

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**A COMPARISON OF  
ALBUTEROL SULFATE PRICES**



**JUNE GIBBS BROWN**  
Inspector General

JUNE 1996  
OEI-03-94-00392

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#### PHILADELPHIA REGIONAL STAFF

Linda M. Ragone, *Project Leader*  
Robert Katz, *Program Analyst*  
Nancy Molyneaux, *Program Analyst*  
Cynthia Hansford, *Program Assistant*

#### HEADQUARTERS STAFF

Mary Beth Clarke, *Program Specialist*

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# EXECUTIVE SUMMARY

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## PURPOSE

To assess the appropriateness of the amount Medicare allows for albuterol sulfate, a prescription inhalation drug used in nebulizers.

## BACKGROUND

A nebulizer is a type of durable medical equipment (DME) through which prescription drugs are administered for inhalation therapy. Patients with conditions such as asthma or emphysema may require treatment that involves the use of a nebulizer. The nebulizer is used by placing an inhalation prescription drug into its reservoir which is then converted into a fine spray by the power source and inhaled by the user.

One prescription drug that is commonly used for inhalation therapy with nebulizers is albuterol sulfate (0.083% concentration). Between January of 1994 and February of 1995, Medicare allowed \$182 million for this drug, 68 percent of the \$269 million in total Medicare allowances for all nebulizer drugs.

We surveyed pharmaceutical buying groups, mail-order pharmacies, and retail pharmacy stores and compared their prices for generic versions of albuterol sulfate to the amount that Medicare allows.

## FINDINGS

*Many pharmacies surveyed charged customers less for generic albuterol sulfate than Medicare allowed.*

A customer would pay less than Medicare for albuterol sulfate in more than half of the retail stores surveyed and in all of the mail-order pharmacies contacted. Fifty-five percent of retail pharmacy stores (60 of 109) charged less for generic versions of albuterol sulfate than the \$0.43 per milliliter that Medicare allowed. Four mail-order pharmacies charged between 2 and 12 percent less than Medicare reimburses, and one charged 53 percent less.

*All five buying groups surveyed had negotiated prices substantially lower than Medicare reimbursement for albuterol sulfate.*

The generic drug prices the five buying groups negotiated ranged from 56 to 70 percent less than the \$0.43 Medicare allowed per milliliter of albuterol sulfate. The pharmacies that are members of these buying groups purchase albuterol sulfate at these lower prices. Therefore, the average wholesale price used to determine

Medicare's allowance for albuterol sulfate was significantly higher than the wholesale price paid by thousands of the buying groups' member pharmacies.

## RECOMMENDATION

We believe the findings of this report complement and reinforce those of our earlier report, *Medicare Payments for Nebulizer Drugs*, by providing evidence that Medicare's allowance for nebulizer drugs may be inappropriately high. In the earlier report, we found that Medicaid State agencies were reimbursing less for albuterol sulfate than Medicare. We have provided evidence in this report that mail-order pharmacies and many retail pharmacy stores charge customers less for generic versions of albuterol sulfate than Medicare allows. Currently, the DMERCs are utilizing the median of average wholesale prices for generic versions of albuterol sulfate to determine the allowance amount. We believe using the median of the published average wholesale prices does not reflect the actual wholesale pricing of albuterol sulfate that is occurring in the marketplace.

We therefore continue to believe that **HCFA should reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments for prescription drugs**, as we recommended in our earlier report.

## AGENCY COMMENTS

The HCFA concurred with our recommendation. In exploring new strategies for changing Medicare's payment for prescription drugs, HCFA has constructed a framework to calculate drug prices centrally. They are also reviewing other approaches that could improve Medicare drug reimbursement. For the complete text of HCFA's comments, see Appendix A.

## OIG RESPONSE

We support HCFA's efforts to revise its drug reimbursement mechanisms to more appropriately pay for prescription drugs covered under the Medicare program. We believe revisions to the current payment methodologies that take into account the actual costs of these drugs would provide significant savings to the Medicare program.

# TABLE OF CONTENTS

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	PAGE
EXECUTIVE SUMMARY .....	i
INTRODUCTION .....	1
FINDINGS .....	4
• Pharmacies' prices were less than Medicare allowances .....	4
• Buying groups negotiated lower prices than Medicare allowed .....	5
RECOMMENDATION .....	7
APPENDIX A: Agency Comments .....	A - 1

# INTRODUCTION

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## PURPOSE

To assess the appropriateness of the amount Medicare allows for albuterol sulfate, a prescription inhalation drug used in nebulizers.

## BACKGROUND

A nebulizer is a type of durable medical equipment (DME) through which prescription drugs are administered for inhalation therapy. It consists essentially of two components: (1) a power source such as an air compressor or ultrasonic device, and (2) a dispensing mechanism consisting of flexible tubing, a mouthpiece, and liquid reservoir. Patients with conditions such as asthma or emphysema may require treatment that involves the use of a nebulizer. The nebulizer is used by placing an inhalation prescription drug into its reservoir which is then converted into a fine spray by the power source and inhaled by the user.

One prescription drug that is commonly used for inhalation therapy with nebulizers is albuterol sulfate (0.083% concentration). Between January of 1994 and February of 1995, Medicare allowed \$182 million for albuterol sulfate (code J7620). This represents 68 percent of the \$269 million in total Medicare allowances for all nebulizer drugs. Medicare allowances for all nebulizer drugs have increased more than 200 percent between 1992 and 1994.

### *Payment of Nebulizer Drugs in the Medicare Program*

Title XVIII of the Social Security Act authorizes coverage of DME under Medicare Part B. Section 2100.5 of the Medicare Carriers Manual specifies instances involving covered uses of outpatient prescription drugs, including drugs used in conjunction with DME. The Manual specifies that drugs are covered under Medicare Part B as long as the drugs are necessary for the effective use of the DME. This includes inhalation drugs used in nebulizers.

According to 42 Code of Federal Regulations 405.517, Medicare computes an allowed amount for drugs based on the lower of the Estimated Acquisition Cost (EAC) or the national Average Wholesale Price (AWP). The allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. If a drug has multiple sources (as does albuterol sulfate), the price is based on the lower of the EAC or the median of the national AWP for all generic sources. The EAC is determined based on surveys of the actual invoice prices paid for the drug. The AWP is determined through *The Red Book* or similar price listings used in the pharmaceutical industry.

The Health Care Financing Administration (HCFA) designated four Durable Medical Equipment Regional Carriers (DMERCs) to process all claims for durable medical

equipment, prosthetics, orthotics, and supplies, including nebulizer drugs. Effective October 1, 1993, the DMERCs replaced the local carriers which had previously processed these claims. Each DMERC is responsible for determining the pricing for albuterol sulfate in their regions based on the computation stated in the regulations.

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

In a recent report entitled, *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390), the OIG found that Medicaid reimbursed albuterol sulfate and other nebulizer drugs at significantly lower prices than Medicare. For albuterol sulfate, Medicare and its beneficiaries paid \$34 million more in 17 States than the amount that Medicaid would have paid. In a related report, *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393), Medicare's allowances for albuterol sulfate were found to substantially exceed suppliers' actual acquisition costs for the drug.

This inspection was conducted as part of Operation Restore Trust (ORT). The initiative, focused in five States, involves multi-disciplinary teams of State and Federal personnel seeking to reduce fraud, waste, and abuse in nursing homes, hospices, home health agencies, and by durable medical equipment suppliers.

### **METHODOLOGY**

For the purposes of comparing pricing information, we collected data from pharmaceutical purchasing organizations or buying groups, mail-order pharmacies, and retail pharmacy stores. We used Medicare's allowed amount for this comparison. The allowed amount includes the 80 percent the Medicare program pays directly to the supplier and the 20 percent copayment for which the beneficiary is responsible.

Since albuterol sulfate (0.083% concentration) is a multiple source drug with both brand and generic versions, the DMERCs base their reimbursement on the lower of the estimated acquisition cost (EAC) or the median of the national average wholesale price (AWP) for all generic sources. At the present time, the four DMERCs base their reimbursement allowance on the AWP for the generic sources of albuterol sulfate. Due to the fact that Medicare uses the prices of generic drugs to compute reimbursement for albuterol sulfate, we compared Medicare's reimbursement amount with the prices that buying groups negotiated or pharmacies charged for the generic versions of albuterol sulfate.

The pricing for albuterol sulfate, during the time of our beginning survey work in April 1995, was \$0.43 per milliliter in three DMERCs and \$0.40 in one DMERC. Since 90 percent of the albuterol sulfate paid for by the DMERCs in 1994 was in the three DMERCs with reimbursement of \$0.43, we believe it is fair to use this single price for comparison purposes. The allowance for albuterol sulfate can be updated on a quarterly basis by the DMERCs. Since the time of our inspection work, one DMERC has increased the allowance amount, one has decreased the allowance amount, and



two remain at \$0.43. We have chosen to use \$0.43 as the Medicare allowance since that was the amount that was in effect at the start of our data collection.

### ***Survey of Buying Groups and Mail-Order Pharmacies***

Using a standardized data collection instrument, we obtained pricing information on albuterol sulfate from buying groups and mail order pharmacies. We surveyed five buying groups which were considered prominent within the industry. The groups ranged in size from 970 to 2500 member stores nationwide. Buying groups negotiate prices for prescription drugs from drug manufacturers/suppliers. Pharmacies that belong to the buying groups are able to purchase drugs based on these negotiated prices. We also selected five of the largest mail-order pharmacies that did not require customers to be a member of a particular insurance plan but would service any eligible person. However, for one of the mail-order pharmacies, the customer had to be a member of a senior citizen organization and the membership fee for joining the organization was factored into the price. We also obtained any additional fees such as shipping and handling or membership fees that might be charged by the mail-order pharmacies. We factored these charges into the prices.

### ***Survey of Retail Pharmacy Stores***

Using a standardized data collection instrument, we contacted retail pharmacy stores in four States to determine their prices for albuterol sulfate. We purposefully selected four States (California, Florida, Missouri, and North Carolina) for which statewide information on pharmacies was available through our Office of Audit Services (OAS). For each State, we randomly selected 35 retail chain pharmacies. Ninety-six percent of the pharmacies in our survey (134 of 140) provided information to us. Seventy-eight percent of the retail pharmacies (109 of 140) provided us with prices for the generic versions of albuterol sulfate.

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

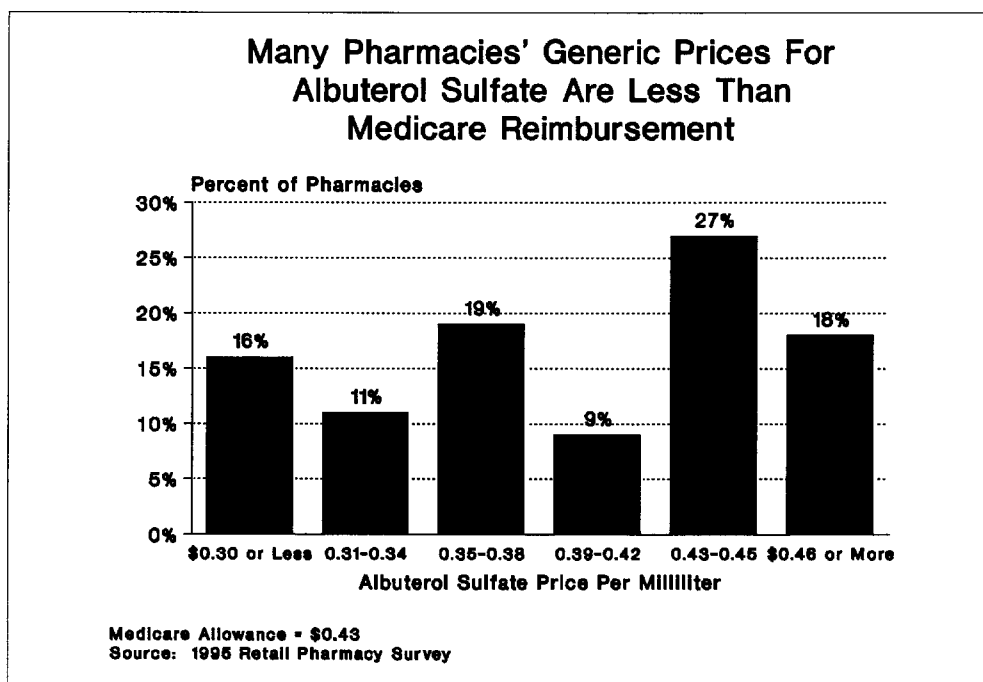
# FINDINGS

## MANY PHARMACIES SURVEYED CHARGED CUSTOMERS LESS FOR GENERIC ALBUTEROL SULFATE THAN MEDICARE ALLOWED.

A customer would pay less than Medicare for albuterol sulfate in more than half of the retail stores surveyed and in all of the mail-order pharmacies contacted.

*More than half of retail pharmacies surveyed charged customers less for generic albuterol sulfate than Medicare allowed.*

Fifty-five percent of retail pharmacy stores (60 of 109) charged less for generic versions of albuterol sulfate than the \$0.43 per milliliter that Medicare allowed. The chart below summarizes the prices that pharmacies charged for albuterol sulfate.



Many of the pharmacies' prices were significantly less than the amounts Medicare and its beneficiaries paid for albuterol sulfate. Sixteen percent of pharmacies charged at least 30 percent less for generic versions of albuterol sulfate than Medicare would have allowed for the same drugs. Eleven percent of pharmacies had prices between 20 and 30 percent less than Medicare. Almost one-fifth of pharmacies (19 percent) charged between 10 and 19 percent less than the Medicare allowance of \$0.43. In addition, more than one-third of pharmacies in our survey (39 percent) provide a further discount to senior citizens purchasing prescription drugs.

***All five mail-order pharmacies charged less than the Medicare allowance for albuterol sulfate.***

All five of the mail-order pharmacies charged their customers less for albuterol sulfate than Medicare and its beneficiaries paid for albuterol sulfate. Four of these pharmacies' charges ranged from \$0.38 to \$0.42, or between 2 to 12 percent less than Medicare allowances per milliliter of drug. One of them charged only \$0.20, or 53 percent less. If a Medicare beneficiary received 375 milliliters of albuterol sulfate per month for inhalation therapy, Medicare and the beneficiary would save anywhere from \$4 to \$87 a month if Medicare based its reimbursement on the prices charged by these mail order companies. The savings to Medicare and its beneficiaries could be even greater since four of the mail-order companies offer lower prices when larger volumes of drugs are purchased. For the example used above of 375 milliliters of albuterol sulfate, these pharmacies would have charged an additional 2 to 20 percent less per milliliter.

***ALL FIVE BUYING GROUPS SURVEYED HAD NEGOTIATED PRICES SUBSTANTIALLY LOWER THAN MEDICARE REIMBURSEMENT FOR ALBUTEROL SULFATE.***

The generic drug prices that five buying groups negotiated ranged from 56 to 70 percent less than the \$0.43 Medicare allowed per milliliter of albuterol sulfate. The thousands of pharmacies that are members of these buying groups purchase albuterol sulfate for the prices listed in the table below. These prices were significantly lower than the average wholesale prices for generic drugs that the DMERCs had been using to establish the pricing for albuterol sulfate.

**Price for Generic Version of Albuterol Sulfate**

Type of Payer	Price per milliliter
Medicare Allowance	\$0.43
Pharmaceutical Buying Groups	\$0.13/\$0.15 <sup>1</sup>
	\$0.16
	\$0.16
	\$0.18
	\$0.18/\$0.19 <sup>1</sup>

<sup>1</sup> Provided prices for more than one manufacturer of generic albuterol sulfate.

The buying groups were able to offer lower drug purchase prices to their member pharmacies because they negotiate prices directly with drug manufacturers/suppliers. The member pharmacy would then purchase the prescription drug at the negotiated price plus a wholesaler upcharge. The upcharge is a percentage of the negotiated price that is applied to their members' purchases. The upcharges that members of

these five buying groups paid ranged from 3 to 6 percent. The prices in the table include these upcharges and thereby represent a pharmacy's total wholesale purchase price for one milliliter of albuterol sulfate. Therefore, the average wholesale price used to determine Medicare's allowance for albuterol sulfate was more than double the wholesale price paid by thousands of the buying groups' member pharmacies.

## RECOMMENDATION

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We believe the findings of this report complement and reinforce those of our earlier report, *Medicare Payments for Nebulizer Drugs*, by providing evidence that Medicare's allowance for nebulizer drugs may be inappropriately high. In the earlier report, we found that Medicaid State agencies were reimbursing less for albuterol sulfate than Medicare. We have provided evidence in this report that mail-order pharmacies and many retail pharmacy stores charge customers less for generic versions of albuterol sulfate than Medicare allows. Currently, the DMERCs are utilizing the median of average wholesale prices for generic versions of albuterol sulfate to determine the allowance amount. We believe using the median of the published average wholesale prices does not reflect the actual wholesale pricing of albuterol sulfate that is occurring in the marketplace.

**We therefore continue to believe that HCFA should reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments for prescription drugs, as we recommended in our earlier report.**

For our readers' convenience, we repeat here the options contained in our prior report for changing Medicare's payment for prescription drugs.

### Discounted Wholesale Price

Many State agencies use a discounted AWP to establish drug prices. Medicare should have a similar option. Medicare could base its drug payment on the lower of a discounted AWP or the median of the AWP for all generic sources, whichever results in the lower cost to Medicare and its beneficiaries. To implement this recommendation, HCFA would have to revise Medicare's claims coding system which does not identify the manufacturer or indicate if the drug is a brand name or a generic equivalent, information that is needed to discount the AWP and obtain a rebate for a specific drug. Medicaid uses the National Drug Code (NDC) in processing drug claims. The NDC identifies the manufacturer and reflects whether the drug is a brand name or a generic equivalent.

### Manufacturers' Rebates

Medicare could develop a legislative proposal to establish a mandated manufacturers' rebate program similar to Medicaid's rebate program. We recognize that HCFA does not have the authority to simply establish a mandated manufacturers' rebate program similar to the program used in Medicaid. Legislation was required to establish the Medicaid rebate program, and would also be required to establish a Medicare rebate program. We have not thoroughly assessed how a Medicare rebate program might operate, what administrative complexities it might pose, or how a Medicare rebate program might differ from a Medicaid rebate program. We believe, however, the legislative effort would be worthwhile. The same manufacturers that provide rebates

to Medicaid make the drugs that are used by Medicare beneficiaries and paid for by the Medicare program.

### Competitive Bidding

Medicare could develop a legislative proposal to allow it to take advantage of its market position. While competitive bidding is not appropriate for every aspect of the Medicare program or in every geographic location, we believe that it can be effective in many instances, including the procurement of drugs. Medicare could ask pharmacies to compete for business to provide Medicare beneficiaries with prescription drugs. All types of pharmacies could compete for Medicare business, including independents, chains, and mail-order pharmacies.

### Inherent Reasonableness

Since Medicare's guidelines for calculating reasonable charges for drugs result in excessive allowances, the Secretary can use her "inherent reasonableness" authority to set special reasonable charge limits. If this option is selected, however, it will not be effective unless the Secretary's authority to reduce inherently unreasonable payment levels is streamlined. The current inherent reasonableness process is resource intensive and time consuming, often taking two to four years to implement. Medicare faces substantial losses in potential savings--certainly in the millions of dollars--if reduced drug prices cannot be placed into effect quickly.

### Acquisition Cost

Medicare could base the payment of drugs on the EAC. The DMERCs currently have this option; however, HCFA has been unsuccessful in gathering the necessary data to fully implement it. Once the problem of gathering the necessary data is overcome, the use of the EAC would result in lower allowed amounts. A variation of this option is to use actual rather than estimated acquisition cost.

## **AGENCY COMMENTS**

The HCFA concurred with our recommendation to reexamine Medicare's drug reimbursement methodologies with a goal of reducing payments. In exploring new strategies for changing Medicare's payment for prescription drugs, HCFA has constructed a framework to calculate drug prices centrally. They have also developed a crosswalk between Medicare's current coding system and the National Drug Codes (NDCs) to enable claims processing using the NDC. In addition, HCFA is examining the use of competitive bidding for nebulizers and associated drugs under its demonstration authority.

The HCFA agreed with our concerns about invoking the inherent reasonableness authority and stated that it appreciated the OIG's work in this area. The HCFA is

currently addressing this issue through the regulatory process. The full text of HCFA's comments are presented in Appendix A.

#### **OIG RESPONSE**

We support HCFA's efforts to revise its drug reimbursement mechanisms to more appropriately pay for prescription drugs covered under the Medicare program. We believe revisions to the current payment methodologies that take into account the actual costs of these drugs would provide significant savings to the Medicare program.

# APPENDIX A

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## AGENCY COMMENTS





The Administrator  
Washington, D.C. 20201

**DATE:** MAY - 3 1996

**TO:** June Gibbs Brown  
Administrator

**FROM:** Bruce C. Vladeck  
Administrator

A handwritten signature in black ink, appearing to read "Bruce C. Vladeck", written over the printed name.

**SUBJECT:** Office of Inspector General (OIG) Working Draft Reports: Appropriateness of Medicare Prescription Drug Allowance”(OEI-03-94-00420), “Supplier Acquisition Costs for Albuterol Sulfate” (OEI-03-94-00393), “A Comparison of Albuterol Sulfate Prices”(OEI-03-94-00392)

We reviewed the subject reports concerning Medicare payments for outpatient prescription drugs. Our detailed comments on the findings and recommendations are attached for your consideration. Thank you for the opportunity to review and comment on the reports.

Attachment

Health Care Financing Administration (HCFA) Comments on  
Office of Inspector General (OIG) Working Draft Reports:  
“Medicare Prescription Drug Allowances.”(OEI-03-94-00420),  
“Supplier Acquisition Costs for Albuterol Sulfate.”  
(OEI-03-94-00393), and “A Comparison of Albuterol Sulfate Prices.”  
(OEI-03-94-00392)

OIG Recommendation

HCFA should reexamine its Medicare drug reimbursement methodologies, with a goal of reducing payments as appropriate.

HCFA Response

We concur. HCFA is examining ways to reduce payments for prescription drugs as follows:

Discounted Wholesale Price

In exploring new strategies for changing Medicare’s payment for prescription drugs, we have constructed a framework to calculate drug prices centrally. Also, we are developing a crosswalk between the current HCFA Common Procedure Coding Systems and the National Drug Code (NDC) to process claims using the NDC.

Manufacturer’s Rebates

While the Administration included a rebate mechanism in its proposed Medicare drug benefit in the Health Care Reform legislation, it is not an option that HCFA is currently considering.

Competitive Bidding

HCFA is exploring the use of competitive bidding for nebulizers and associate drugs under its demonstration authority.

Inherent Reasonableness

We agree and appreciate OIG’s work in this area. HCFA is addressing this issue through the regulatory process. This process has a comment period; therefore, it requires time to implement.

Acquisition Cost

This option involves lowering drug payments by basing them on the estimated acquisition cost. A 1994 survey attempt was made by HCFA to collect the necessary data to fully implement current regulations. The survey was not approved by the Office of Management and Budget because it was found to be too burdensome to pursue due to the large number of physicians and drugs involved.

Technical Comment

We suggest OIG review the proportion of albuterol actually obtained through a pharmacy, as opposed to a pharmacy selling to a durable medical equipment provider who in turn sells to the Medicare patient.