

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**EXCESSIVE MEDICARE  
REIMBURSEMENT  
FOR IPRATROPIUM BROMIDE**



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# ***OFFICE OF INSPECTOR GENERAL***

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# EXECUTIVE SUMMARY

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## PURPOSE

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

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## 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, ipratropium bromide, is an inhalation drug commonly used with a nebulizer to treat patients suffering from bronchitis or emphysema. Medicare and its beneficiaries paid \$348 million for ipratropium bromide in 2000. 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.

Ipratropium bromide is usually provided to Medicare beneficiaries by suppliers, who then submit claims for reimbursement to Medicare. Suppliers can purchase drugs 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 ipratropium bromide to amounts paid by the VA and acquisition costs for suppliers and wholesalers. We obtained reimbursement amounts for ipratropium bromide 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*.

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## FINDINGS

### **Medicare and its beneficiaries would save \$279 million a year if ipratropium bromide were reimbursed at the median price paid by the VA**

The Medicare reimbursement amount for ipratropium bromide is more than five times greater than the VA price. The VA purchases generic ipratropium bromide through the Federal Supply Schedule for a median price of only \$0.66 per milligram (mg), while Medicare reimburses \$3.34 per mg. We estimate that Medicare and its beneficiaries would save \$279 million a year if reimbursement for ipratropium bromide were set at the median amount available to the VA. Medicare beneficiaries would receive \$56 million of this savings through reduced coinsurance payments. The VA's median acquisition cost for ipratropium bromide through the Federal Supply Schedule has fallen by almost 50 percent over the last three years, from \$1.29 per mg in 1998 to \$0.66 per mg in 2001. During the same time period, Medicare's reimbursement amount has remained constant at \$3.34 per mg.

### **Medicare and its beneficiaries would save between \$223 million and \$262 million a year if ipratropium bromide were reimbursed at prices available to suppliers**

We found that the median catalog price of ipratropium bromide was \$0.82 per mg, the median supplier invoice price was \$1.18 per mg, and the median wholesale acquisition cost reported by manufacturers was \$1.20 per mg. If Medicare based ipratropium bromide reimbursement on these prices, the program and its beneficiaries would save between \$223 million and \$262 million a year.

### **Less than 1 percent of ipratropium bromide suppliers were responsible for providing the majority of the product to Medicare beneficiaries in 2000**

Medicare reimbursed 5,652 pharmaceutical suppliers for ipratropium bromide claims in 2000. However, just 23 suppliers received more than \$2 million each in reimbursement for ipratropium bromide that year, with five suppliers having between \$10 million and \$58 million in paid claims. These 23 suppliers, who all provided home-delivery/mail order services to beneficiaries, received nearly 60 percent of the Medicare payments for ipratropium bromide in 2000. Therefore, the majority of the ipratropium bromide supplied to Medicare beneficiaries was provided by suppliers that purchase a large quantity of the product. We believe that suppliers that purchase such large quantities of ipratropium bromide may receive volume discounts from manufacturers and wholesalers.

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## RECOMMENDATION

### Medicare should reduce excessive reimbursement amounts for ipratropium bromide

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 pays too much for ipratropium bromide. 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, ipratropium bromide 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 ipratropium bromide and the price at which suppliers are able to purchase the drug is significant. Reimbursement levels for ipratropium bromide 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 of 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.

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# INTRODUCTION

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## PURPOSE

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

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## BACKGROUND

### Medicare Coverage of Ipratropium Bromide

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, ipratropium bromide, is an inhalation drug commonly used with a nebulizer to treat patients suffering from chronic bronchitis or emphysema. Ipratropium bromide is usually provided to beneficiaries by suppliers, who then submit claims for reimbursement to Medicare. Medicare and beneficiary payments for ipratropium bromide have risen substantially over the last several years, from \$14 million in 1995 to \$348 million in 2000. Payments for ipratropium bromide accounted for more than half of the \$683 million Medicare paid for all inhalation drugs in 2000. 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 ipratropium bromide 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. 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 other items. The Department has not issued any new inherent reasonableness regulations since the publication of the GAO report.

The CMS has also included ipratropium bromide and several other inhalation drugs in a competitive bidding project in the San Antonio, Texas area that seeks to use market forces to set accurate reimbursement amounts for durable medical equipment and related supplies. In November 2000, CMS announced the selection of durable medical equipment suppliers who had submitted competitive bids for the included items. New reimbursement amounts for these items went into effect on February 1, 2001. The new reimbursement amount for ipratropium bromide set by the competitive bidding process is approximately 24 percent below the usual Medicare amount. 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. 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, to be released before the end of 2001, will address whether Medicare is adequately reimbursing certain Medicare providers for related practice expenses.

## **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.

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## **METHODOLOGY**

### **Medicare Reimbursement**

Medicare classifies drugs using codes in the Healthcare Common Procedure Coding System. These codes, commonly referred to as procedure codes, specify the type of drug, the form of

the drug, and in most cases a dosage amount. The procedure code for ipratropium bromide is J7644, defined as “ipratropium bromide, inhalation solution administered through durable medical equipment, unit dose form, per milligram (mg).” The term “unit dose” refers to a 2.5 milliliter (ml) solution of 0.02 percent ipratropium bromide. We obtained current fee schedule reimbursement amounts for procedure code

J7644 from the four durable medical equipment regional carriers. The reimbursement amount for ipratropium bromide was the same for each of the four carriers.

We accessed CMS’ National Claims History File to determine Medicare’s total payments for ipratropium bromide and other inhalation drugs in 2000. We also used this file to analyze ipratropium bromide 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 ipratropium bromide. 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 ipratropium bromide to determine its reimbursement amount, we only selected generic ipratropium bromide national drug codes. We found 17 national drug codes for generic ipratropium bromide that matched the procedure code definition of J7644.

The procedure code for the unit dose form of ipratropium bromide is reimbursed per mg. However, VA prices and wholesale prices were all based on 2.5 ml vials of 0.02 percent ipratropium bromide solution. Consequently, we needed to convert ml prices of ipratropium bromide into mg prices. A 2.5 ml vial of 0.02 percent ipratropium bromide solution contains 0.5 mg of the drug. Therefore, 1 ml of solution contains 0.2 mg of ipratropium bromide (0.5 divided by 2.5). For each national drug code, we multiplied the number of milliliters of ipratropium bromide solution by 0.2 to determine the milligram amount, e.g., 75 ml of solution multiplied by 0.2 equals 15 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 ipratropium bromide, we obtained a file from the VA website containing their 2001 contracted prices. The VA pricing file contained Federal Supply Schedule prices for 9 of the 17 matching ipratropium bromide national drug codes. To determine a single VA price, we calculated the median price per mg for these 9 codes.

We also compared the 2001 VA prices for ipratropium bromide to VA prices in the years 1998 through 2000. We determined the total percentage change in VA prices between 1998 and subsequent years. We then multiplied these numbers by the amount Medicare paid in a given year. These figures represent the amount Medicare total payments would have differed if the Medicare reimbursement amount changed at the same rate as the VA price. Since 2001 payment data is not yet available, we estimated 2001 Medicare payments by using the dollar amount actually paid for ipratropium bromide in 2000.

## Prices Available to Suppliers and Wholesalers

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

In addition to catalog prices, we also used actual ipratropium bromide 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 ipratropium bromide purchased between June 1998 and June 2000. To determine a single invoice price, we calculated the median price per mg for the 48 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. Five of the 17 ipratropium bromide national drug codes had wholesale acquisition costs reported in 2001. From these costs, we calculated a median per mg wholesale acquisition cost for ipratropium bromide.

## Calculating Potential Medicare Savings

To calculate potential Medicare savings, we compared Medicare's reimbursement amount for 1 mg of ipratropium bromide 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 reimbursement amount, and then dividing this number by the Medicare reimbursement amount. These percentages indicate how much Medicare would save if reimbursement for ipratropium bromide was based on prices provided by other sources. We then multiplied these percentages by the total amount Medicare paid for ipratropium bromide in 2000 to calculate dollar savings. A table showing the data used to calculate potential savings is presented in Appendix B.

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

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# FINDINGS

## Medicare and its beneficiaries would save \$279 million a year if ipratropium bromide were reimbursed at the price paid by the VA

### The Medicare reimbursement amount for ipratropium bromide is over five times greater than the median VA price

The median Federal Supply Schedule price available to the VA for generic ipratropium bromide is only \$0.66 per mg, compared to Medicare’s reimbursement of \$3.34 per mg. We estimate that Medicare and its beneficiaries would save \$279 million a year if reimbursement for ipratropium bromide were set at the median amount paid by the VA under the Federal Supply Schedule. The savings represent 80 percent of the \$348 million Medicare paid for ipratropium bromide in 2000.

Medicare beneficiaries would receive \$56 million of the \$279 million in savings through reduced coinsurance payments. A Medicare beneficiary using a typical monthly amount of ipratropium bromide (50 mg) would pay \$33.40 in Medicare coinsurance. That coinsurance amount is slightly more than what the VA would pay outright (\$33.00) to purchase one month’s supply of the drug. Table 1 below compares the Medicare reimbursement amount to median prices available to the VA. It also provides Medicare savings and beneficiary coinsurance based on Medicare reimbursement and VA prices.

TABLE 1: COMPARING MEDICARE REIMBURSEMENT TO VA PRICES

Pricing Source for Ipratropium Bromide	Median Price per mg	Cost of Typical Individual Monthly Usage (50 mg)	Monthly Medicare Beneficiary Coinsurance Based on Source Price	Potential Annual Medicare and Beneficiary Savings
Medicare	\$3.34	\$167.00	\$33.40	N/A
Department of Veterans Affairs	\$0.66	\$33.00	\$6.60	\$278,854,770

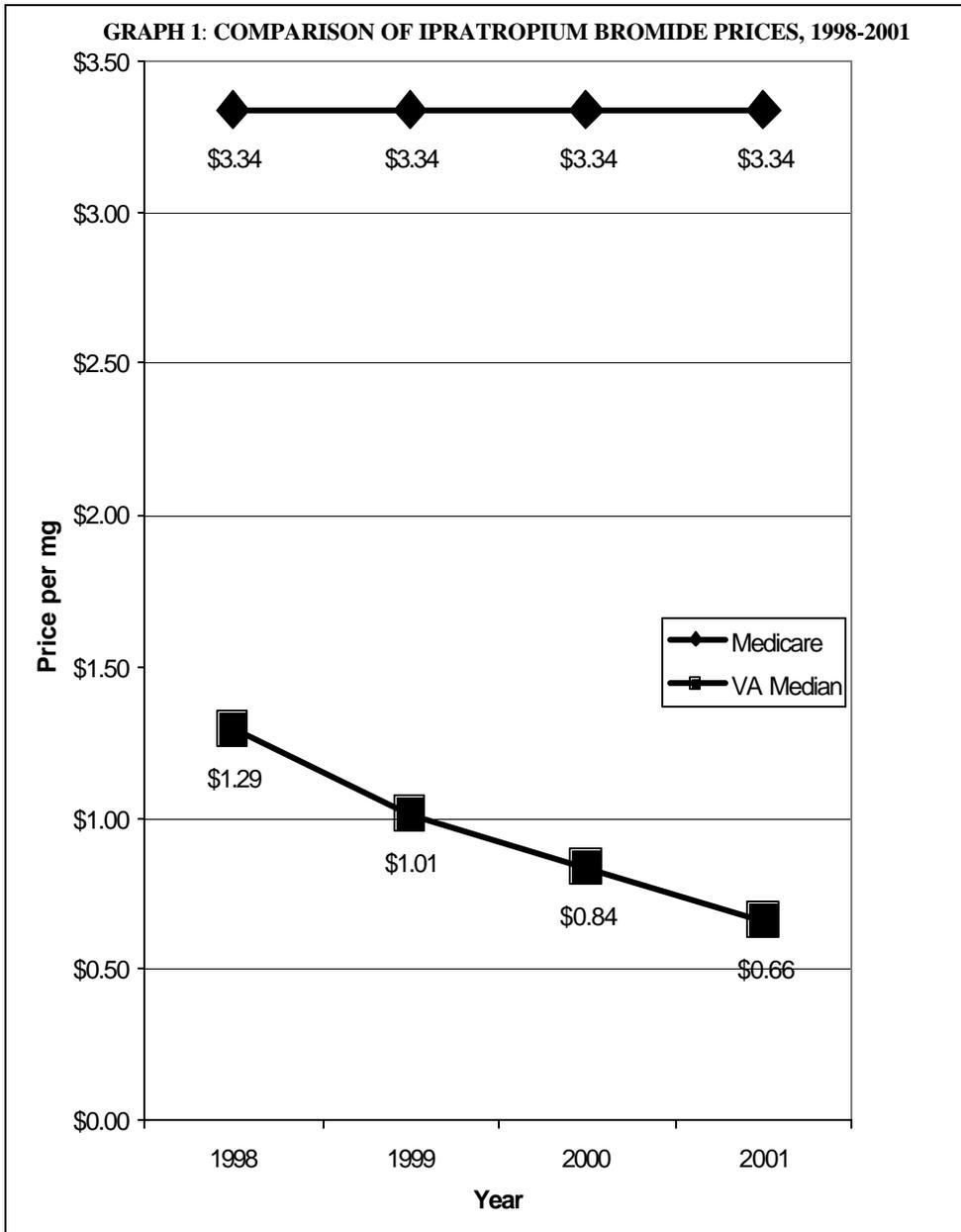
Sources: 2001 Medicare carrier and Department of Veterans Affairs websites

### Between 1998 and 2001, the median VA cost for ipratropium bromide decreased by almost half, while the Medicare reimbursement amount remained the same

The median VA price for generic ipratropium bromide has fallen by almost 50 percent over the last three years, from \$1.29 per mg in 1998 to \$0.66 per mg in 2001. During the same time

period, Medicare's reimbursement amount (based on reported average wholesale prices) has remained constant at \$3.34 per mg. The graph on the next page illustrates the changes in VA and Medicare pricing over the last 3 years. If the Medicare reimbursement amount for ipratropium bromide decreased at a rate equal to the VA's

purchase price, Medicare and its beneficiaries would have saved \$55 million in 1999 and \$121 million in 2000. The program could save \$170 million in 2001.



Sources: Medicare carrier and Department of Veterans Affairs websites

**Medicare and its beneficiaries would save between \$223 million and \$262 million a year if ipratropium bromide were reimbursed at prices available to wholesalers and suppliers**

**Medicare payments for ipratropium bromide would be reduced by 75 percent if reimbursement amounts were based on prices listed in wholesale catalogs**

Medicare and its beneficiaries would save \$262 million a year if the reimbursement amount for ipratropium bromide equaled the median price available to suppliers through wholesalers and group purchasing organizations. This represents 75 percent of the \$348 million Medicare and its beneficiaries paid for the drug in 2000. Catalog prices for generic ipratropium bromide ranged from a low of \$0.64 per mg to a high of \$1.56 per mg. The Medicare reimbursement amount (\$3.34 per mg) was over four times more than the median catalog price (\$0.82 per mg). Table 2 below compares the Medicare reimbursement amount to median prices available to suppliers and wholesalers. It also provides Medicare savings and beneficiary coinsurance based on various sources.

**TABLE 2 : COMPARING MEDICARE REIMBURSEMENT TO SUPPLIER/WHOLESALE PRICES**

<b>Pricing Source for Ipratropium Bromide</b>	<b>Median Price per mg</b>	<b>Cost of Typical Individual Monthly Usage (50 mg)</b>	<b>Monthly Medicare Beneficiary Coinsurance Based on Source Price</b>	<b>Potential Annual Medicare and Beneficiary Savings</b>
Medicare	\$3.34	\$167.00	\$33.40	N/A
Wholesale Catalogs	\$0.82	\$41.00	\$8.20	\$262,206,724
Supplier Invoices	\$1.18	\$59.00	\$11.80	\$224,748,621
Wholesale Acquisition Cost	\$1.20	\$60.00	\$12.00	\$222,667,615

Sources: 2001 Medicare carrier websites, 2001 wholesale catalogs, 1998-2000 supplier invoices, 2001 *Drug Topics Red Book*

**Medicare payments for ipratropium bromide would be reduced by 65 percent if reimbursement amounts were based on supplier invoice prices**

Invoices reviewed by the OIG listed prices ranging from \$0.95 to \$1.46 per mg for ipratropium bromide purchased by suppliers between 1998 and 2000. The median price for ipratropium bromide purchased by these suppliers was \$1.18 per mg, 65 percent less than the Medicare

reimbursement amount. Medicare and its beneficiaries would save \$225 million a year if ipratropium bromide were reimbursed at the median invoice price.

### **Medicare payments for ipratropium bromide would be reduced by 64 percent if reimbursement amounts were based on manufacturer-reported wholesale acquisition costs**

Published wholesale acquisition costs for ipratropium bromide ranged from \$1.12 to \$1.20 per mg in April 2001. The median wholesale acquisition cost was \$1.20 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; these prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts. If Medicare based its reimbursement for ipratropium bromide on manufacturer-reported wholesale acquisition costs rather than average wholesale prices, the program and its beneficiaries would save \$223 million a year.

### **Less than 1 percent of ipratropium bromide suppliers were responsible for providing the majority of the product to Medicare beneficiaries in 2000**

Medicare reimbursed 5,652 pharmaceutical suppliers for ipratropium bromide claims in 2000. However, just 23 suppliers received more than \$2 million each in reimbursement for ipratropium bromide that year, with five suppliers having between \$10 million and \$58 million in paid claims. These 23 suppliers, who all provided home-delivery/mail order services to beneficiaries, received nearly 60 percent of the Medicare payments for ipratropium bromide in 2000. Therefore, the majority of the ipratropium bromide supplied to Medicare beneficiaries was provided by suppliers that purchase a large quantity of the product. We believe that suppliers that purchase such large quantities of ipratropium bromide may receive volume discounts from manufacturers and wholesalers.

# RECOMMENDATION

## Medicare should reduce excessive reimbursement amounts for ipratropium bromide

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, the findings of this report illustrate that Medicare pays too much for ipratropium bromide. 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, ipratropium bromide 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 ipratropium bromide and the price at which suppliers are able to purchase the drug is significant. Reimbursement levels for ipratropium bromide 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 of 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

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***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 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.

## Selected OIG Reports on Drug Reimbursement

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***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 Ipratropium Bromide

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- (1) To determine percentage differences in ipratropium bromide 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 (\$347,527,960) for ipratropium bromide by the percentage difference in price.

<b>Price Source</b>	<b>Range of per mg Prices</b>	<b>Median Price per mg</b>	<b>Medicare Price per mg</b>	<b>Percentage Difference in Price*</b>	<b>Potential Medicare and Beneficiary Savings</b>
Department of Veterans Affairs	\$0.59 to \$0.73	\$0.66	\$3.34	80.2%	\$278,854,770
Wholesale Catalogs	\$0.64 to \$1.56	\$0.82	\$3.34	75.4%	\$262,206,724
Supplier Invoices	\$0.95 to \$1.46	\$1.18	\$3.34	64.7%	\$224,748,621
Wholesale Acquisition Cost	\$1.12 to \$1.20	\$1.20	\$3.34	64.1%	\$222,667,615

\*Percentage rounded to the nearest tenth

# Centers for Medicare and Medicaid Services Comments

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DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services

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OFFICE OF INSPECTOR GENERAL

DATE: MAR 7 2002

TO: Janet Reluquist  
Inspector General  
Office of Inspector General

FROM: Thomas A. Scully  
Administrator  
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Excessive Medicare Reimbursement for Ipratropium Bromide* (OEI-03-01-00411)

Thank you for the opportunity to comment on your report discussing Medicare payments for ipratropium bromide. The Centers for Medicare & Medicaid Services (CMS) agrees that the amounts we are reimbursing for drugs in the Medicare program are excessive. We are looking forward to working with the Congress and the OIG to revise our payment system. Unfortunately, our progress in this area has been slow.

Prescription drugs are becoming an increasingly important component of modern health care, particularly for Medicare beneficiaries. We are working with the Congress to modernize Medicare to cover prescription drugs and provide relief to seniors from high drug costs. In addition, it is clear that the payment system for selected outpatient drugs that are now covered by Medicare needs revision. Medicare now pays more than many other purchasers for the drugs we cover due to the way that drug manufacturers report their prices, and Medicare's payment policies. Medicare should pay appropriately for all Medicare benefits, including the drugs we currently cover, and it is unacceptable that the current system results in Medicare paying excessive prices. We also need to pay appropriately for the services required to furnish these drugs.

When Medicare does pay for drugs, the law mandates that we pay physicians and other providers based on the lower of the billed charge or 95 percent of the drug's average wholesale price (AWP). Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare payments are based, are vastly higher than the amounts that drug manufacturers and wholesalers actually charge physicians and providers. That means Medicare beneficiaries, through their premiums and cost sharing, and U.S. taxpayers, are spending far more than the 'average' price that we believe the law intended. Some affected physicians and providers have suggested that they need these Medicare 'drug profits' to cross-subsidize what they believe are inadequate Medicare payments for services related to furnishing the drugs, such as the administration

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Page 2- Janet Rchnquist

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 to 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 the Congress on a bipartisan basis to ensure that Medicare pays accurately for all of its benefits.

The 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, the 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, the 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 the 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.