

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**EXCESSIVE MEDICARE  
REIMBURSEMENT FOR ALBUTEROL**



**JANET REHNQUIST**  
Inspector General

**MARCH 2002**  
**OEI-03-01-00410**

# ***OFFICE OF INSPECTOR GENERAL***

**<http://www.oig.hhs.gov/>**

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## ***Office of Audit Services***

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

## ***Office of Evaluation and Inspections***

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

## ***Office of Investigations***

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

## ***Office of Counsel to the Inspector General***

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

# EXECUTIVE SUMMARY

## PURPOSE

This report compares the amount Medicare reimburses for albuterol to the prices available to the Department of Veterans Affairs (VA) and to acquisition costs for suppliers.

## BACKGROUND

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs that are necessary for the effective use of durable medical equipment. One such product, albuterol, is an inhalation drug commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Medicare paid \$296 million for albuterol in 2000. In general, Medicare reimburses a covered drug at 95 percent of the drug's average wholesale price. Medicare payments include both the 80 percent that Medicare reimburses and the 20 percent coinsurance payment for which beneficiaries are responsible.

Albuterol is usually provided to Medicare beneficiaries by suppliers, who then submit claims for reimbursement to Medicare. Suppliers can purchase drug products through group purchasing organizations, wholesalers, and directly from manufacturers. Unlike Medicare, the VA provides veterans with drugs purchased directly from manufacturers or wholesalers. There are several purchase options available to the VA, including the Federal Supply Schedule, blanket purchase agreements, and VA national contracts.

We compared Medicare's current reimbursement amount for albuterol to amounts paid by the VA and to acquisition costs for suppliers and wholesalers. We obtained reimbursement amounts for albuterol from Medicare and acquisition costs from the VA. To obtain supplier and wholesaler acquisition costs, we collected prices from wholesale catalogs, supplier invoices, and *Drug Topics Red Book*.

---

## **FINDINGS**

### **Medicare and its beneficiaries would save \$264 million a year if albuterol were reimbursed at the median price paid by the VA**

The Medicare reimbursement amount for albuterol is more than nine times greater than the VA price. The VA purchases generic albuterol through the Federal Supply Schedule for a median price of only \$0.05 per milligram (mg), while Medicare reimburses at \$0.47 per mg. We estimate that Medicare and its beneficiaries would save \$264 million a year if reimbursement for albuterol were set at the median amount available to the VA. Medicare beneficiaries would receive \$53 million of this savings through reduced coinsurance payments. Based on the Federal Supply Schedule, the VA's median acquisition cost for albuterol has fallen by more than 50 percent over the last three years, from \$0.11 per mg in 1998 to \$0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount has remained constant at \$0.47 per mg.

### **Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to suppliers**

Medicare's reimbursement amount for albuterol was nearly six times higher than the median catalog price. Like the VA, catalog prices for albuterol have fallen over the last several years, from \$0.23 per mg in 1996 to its current median price of \$0.08 per mg. We found that Medicare would save \$245 million a year by basing albuterol reimbursement on the current median catalog price. In addition, we found that the median supplier invoice price was \$0.09 per mg, and the median wholesale acquisition cost reported by manufacturers was \$0.11 per mg. If Medicare based albuterol reimbursement on these prices, the program and its beneficiaries would save between \$226 million and \$239 million a year.

### **Less than one percent of albuterol suppliers were responsible for providing the majority of the product to Medicare beneficiaries in 2000**

Medicare reimbursed 6,522 suppliers for albuterol claims in 2000. However, just 34 of these suppliers received more than \$1 million each in Medicare reimbursement for albuterol in 2000, with five having between \$11 million and \$35 million in paid claims. These 34 suppliers, who all provided home-delivery/mail-order services to beneficiaries, received 63 percent of the Medicare payments for albuterol in 2000. Therefore, the majority of the albuterol supplied to Medicare beneficiaries was provided by suppliers that purchase a large quantity of the

product. We believe that suppliers that purchase albuterol in such large quantities may receive volume discounts from manufacturers and wholesalers.

---

## **RECOMMENDATION**

### **Medicare should reduce excessive reimbursement amounts for albuterol**

Despite numerous attempts by the Centers for Medicare & Medicaid Services (CMS) to lower reimbursement amounts for prescription drugs, the findings of this report illustrate that Medicare still pays too much for albuterol. We have consistently found that the published average wholesale prices currently used by Medicare to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to suppliers and large government purchasers.

We understand that unlike most drugs covered by Medicare, albuterol is usually provided by suppliers rather than administered by physicians. These suppliers obviously need to make a profit from the products they provide, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant. Reimbursement levels for albuterol not only impact the Medicare program, but also affect Medicare beneficiaries who pay increased coinsurance amounts.

We offer the following options for reducing excessive reimbursement amounts for covered drugs:

- ▶ Authorizing a commission to set payment rates.
- ▶ Calculating national estimated acquisition costs based upon the average manufacturer prices reported to the Medicaid program.
- ▶ Collecting more accurate average wholesale prices from drug pricing catalogs or other sources.
- ▶ Increasing the discount off the published average wholesale prices.
- ▶ Basing payment on physician/supplier acquisition costs.

- ▶ Establishing manufacturers' rebates similar to those used in the Medicaid program.
- ▶ Creating a fee schedule for covered drugs based on the Federal Supply Schedule.
- ▶ Using CMS' inherent reasonableness authority.
- ▶ Using competitive bidding.

## **Agency Comments**

The CMS agreed that the amounts being reimbursed for drugs in the Medicare program are excessive, and that it is clear that the payment system for outpatient drugs needs revision. The agency noted that it must find a way to ensure that the program pays appropriately for all Medicare benefits, including covered drugs and the services required to furnish those drugs. The CMS went on to state that they are looking forward to working with the Congress and the OIG to revise the Medicare payment system for prescription drugs.

# TABLE OF CONTENTS

|  | <b>PAGE</b> |
|--|-------------|
| <b>EXECUTIVE SUMMARY</b> .....                             | I           |
| <b>INTRODUCTION</b> .....                                  | 1           |
| <b>FINDINGS</b>  |             |
| Department of Veterans Affairs Costs .....                 | 6           |
| Supplier Acquisition Costs .....                           | 7           |
| Suppliers Reimbursed by Medicare .....                     | 8           |
| <b>RECOMMENDATION</b> .....                                | 9           |
| <b>APPENDICES</b>  |             |
| A. Selected OIG Reports on Drug Reimbursement .....        | 11          |
| B. Calculation of Potential Savings for Albuterol .....    | 12          |
| C. Centers for Medicare & Medicaid Services Comments ..... | 13          |

# INTRODUCTION

---

## PURPOSE

This report compares the amount Medicare reimburses for albuterol to the prices available to the Department of Veterans Affairs (VA) and to acquisition costs for suppliers.

---

## BACKGROUND

### Medicare Coverage of Albuterol

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs that are necessary for the effective use of durable medical equipment. One such product, albuterol, is an inhalation drug commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Albuterol is usually provided to beneficiaries by suppliers, who then submit claims for reimbursement to Medicare. Medicare paid \$296 million for the unit dose form of albuterol in 2000. This total represents over 43 percent of the \$683 million Medicare paid for all inhalation drugs that year. Medicare payments include both the 80 percent that Medicare reimburses and the 20 percent coinsurance payment for which beneficiaries are responsible.

### Medicare Drug Reimbursement

The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, contracts with four durable medical equipment regional carriers to process all claims for durable medical equipment and associated supplies, including inhalation drugs. Each carrier is responsible for determining the reimbursement amount for inhalation drugs in their respective region based on Medicare's reimbursement methodology.

Medicare's current reimbursement methodology for prescription drugs is defined by Section 4556 of the Balanced Budget Act of 1997. The carriers base their reimbursement amount for a covered drug on its average wholesale price as published in *Drug Topics Red Book* or similar pricing publications used by the pharmaceutical industry. If a drug is available only as a single brand-name product, reimbursement is calculated by taking 95 percent of the drug's average wholesale price. For drugs like albuterol that have both brand and generic sources



available, reimbursement is based on 95 percent of the median average wholesale price for generic sources. However, if a brand-name product's average wholesale price is lower than the median generic price, Medicare reimburses 95 percent of the lowest brand price.

## Recent Attempts to Lower Medicare Drug Reimbursement

Section 4316 of the Balanced Budget Act of 1997 allows the Department of Health and Human Services to diverge from Medicare's statutorily defined payment method if the method results in payment amounts which are not inherently reasonable. In late 1998, CMS regional carriers attempted to use this authority to lower what it considered excessive reimbursement for several items. One of these items was albuterol, which was targeted for an 11 percent fee reduction. However, the lower reimbursement amounts were never implemented as Congress suspended the use of inherent reasonableness through a provision of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. This provision required (1) the General Accounting Office (GAO) to complete a study on the potential effects of using inherent reasonableness measures, and (2) the Department of Health and Human Services to publish new inherent reasonableness regulations based on the findings of the GAO report. The GAO report, issued in July 2000, found that inherent reasonableness reductions for some items were justified; however, the GAO questioned the methodology the carriers used in their collection of pricing data for albuterol. The Department has not issued any new inherent reasonableness regulations since the publication of the GAO report.

The CMS has also included albuterol and several other inhalation drugs in a competitive bidding project in the San Antonio, Texas area that uses market forces to set accurate prices for durable medical equipment and related supplies. In November 2000, CMS announced the selection of suppliers who had submitted competitive bids for the included items. New prices for these items went into effect on February 1, 2001. The new reimbursement amount for albuterol set by the competitive bidding process is approximately 32 percent below the usual Medicare price. The CMS hopes to use the results from these demonstrations more generally in the Medicare program.

On May 31, 2000, CMS announced plans for Medicare to utilize newly available average wholesale prices for approximately 50 drugs, including albuterol. The new prices were developed for Medicaid through investigations conducted by the Department of Justice and the National Association of Medicaid Fraud Control Units. The revised pricing data was obtained from wholesale pricing catalogs and then provided to First DataBank, publisher of a pricing compendium used by the pharmaceutical industry. First DataBank agreed to use the new data when reporting average wholesale prices to the States. However, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, enacted by Congress in December 2000, placed a moratorium on any decreases in Medicare drug reimbursement amounts. The Act required GAO to complete a comprehensive study addressing both the appropriateness of drug reimbursement amounts and the adequacy of current payments for related practice expenses. The Department of Health and Human Services must then revise CMS' drug reimbursement methodology based on GAO's recommendations.

The GAO issued the first of two reports addressing drug pricing issues on September 21, 2001. This report found that physicians and suppliers can obtain covered drugs for substantially less than the Medicare reimbursement amount. The GAO concluded that Medicare should revise its drug payment methodology to more closely reflect available market prices. The second report, released October 31, 2001, found that payments made to oncologists relative to their practice expenses are close to the average for all specialties, and that the payments are 8 percent higher under the physician fee schedule than under the previous method that reimbursed based on the charges physicians billed for services. However, the GAO also found that recent modifications to the physician fee schedule substantially lowered payments for certain services, including chemotherapy administration. The GAO recommended changes to improve Medicare's physician payment system.

## **Department of Veterans Affairs Drug Reimbursement**

Unlike Medicare, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. There are several options available to the VA when purchasing drugs, with the most common being the Federal Supply Schedule. The Federal Supply Schedule provides agencies like the VA with a simple process for purchasing commonly used products in any quantity while still obtaining the discounts associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide supplies over a given period of time at the Federal Supply Schedule price. However, the VA is sometimes able to negotiate prices lower than Federal Supply Schedule amounts through other avenues such as blanket purchase agreements and VA national contracts.

## **Cost of Drugs for Suppliers**

Suppliers can purchase drug products through group purchasing organizations, wholesalers, and directly from manufacturers. Group purchasing organizations provide their members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or from a wholesaler who accepts the group purchasing organization's price. Wholesalers purchase large volumes of drugs from manufacturers and sell them directly to suppliers.

## **Related Work by the Office of Inspector General**

The Office of Inspector General (OIG) has studied a number of issues relating to Medicare drug reimbursement. Brief summaries of selected studies are presented in Appendix A.

---

## METHODOLOGY

### Medicare Reimbursement

Medicare classifies drugs using codes in the Healthcare Common Procedure Coding System. These codes, commonly referred to as procedure codes, define the type of drug and, in most cases, a dosage amount. There are currently two procedure codes for albuterol, one for a unit dose solution and another for a concentrated solution. Because nearly all of the billing for albuterol is for the unit dose form of the drug, we only reviewed the reimbursement amounts for the unit dose code. The term “unit dose” refers to a 3 milliliter (ml) solution of 0.083 percent albuterol. The procedure code for the unit dose form of albuterol is J7619. This code is defined as, “albuterol, all formulations including separated isomers, inhalation solution administered through durable medical equipment, unit dose form, per 1 milligram (mg).” We obtained current fee schedule reimbursement amounts for procedure code J7619 from the four durable medical equipment regional carriers. The reimbursement amount for albuterol was the same for each of the four carriers.

We accessed CMS’ National Claims History File to determine Medicare’s total payments for albuterol and other inhalation drugs in 2000. We also used this file to analyze albuterol supplier data for the year 2000.

### Matching Procedure Codes to National Drug Codes

The VA and suppliers use national drug codes rather than procedure codes to identify drug products. Because of these coding differences, we used the April 2001 CD-ROM edition of *Drug Topics Red Book* to identify the specific national drug codes that match the procedure code definition for albuterol. Each drug manufactured or distributed in the United States has a unique national drug code. National drug codes identify the manufacturer of the drug, the product dosage form, and the package size. Because Medicare uses only generic versions of albuterol to determine its reimbursement amount, we only selected generic albuterol national drug codes. We found 19 national drug codes for generic albuterol that matched the procedure code definition of J7619.

The procedure code for the unit dose form of albuterol is reimbursed per mg. However, VA prices and wholesale prices were all based on 3 ml vials of 0.083 percent albuterol solution. Consequently, we needed to convert ml prices of albuterol into mg prices. A 3 ml vial of 0.083 percent albuterol solution contains 2.5 mg of albuterol. Therefore, 1 ml of solution contains 0.833 mg of albuterol (2.5 divided by 3). For each national drug code, we multiplied

the number of milliliters of albuterol solution by 0.833 to determine the milligram amount, e.g., 75 ml of solution multiplied by 0.833 equals 62.5 mg. We then divided the drug price by the number of milligrams to determine a per mg price.

## **Department of Veterans Affairs Prices**

To determine the VA's current costs for albuterol, we obtained a file from the VA website containing their 2001 contracted prices. The VA pricing file contained Federal Supply Schedule prices for 11 of the 19 matching albuterol national drug codes. To determine a single VA price, we calculated the median price per mg for these 11 codes.

We also compared the 2001 VA prices to VA prices in the years 1998 through 2000. We determined the percentage change each year in VA prices, and multiplied this number by the amount Medicare paid in a given year. These figures represent the amount Medicare total payments would have increased or decreased if the Medicare reimbursement amount changed at the same rate as the VA price. In order to estimate this figure for 2001, we assumed that 2001 Medicare payments for albuterol would equal 2000 payments.

## **Prices Available to Suppliers and Wholesalers**

To determine actual wholesale prices for albuterol, we reviewed year 2001 print and online catalogs from four drug wholesalers and two group purchasing organizations. The six pricing sources we used provide drug products to suppliers and physician practices. We then computed a single catalog price for albuterol by calculating the median price per mg of the corresponding national drug codes.

In addition to catalog prices, we also used actual albuterol invoices to determine supplier acquisition costs. The invoices were collected by the OIG during a review of inhalation drug utilization. The invoices were obtained during site visits to suppliers throughout the country, and were for albuterol purchased between June 1998 and August 2000. To determine a single invoice price, we calculated the median price per mg for the 91 invoice prices collected from suppliers.

We also obtained manufacturer-reported wholesale acquisition costs from the April 2001 CD-ROM edition of *Drug Topics Red Book*. The *Drug Topics Red Book* defines wholesale acquisition cost as manufacturer-quoted list prices to wholesale distributors; these prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts. Eleven of the 19 albuterol national drug codes had wholesale acquisition costs

reported in 2001. From these costs, we calculated a median per mg wholesale acquisition cost for albuterol.

## Calculating Potential Medicare Savings

To calculate potential Medicare savings, we compared Medicare's reimbursement amount for 1 mg of albuterol to VA prices, wholesale acquisition costs, catalog prices, and invoice prices. We determined the percentage difference in prices by subtracting the median source price from the Medicare price, and then dividing this number by the Medicare price. These percentages indicate how much Medicare would save if reimbursement for albuterol were based on prices provided by other sources. We then multiplied these percentages by the total amount Medicare paid for albuterol in 2000 to calculate dollar savings. A table showing the data used to calculate potential savings is presented in Appendix B.

---

This inspection was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

# FINDINGS

## Medicare and its beneficiaries would save \$264 million a year if albuterol were reimbursed at the price paid by the VA

### The Medicare reimbursement amount for albuterol is over nine times greater than the median VA price

The median Federal Supply Schedule price available to the VA for generic albuterol is only \$0.05 per mg, compared to \$0.47 per mg for Medicare. We estimate that Medicare and its beneficiaries would save \$264 million a year if reimbursement for albuterol were set at the median amount paid by the VA under the Federal Supply Schedule. The savings represent 89 percent of the \$296 million Medicare paid for albuterol in 2000.

Medicare beneficiaries would receive \$53 million of the \$264 million in savings through reduced coinsurance payments. A Medicare beneficiary using a typical monthly amount of albuterol (250 mg) would pay \$23.50 in Medicare coinsurance. That coinsurance amount is nearly double what the VA would pay outright (\$12.50) to purchase one month's supply of the drug. Table 1 below compares the Medicare reimbursement amount to median prices available through other sources. It also provides Medicare savings and beneficiary coinsurance based on various reimbursement levels.

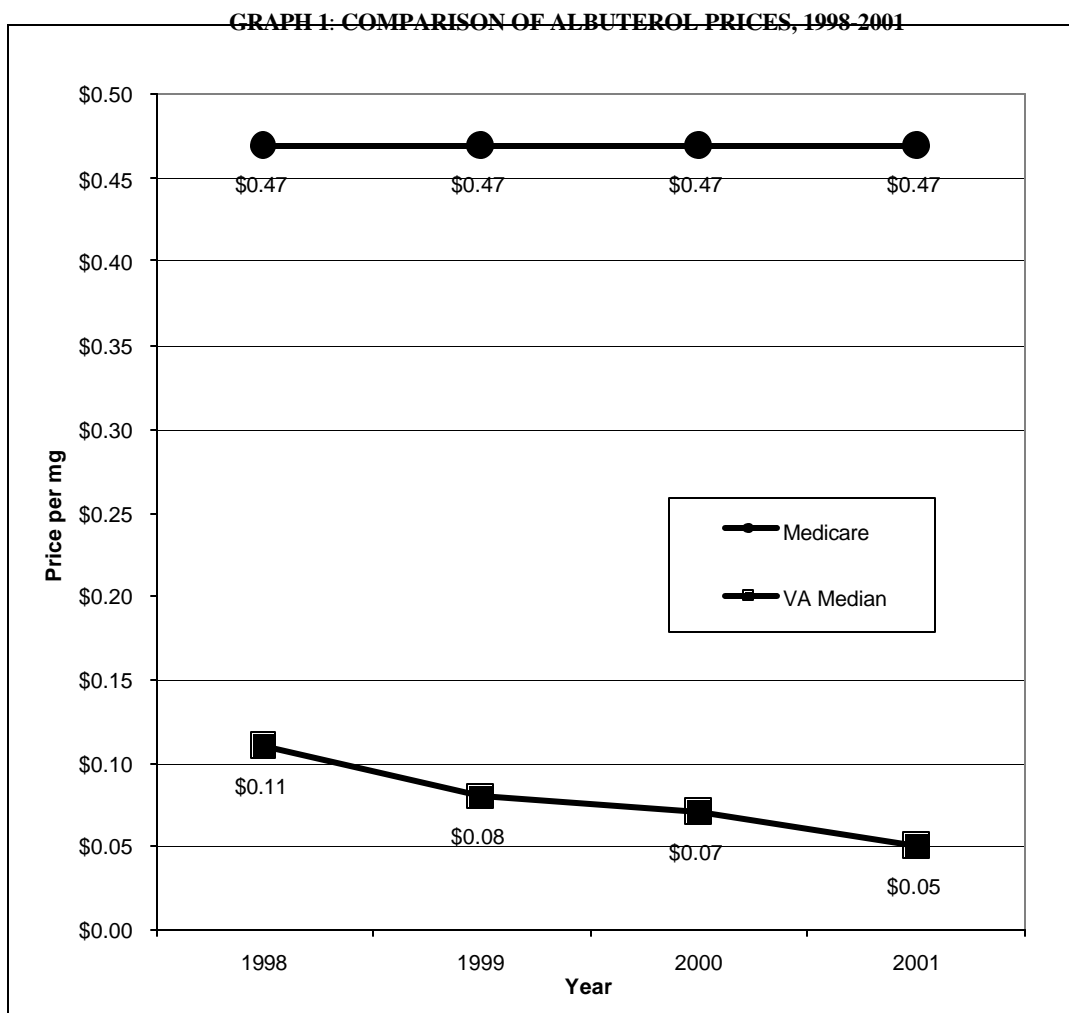
**TABLE 1: COMPARISON OF ALBUTEROL PRICES**

| Pricing Source                 | Median Price per mg | Cost of Typical Individual Monthly Usage (250 mg) | Monthly Medicare Beneficiary Coinsurance Based on Source Price | Potential Annual Medicare and Beneficiary Savings |
|--------------------------------|---------------------|---|--|---|
| Medicare                       | \$0.47              | \$117.50  | \$23.50  | N/A   |
| Department of Veterans Affairs | \$0.05              | \$12.50   | \$2.50   | \$264,222,803                                     |
| Wholesale Catalogs             | \$0.08              | \$20.00   | \$4.00   | \$245,349,746                                     |
| Supplier Invoices              | \$0.09              | \$22.50   | \$4.50   | \$239,058,727                                     |
| Wholesale Acquisition Cost     | \$0.11              | \$27.50   | \$5.50   | \$226,476,689                                     |

Sources: 2001 Medicare Carrier and Department of Veterans Affairs Websites, 2001 Wholesale Catalogs, 1998-2000 Supplier Invoices Collected by OIG, 2001 *Drug Topics Red Book*

**Between 1998 and 2001, the median VA cost for albuterol decreased by over 50 percent, while the Medicare reimbursement amount remained the same**

The VA price for albuterol has fallen by more than 50 percent over the last three years, from \$0.11 per mg in 1998 to \$0.05 per mg in 2001. During the same time period, Medicare's reimbursement amount (based on reported average wholesale prices) has remained constant at \$0.47 per mg. If the Medicare reimbursement amount for albuterol decreased at a rate equal to the VA's purchase price, Medicare and its beneficiaries would have saved \$68 million in 1999 and \$108 million in 2000. The program could save another \$161 million in 2001. The graph below illustrates the changes in VA and Medicare pricing over the last 3 years.



Sources: Medicare Carrier and Department of Veterans Affairs Websites



---

## **Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to wholesalers and suppliers**

### **Medicare payments for albuterol would be reduced by 83 percent if reimbursement amounts were based on prices listed in wholesale catalogs**

Medicare and its beneficiaries would save \$245 million a year if the reimbursement amount for albuterol equaled the median price available to suppliers through wholesalers and group purchasing organizations. This represents 83 percent of the \$296 million Medicare and its beneficiaries reimbursed for the drug in 2000. Catalog prices for generic albuterol ranged from a low of \$0.07 per mg to a high of \$0.15 per mg. The Medicare reimbursement amount (\$0.47 per mg) was nearly six times more than the median catalog price (\$0.08 per mg).

Like VA prices, catalog prices for albuterol have gone down over the last several years. In earlier reports, we found that the average catalog price for albuterol was \$0.23 per mg in 1996, and \$0.13 per mg in 2000. The current catalog price of \$0.08 per mg of albuterol is 65 percent less than the catalog price of the drug five years earlier.

### **Medicare payments for albuterol would be reduced by 81 percent if reimbursement amounts were based on supplier invoice prices**

Invoices reviewed by the OIG listed prices ranging from \$0.08 to \$0.14 per mg for albuterol purchased by suppliers between 1998 and 2000. The median price for albuterol purchased by these suppliers was \$0.09 per mg, 81 percent less than the Medicare reimbursement amount. Medicare and its beneficiaries would save \$239 million a year if albuterol were reimbursed at the median invoice price.

### **Medicare payments for albuterol would be reduced by 77 percent if reimbursement amounts were based on manufacturer-reported wholesale acquisition costs**

Published wholesale acquisition costs for albuterol ranged from \$0.09 to \$0.18 per mg in April 2001. The median wholesale acquisition cost was \$0.11 per mg. Individual drug manufacturers reported these wholesale acquisition costs to *Drug Topics Red Book*. The *Drug Topics Red Book* defines wholesale acquisition cost as manufacturer-quoted list prices

to wholesale distributors, not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

If Medicare based its reimbursement for albuterol on manufacturer-reported wholesale acquisition costs rather than average wholesale prices, the program and its beneficiaries would save \$226 million a year.

---

## **Less than one percent of albuterol suppliers were responsible for providing the majority of the product to Medicare beneficiaries in 2000**

Medicare reimbursed 6,522 suppliers for albuterol claims in 2000. However, just 34 of these suppliers received more than \$1 million each in Medicare reimbursement for albuterol in 2000, with five having between \$11 million and \$35 million in paid claims. These 34 suppliers, who all provided home-delivery/mail-order services to beneficiaries, received 63 percent of the Medicare payments for albuterol in 2000. Therefore, the majority of the albuterol supplied to Medicare beneficiaries was provided by suppliers that purchase a large quantity of the product. We believe that suppliers that purchase albuterol in such large quantities may receive volume discounts from manufacturers and wholesalers.

# RECOMMENDATION

## Medicare should reduce excessive reimbursement amounts for albuterol

Despite numerous attempts by the Centers for Medicare & Medicaid Services (CMS) to lower reimbursement amounts for prescription drugs, the findings of this report illustrate that Medicare still pays too much for albuterol. We have consistently found that the published average wholesale prices currently used by Medicare to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to suppliers and large government purchasers.

We understand that unlike most drugs covered by Medicare, albuterol is usually provided by suppliers rather than administered by physicians. These suppliers obviously need to make a profit from the products they provide, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant. Reimbursement levels for albuterol not only impact the Medicare program, but also affect Medicare beneficiaries who pay increased coinsurance amounts.

We offer the following options for reducing excessive reimbursement amounts for covered drugs:

- ▶ Authorizing a commission to set payment rates.
- ▶ Calculating national estimated acquisition costs based upon the average manufacturer prices reported to the Medicaid program.
- ▶ Collecting more accurate average wholesale prices from drug pricing catalogs or other sources.
- ▶ Increasing the discount off the published average wholesale prices.
- ▶ Basing payment on physician/supplier acquisition costs.
- ▶ Establishing manufacturers' rebates similar to those used in the Medicaid program.
- ▶ Creating a fee schedule for covered drugs based on the Federal Supply Schedule.

- ▶ Using CMS' inherent reasonableness authority.
- ▶ Using competitive bidding.

## Agency Comments

The CMS agreed that the amounts being reimbursed for drugs in the Medicare program are excessive, and that it is clear that the payment system for outpatient drugs needs revision. The agency noted that it must find a way to ensure that the program pays appropriately for all Medicare benefits, including covered drugs and the services required to furnish those drugs. The CMS went on to state that they are looking forward to working with the Congress and the OIG to revise the Medicare payment system for prescription drugs. The full text of CMS' comments is presented in Appendix C.

## Selected OIG Reports on Drug Reimbursement

---

***Medicare Reimbursement of Prescription Drugs (OEI-03-00-00310), January 2001.*** We found that Medicare and its beneficiaries would save \$1.6 billion a year if 24 drugs were reimbursed at amounts available to the VA. We also found that Medicare would save \$761 million a year by paying the actual wholesale price for 24 drugs.

***Medicare Reimbursement of Albuterol (OEI-03-00-00311), June 2000.*** We found that Medicare and its beneficiaries would save \$120 million or \$209 million a year if albuterol was reimbursed at amounts available through Medicaid and the VA, respectively. Medicare and its beneficiaries would save \$47 million or \$115 million a year if Medicare reimbursed albuterol at prices available at chain and Internet pharmacies.

***Comparing Drug Reimbursement: Medicare and the Department of Veterans Affairs (OEI-03-97-00293), November 1998.*** We found that Medicare and its beneficiaries would save \$1 billion in 1998 if the allowed amounts for 34 drugs were equal to prices obtained by the VA. Furthermore, Medicare allowed between 15 and 1600 percent more than the VA for the 34 drugs reviewed.

***Are Medicare Allowances for Albuterol Sulfate Reasonable? (OEI-03-97-00292), August 1998.*** We found that Medicare would allow between 56 to 550 percent more than the VA would pay for generic versions of albuterol sulfate in 1998, and 20 percent more than the average Medicaid payment for albuterol sulfate in 1997. We also found that Medicare allowed 333 percent more than available acquisition costs for the drug in 1998. Customers of mail-order pharmacies would pay up to 30 percent less than Medicare for albuterol sulfate in 1998.

***Excessive Medicare Payments for Prescription Drugs (OEI-03-97-00290), December 1997.*** We found that Medicare allowances for 22 drugs exceeded actual wholesale prices by \$447 million in 1996. For more than one-third of the 22 drugs reviewed, Medicare allowed amounts were more than double the actual wholesale prices available to physicians and suppliers. Furthermore, we found that there was no consistency among Medicare carriers in establishing and updating drug reimbursement amounts.

***A Comparison of Albuterol Sulfate Prices (OEI-03-94-00392), June 1996.*** We found that many of the pharmacies surveyed charged customers less than the Medicare allowed amount for generic albuterol sulfate. The five buying groups surveyed had negotiated prices between 56 and 70 percent lower than Medicare's reimbursement amount for the drug.

***Suppliers' Acquisition Costs for Albuterol Sulfate (OEI-03-94-00393), June 1996.*** We found that Medicare's allowances for albuterol sulfate substantially exceeded suppliers' acquisition costs for the drug. The Medicare program could have saved \$94 million of the \$182 million allowed for albuterol during the 14-month review period if Medicare reimbursement amounts had been based on average supplier invoice costs.

## Calculation of Potential Savings for Albuterol

---

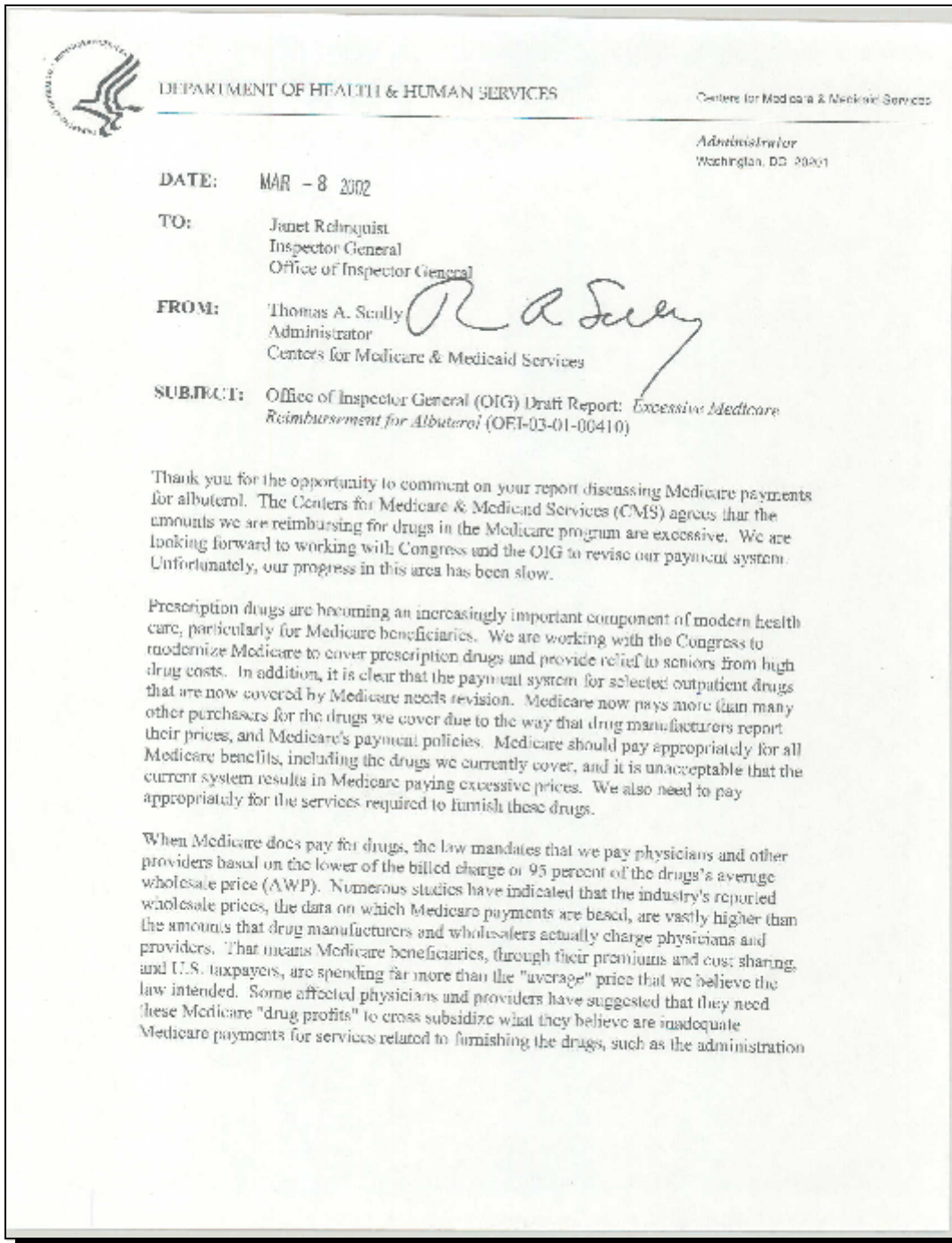
- (1) To determine percentage differences in albuterol prices, we subtracted the source price from the Medicare price. We then divided this number by the Medicare price.
- (2) To calculate potential savings, we multiplied Medicare’s 2000 total payments (\$295,677,899) for albuterol by the percentage difference in price.

| Price Source                   | Range of per mg Prices | Median Price per mg | Medicare Price per mg | Percentage Difference in Price* | Potential Medicare and Beneficiary Savings |
|--------------------------------|------------------------|---------------------|-----------------------|---------------------------------|--|
| Department of Veterans Affairs | \$0.05 to \$0.10       | \$0.05              | \$0.47                | 89.4%                           | \$264,222,803                              |
| Wholesale Catalogs             | \$0.07 to \$0.15       | \$0.08              | \$0.47                | 83.0%                           | \$245,349,746                              |
| Supplier Invoices              | \$0.08 to \$0.14       | \$0.09              | \$0.47                | 80.9%                           | \$239,058,727                              |
| Wholesale Acquisition Cost     | \$0.09 to \$0.18       | \$0.11              | \$0.47                | 76.6%                           | \$226,476,689                              |

\*Percentage rounded to the nearest tenth



**Centers for Medicare & Medicaid Services Comments**



Page 2- Janet Rehnquist

of chemotherapy for cancer. We need to pay appropriately for both the drugs and the services related to furnishing the drugs.

Clearly, Medicare drug pricing is a complex issue. Over the years, numerous legislative efforts have failed to develop an effective alternative to AWP and ensure that Medicare and its beneficiaries do not pay more than they should for the limited number of prescription drugs that Medicare covers. We are committed to working with Congress on a bipartisan basis to ensure that Medicare pays accurately for all of its benefits.

Congress, CMS, and your office have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs. Your office has published numerous reports showing that true market prices for the top drugs billed to the Medicare program by physicians, independent dialysis facilities, and durable medical equipment suppliers were significantly less than the AWP reported in the *Red Book* and like publications. As competitive discounts have become widespread, the AWP mechanism has resulted in increasing payment distortions. However, Medicare has continued to pay for these drugs based on the reported AWP amount. By offering physicians and providers deep discounts, your reports conclude that the drug manufacturers are able to use profit margins to manipulate physicians and providers to use their products for Medicare beneficiaries. It is simply unacceptable for Medicare to continue paying for drugs in a way that results in excessive prices.

In the past, Congress and the Agency has attempted to remedy disparities between Medicare payments based on AWP and the amount actually paid competitively by physicians and providers. However, these efforts have not been successful.

In December 2000, Congress enacted the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Protection Act, which established a moratorium on decreases in the rates of Medicare drug payments, while the General Accounting Office (GAO) conducted a study of Medicare drug pricing and related payment issues. We look forward to reviewing the GAO's findings and working with Congress to revise Medicare's drug payment policy. We must ensure that beneficiaries and Medicare pay appropriately for both the drugs that we cover and the services related to furnishing the drugs.

Medicare beneficiaries rely on prescription drugs, and the coinsurance they pay for covered drugs is tied directly to the prices that Medicare pays. We must find a competitive way to ensure that Medicare beneficiaries and taxpayers are no longer paying excessive prices for drugs that are far above the competitive discounts that are widely available today. We need to pay appropriately for all Medicare benefits, including the prescription drugs we cover and the services required to furnish those drugs.