPCS codes under review, the volume-weighted ASPs exceeded widely available market prices by the 5-percent threshold specified in section 1847A(d)(3) of the Act. As estimated in OIG's report, lowering the payment amount for these five codes to widely available market prices would have reduced Medicare expenditures by $67 million in 2006.

In addition, OIG issued several reports that focused specifically on concerns about Medicare payment amounts for the inhalation drugs albuterol and ipratropium bromide prior to MMA's passage.[20] For example, two January 2004 OIG reports found that in 2003 (when payment was based on AWP), the Medicare payment amounts for albuterol and ipratropium bromide were substantially higher than the amounts paid by other Government payers (i.e., the Department of Veterans Affairs, Medicaid) and prices paid by distributors.[21]

METHODOLOGY

Scope and Data Collection

Scope. This review compared the volume-weighted ASPs to widely available market prices for the five inhalation drugs with the highest Medicare expenditures in 2006 (see Table 1 on page 3). We obtained the ASP data from CMS and widely available market price data from inhalation drug distributors.

[19] "Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients" (A-06-05-00024), September 2005.

[20] OIG issued several reports focusing on Medicare payment for inhalation drugs: OEI-03-01-00410, March 2002; OEI-03-03-00510, January 2004; OEI-03-01-00411, March 2002; OEI-03-03-00520, January 2004.

[21] OEI-03-03-00510, January 2004; OEI-03-03-00520, January 2004.

Widely Available Market Price Data. In July 2007, we sent surveys to 31 distributors identified by Sepracor (the manufacturer of levalbuterol) as having sold inhalation drugs during recent quarters.[22] The surveys requested that the distributors provide total sales[23] and sales volume for the second quarter of 2007 by NDC for the five inhalation drugs under review. We also asked distributors to include any discounts and rebates that they offered to their customers.[24] Between July and October 2007, 24 of 31 distributors provided us with inhalation drug sales data. Three additional distributors provided data after the collection deadline; we did not include these data in our analysis. The remaining four distributors have not provided sales data for inhalation drugs as of May 2008.[25]

CMS Data. We obtained volume-weighted ASP data from CMS for the fourth quarter of 2006 (basis for second-quarter 2007 Medicare payment amounts) and first quarter of 2007 (basis for third-quarter 2007 Medicare payment amounts).

Data Analysis

We excluded from our analysis any sales data submitted by distributors related to NDCs that were not associated with the five inhalation drugs included in this review.[26] In addition, we excluded from this analysis any sales transactions in which both the sales volume and total amount paid (net discounts, where applicable) were negative. Finally, we excluded data that did not include the dates of sale. Two of the

[22] OIG obtained a list of distributors only from Sepracor because the scope of the inspection was limited to levalbuterol at the time of sample selection. Because the list obtained from Sepracor included the largest national distributors of prescription drugs as well as numerous regional distributors, OIG believes that the distributors surveyed for this review are an accurate reflection of the inhalation drug market.

[23] Most distributors provided total sales. However, two distributors do not resell inhalation drugs; they provide the drugs directly to pharmacies. These two distributors provided data on their total purchases for inhalation drugs. For the purpose of this analysis, data from these two distributors is considered "sales" data.

[24] Several distributors responded that they offered price discounts to their customers but were unable to provide any specific data on discounts. We were unable to include the discounts from these distributors in our calculation of widely available market prices. Therefore, the actual widely available market prices could be lower than the prices reported in the findings.

[25] We sent up to two follow-up surveys and made several attempts to contact nonresponding distributors by phone when they did not submit pricing data.

[26] For example, albuterol is produced in both inhalation solution and tablet forms. The scope of this review is limited to albuterol inhalation solution, and therefore, we excluded sales data related to national drug codes for albuterol tablets from this analysis.

twenty-four responding distributors did not provide the dates of sale for any of their sales data; therefore, we excluded all sales from these two distributors from our analysis.

We aggregated the remaining NDCs by their corresponding HCPCS codes. To calculate the widely available market price for each of the inhalation drugs, we summarized the total sales for the second quarter of 2007 to all customers (net of discounts, where available) and divided that number by the total number of units sold during the same quarter.[27]

Comparing ASPs to Widely Available Market Prices. For each HCPCS code under review, we compared the volume-weighted ASPs from the fourth quarter of 2006 (basis for second-quarter 2007 Medicare payment amounts) to the respective widely available market prices from the second quarter of 2007. Consistent with the directive in the MMA, we calculated the percentage difference between the widely available market price and volume-weighted ASP for each inhalation drug HCPCS code and identified the codes that met or exceeded the 5-percent threshold defined by the MMA.

Monetary Impact. For HCPCS codes that met or surpassed the 5-percent threshold, we estimated what the monetary impact would have been in the second quarter of 2007 if Medicare based payment for these HCPCS codes on the widely available market prices found in this report. We subtracted the second-quarter 2007 widely available market price from the second-quarter 2007 Medicare payment amount for the HCPCS code, which is equal to 106 percent of the volume-weighted ASP. To estimate the financial impact for the second quarter of 2007, we multiplied the difference by one-fourth of the number of services allowed by Medicare for each HCPCS code in 2006, as reported in CMS's Part B Extract and Summary System.[28] This estimate assumes that the number of services that were allowed by Medicare in 2006 remained consistent from one quarter to the next and that there were no significant changes in utilization between 2006 and 2007.

[27] The unit values are based on the volume-weighted ASP calculation for each drug. ASPs for albuterol/ipratropium bromide and budesonide are calculated on a per unit basis. ASPs for albuterol and ipratropium bromide are calculated per milligram. The ASP for levalbuterol is calculated per 0.5 milligram.

[28] As of July 30, 2007, CMS's 2006 Medicare Part B Extract and Summary System was 99-percent complete.

Impact of Inhalation Drug Coding Change. We also analyzed the potential impact of recent coding and payment changes regarding albuterol and levalbuterol. We compared the second-quarter 2007 Medicare payment amounts for albuterol and levalbuterol to the third-quarter 2007 Medicare payment amount for the new HCPCS code (Q4094), which is based on ASPs of both drugs. We also compared the third-quarter 2007 Medicare payment amount to the widely available market price for albuterol and levalbuterol to determine the difference between Medicare payment and acquisition costs.

Limitations

We did not verify the accuracy of the sales data provided by the distributors. We were unable to include all distributor discounts and rebates in our calculation of widely available market price. Therefore, the actual widely available market price could be lower than the prices reported in the findings.

After we completed our analysis, but before we issued a draft report, CMS once again established separate HCPCS codes and payment amounts for albuterol (J7613) and levalbuterol (J7614), as required by the Extension Act, effective April 1, 2008.

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.

The volume-weighted average sales price for two of the five inhalation drugs under review exceeded the widely available market price by at least 5 percent in the second quarter of 2007

Consistent with sections 1847A(d)(1) and (2) of the Act, we compared ASPs and widely available market prices for five inhalation drugs to identify instances in which the volume-weighted ASP for a particular drug exceeded the widely available market price by at least 5 percent. Two of the five HCPCS codes surpassed the 5-percent threshold in the second quarter of 2007: albuterol (J7613) and levalbuterol (J7614). As Table 2 illustrates, the volume-weighted ASP for albuterol exceeded the widely available market price by 85 percent; the volume-weighted ASP for levalbuterol exceeded the widely available market price by 19 percent.[29]

Table 2. Inhalation Drugs for Which the Volume-Weighted ASP Exceeded the Widely Available Market Price by at Least 5 Percent in the Second Quarter of 2007

HCPCS Code	Short Description	Second-Quarter 2007 Widely Available Market Price*	Fourth-Quarter 2006 ASP**	Percentage Difference
J7613	Albuterol inhalation solution (unit dose), 1 mg	$0.041	$0.076	85.4%
J7614	Levalbuterol inhalation solution (unit dose), 0.5 mg	$1.218	$1.448	18.9%

*Source: OIG analysis of second-quarter 2007 widely available market prices for inhalation drugs.

**Source: CMS's fourth-quarter 2006 ASP file.

Note: All numbers in this table have been rounded.

Medicare expenditures would have been reduced by $27 million in the second quarter of 2007 had payment amounts for albuterol and levalbuterol been based on widely available market prices. Section 1847A(d)(3)(A) of the Act states that the Secretary may disregard the ASP for the drug when setting reimbursement if OIG finds that the ASP for a drug exceeds the widely available market price by a certain threshold (currently 5 percent). Had Medicare payment amounts for albuterol and levalbuterol been based on widely available market prices in the second quarter of 2007, we estimate that Medicare expenditures for

[29] The actual widely available market prices for these HCPCS codes may be even lower than the prices we calculated, as multiple respondents offered price discounts but did not provide any specific discount data that could be factored into our analysis.

these drugs would have been reduced by $27 million ($6 million for albuterol and $21 million for levalbuterol).[30]

Because of CMS's May 2007 coding change, the Medicare payment amount for albuterol in the third quarter of 2007 may have been 13 times greater than its widely available market price

As reflected in the May 2007 coding announcement, CMS reestablished a single HCPCS code for albuterol and levalbuterol and based Medicare payment amounts for these drugs on the volume-weighted ASPs of both products effective July 1, 2007. From the second to the third quarter of 2007, this coding change resulted in a 650-percent increase in the Medicare payment amount for albuterol (from $0.081 to $0.525 per milligram). Assuming that market prices were similar to those of the previous quarter, this new payment amount for albuterol was 13 times greater than the widely available market price. Furthermore, the Medicare payment amount for albuterol in the third quarter of 2007 was 12 percent higher than the AWP-based Medicare payment amount that was in effect prior to the implementation of the MMA.[31]

In contrast, the Medicare payment amount for levalbuterol decreased by 66 percent between the second and third quarters of 2007 (from $1.535 per 0.5 milligram to $0.525 per 0.5 milligram). This means that Medicare paid for levalbuterol at an amount 57 percent below the widely available market price in the third quarter of 2007 (again, assuming similar market prices).

Table 3 on the following page presents the differences between the Medicare payment amount and widely available market price for albuterol and levalbuterol in the second and third quarters of 2007.

[30] If 103 percent of the AMP is lower than the widely available market price for these drugs, then Medicare expenditures would be reduced even further; however, a comparison of ASPs to AMPs is beyond the scope of this report. OIG has produced several reports that have compared ASPs to AMPs.

[31] In 2003, prior to implementation of the payment reductions based on the MMA, Medicare payment for albuterol was $0.47 per milligram and was based on 95 percent of AWP.

Table 3. Comparison of the Medicare Payment Amount and Widely Available Market Price for Albuterol and Levalbuterol

Drug	Second-Quarter 2007 Widely Available Market Price*	Second-Quarter 2007 Medicare Payment Amount **	Third-Quarter 2007 Medicare Payment Amount***
Albuterol inhalation solution (unit dose), 1 mg	$0.041	$0.081	$0.525
Levalbuterol inhalation solution (unit dose), 0.5 mg	$1.218	$1.535	$0.525

*Source: OIG analysis of second-quarter 2007 widely available market prices for inhalation drugs.

**Source: CMS's second-quarter 2007 ASP file.

***Source: CMS's third-quarter 2007 ASP file.

Note: In the second quarter of 2007, albuterol (J7613) and levalbuterol (J7614) had separate HCPCS codes. Effective July 1, 2007, CMS established a single HCPCS code (Q4094) for albuterol and levalbuterol.

OIG compared ASPs to widely available market prices to identify instances in which the volume-weighted ASPs for five inhalation drugs exceeded the widely available market price by a threshold of 5 percent. We identified two drugs (albuterol and levalbuterol) that exceeded the 5-percent threshold in the second quarter of 2007. However, CMS established a single HCPCS code and payment amount for albuterol and levalbuterol effective July 1, 2007. As a result of this change, the Medicare payment amount for albuterol in the third quarter of 2007 may have been 13 times greater than the widely available market price in the previous quarter. In contrast, the Medicare payment amount for levalbuterol in the third quarter of 2007 was 57 percent below the widely available market price in the previous quarter.

After we completed our analysis, but before we issued a draft report, CMS separated albuterol and levalbuterol back into two codes, thereby establishing separate payment amounts for the two drugs. As of April 1, 2008, the new Medicare payment amount for albuterol is $0.044 per milligram, an amount very close to the widely available market price ($0.041) we calculated for the second quarter of 2007. The new Medicare payment amount for levalbuterol under the new calculation method required by the Extension Act is $0.280 per 0.5 milligrams, which is substantially lower than the widely available market price of $1.218 from the second quarter of 2007. In future studies, OIG will continue to monitor the utilization of and payment for inhalation drugs.

AGENCY COMMENTS

CMS states that the Extension Act not only established a special payment rule for certain inhalation drugs included in this study but also revised the volume-weighting methodology for determining payments based on the ASP.[32] As a result, CMS believes that there are limitations to this study's methodology and findings directly related to the calculation of the volume-weighted ASP. Specifically, CMS notes

[32] For an extensive discussion of volume-weighting methodologies, see "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs" (OEI-03-05-00310). Section 112(a) of the Extension Act required CMS to calculate the volume-weighted ASP based on the method recommended in that report.

that OIG used two different volume-weighting methodologies in its comparison; i.e., CMS's ASPs are based on the pre-Extension Act methodology while OIG's widely available market prices are based on the post-Extension Act methodology. CMS believes that the use of a single volume-weighting methodology would result in a significantly smaller difference between the ASP and the widely available market price.

In addition, CMS states that based on recent statutory changes, (1) the current Medicare payment amount for albuterol is very close to the widely available market price identified by OIG and (2) the current Medicare payment amount for levalbuterol is significantly lower than in the past. CMS then notes that levalbuterol is treated as a multiple-source drug pursuant to section 1847A(c)(6)(C)(ii) of the Act. As a result, CMS is concerned that OIG's comparison between the Medicare payment amount and the widely available market price for levalbuterol may not be accurate.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

Previous OIG work demonstrated the problems with CMS's methodology to calculate ASPs prior to the statutory changes of the Extension Act. Unlike the methodology for determining the ASP, the methodology for determining the widely available market price is not explicitly defined in statute. Rather, the statute indicates that OIG's determination of this price should reflect what a prudent physician or supplier would pay for a drug based on data collected from any number of specified sources taking into account price concessions. In meeting this requirement, we calculated the widely available market price in a manner (total sales divided by total units sold) consistent with the ASP calculation as defined by the Extension Act, rather than CMS's now discontinued methodology.

Furthermore, we understand that provisions of the Act require levalbuterol to be classified as a multiple-source drug for payment purposes. However, levalbuterol has its own patent and, according to the Food and Drug Administration, is not therapeutically equivalent to albuterol. During the period in which we collected widely available market price data, CMS considered levalbuterol to be a single-source drug. CMS's May 2007 coding change affects Medicare payment. However, when suppliers purchase levalbuterol in the marketplace,

they do not pay a price that averages in the price of albuterol as well. The widely available market price that we calculated illustrates how the Medicare payment amount determined under the method required by the Extension Act compares to the actual price of the drug in the marketplace.

APPENDIX ~ A

Changes to Medicare Payment Methodology for Albuterol and Levalbuterol

The way Medicare pays for albuterol and levalbuterol has undergone several changes since 2003. From January 2003 to December 2004, albuterol and levalbuterol were included in the same Healthcare Common Procedure Coding System (HCPCS) code (J7619). Under this method, the payment amount for albuterol and levalbuterol was the same and was based on the median average wholesale price (AWP).[33] Effective January 1, 2005, the Centers for Medicare & Medicaid Services (CMS) established separate HCPCS codes and separate payment amounts for albuterol (J7613) and levalbuterol (J7614). The Medicare payment amount at this time was based on 106 percent of each drug's average sales price (ASP).

As described in a May 2007 coding announcement, CMS reestablished a single HCPCS code (Q4094) for albuterol and levalbuterol effective July 1, 2007.[34] Thus, as of July 1, 2007, the Medicare payment amount for the code was based on a volume-weighted average of both albuterol and levalbuterol. According to the coding announcement, this change was made to ensure that payments reflected the "grandfathering" provision of section 1847A of the Social Security Act (the Act), which states:

> With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.[35]

As a result, CMS established a single HCPCS code (Q4094) for both unit-dose albuterol and unit-dose levalbuterol, effective July 1, 2007. This coding change had a substantial impact on the Medicare payment amounts for albuterol and levalbuterol. For the third quarter of 2007, the Medicare payment amounts increased nearly 650 percent for

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[33] The Medicare payment amount for albuterol and levalbuterol was based on 95 percent of the AWP in 2003 and 80 percent of AWP in 2004.

[34] CMS Coding Announcement. Available online at http://www.cms.hhs.gov/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf. Accessed May 22, 2007.

[35] Section 1847A(c)(6)(C)(ii) of the Act. CMS's change affected the Medicare payment for several other drugs as well. We did not examine the potential impact on Medicare expenditures for any drugs other than albuterol and levalbuterol.

albuterol and decreased by 66 percent for levalbuterol compared to amounts for the previous quarter.[36]

The Medicare, Medicaid, and SCHIP Extension Act of 2007

In December 2007, section 112(b)(2) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Extension Act) established a special rule that addressed the application of the so-called "grandfathering" provision of the Act.[37] This provision of the Extension Act will apply to certain drugs, including albuterol and levalbuterol. The provision establishes a "lower of" analysis that allows flexibility in Medicare payments for the affected drugs. More specifically, section 112(b)(2) of the Extension Act states:

> Beginning with April 1, 2008, the payment amount for each single source drug or biological . . . that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of-
>
> > (i) the payment amount that would be determined for such drug or biological applying such subsection; or
> >
> > (ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied . . .
>
> [The payment amount for] a multiple source drug . . . (excluding a drug or biological that is treated as a multiple source drug because of the application of such subsection) is the lower of-
>
> > (i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or
> >
> > (ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.[38]

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[36] Medicare payment was $0.081 per milligram of albuterol (HCPCS code J7613) and $1.535 per half milligram of levalbuterol (HCPCS code J7614) in the second quarter of 2007. However, in the third quarter of 2007, the beginning of the new coding and payment methodology, Medicare payment for one milligram of albuterol and one half milligram of levalbuterol (HCPCS code Q4094) is $0.525.

[37] Section 1847A(c)(6)(C)(ii) of the Act.

[38] Section 112(b)(2)(7) of the Extension Act, codified at section 1847A(b)(7) of the Act.

For the purposes of albuterol and levalbuterol, the new rule set forth in the Extension Act provided CMS the latitude to once again establish separate payment amounts for each drug. Effective April 1, 2008, CMS implemented provisions of the Extension Act by establishing separate HCPCS codes and payment amounts for albuterol and levalbuterol.[39]

[39] For the second quarter of 2008, the Medicare payment amount for albuterol is $0.044 per milligram and for levalbuterol is $0.280 per 0.5 milligrams.

APPENDIX ~ B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator
Washington, DC 20201

DATE: MAY 0 9 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General Draft Report: "A Comparison of Average Sales Prices to Widely Available Market Prices for Inhalation Drugs" (OEI-03-07-00190)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) Draft Report: "A Comparison of Average Sales Prices to Widely Available Market Prices for Inhalation Drugs" (OEI-03-07-00190). We appreciate OIG's continued work to provide market pricing information on inhalation drugs.

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 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 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 the specified threshold, currently 5 percent. Recently, the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) revised the volume weighting methodology for determining payments based on ASP, and established a special payment rule for certain inhalation drugs included in this study. These changes occurred during the course of OIG's work on this report.

The OIG found that Medicare payment for three of the five inhalation drugs studied did not exceed the threshold for price substitution. We believe this indicates that the ASP methodology results in payments that are consistent with market prices. The OIG also found that for the unit dose forms of albuterol and levalbuterol, the 5- percent threshold was exceeded. However, we believe there are limitations in the study methodology and findings of this report that directly relate to the ASP volume weighting methodology concerns previously reported by OIG in its studies comparing AMP to ASP. We believe these concerns have been resolved by the MMSEA statutory changes.

In comparing prices for their report, OIG uses two different volume weighting methodologies to compare the WAMP to the ASP. The WAMP is identified using the volume weighting methodology specified in the MMSEA. However, the ASP is based on the pre-MMSEA methodology. We believe use of a single volume weighting methodology would result in a significantly smaller difference between the ASP and the WAMP and would reduce the estimated savings from price substitution. Because we do not have access to OIG's study data, we can not examine the impacts of consistently applying the pre-MMSEA volume weighting methodology. However, consistently applying the MMSEA volume weighting methodology, we find that, for albuterol, the percentage difference between the ASP and the WAMP decreases from 85.4 percent, as noted in the report, to 9.8 percent; for levalbuterol, the difference does not exceed the 5- percent threshold. The latter volume weighting methodology is now in effect for the Medicare program. Thus, we anticipate volume weighting methodology concerns will not pertain to future WAMP studies.

This study was performed over the same time period during which Medicare coding and payment for albuterol and levalbuterol changed. These changes correspond with statutory requirements. OIG states that the payment amounts following the coding changes effective July 1, 2007, varied greatly from the WAMP for these products. We note that statutory changes were made to address this payment issue as well as the volume weighting methodology issues previously mentioned. As stated in the report, the current payment for albuterol is very close to the WAMP identified by OIG. Payment for levalbuterol under the new volume weighting methodology and special rule established by section 112 of the MMSEA is significantly lower than past payment levels for this drug.

However, we note that levalbuterol is treated as a multiple source drug pursuant to section 1847A(c)(6)(C)(ii)of the Social Security Act. As a result, we are concerned that the sentence on page 11 (and restated elsewhere in the report), "This means that Medicare paid for levalbuterol at an amount 57 percent below the widely available market price in the third quarter of 2007 (again, assuming similar market prices)," may not be an accurate comparison.

We share OIG's interest in continuing to monitor the utilization of, and payment for, inhalation drugs. We look forward to working with the OIG on these issues.

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

ACKNOWLEDGMENTS

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 Roman Strakovsky; other central office staff who contributed include Linda B. Abbott.