Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Medicare Reimbursement of Albuterol



JUNE GIBBS BROWN Inspector General

JUNE 2000 OEI-03-00-00311

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Philadelphia Regional Office prepared this report under the direction of Robert A. Vito, Regional Inspector General, and Linda M. Ragone, Deputy Regional Inspector General. Principal OEI staff included:

REGION

HEADQUARTERS

David Tawes, *Project Leader*Tara Schmerling, *Program Analyst*

Stuart Wright, *Program Specialist* Linda Moscoe, *Technical Support Staff*

To obtain copies of this report, please call the Philadelphia Regional Office at (800) 531-9562. Reports are also available on the World Wide Web at our home page address:

http://www.dhhs.gov/progorg/oei

EXECUTIVE SUMMARY

PURPOSE

This report compares the amount Medicare reimburses for albuterol with (1) the amounts reimbursed by Medicaid and the Department of Veterans Affairs, and (2) prices available at pharmacies.

BACKGROUND

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs which are necessary for the effective use of durable medical equipment (DME). One such drug, albuterol, is commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Medicare allowed approximately \$246 million for albuterol in 1999.

The Health Care Financing Administration (HCFA) contracts with four DME regional carriers who determine reimbursement amounts for nebulizer drugs. In general, the Medicare reimbursement amount for a covered drug is 95 percent of the drug's average wholesale price (AWP). Of this amount, Medicare pays 80 percent while the beneficiary is responsible for a 20 percent copayment. Each State Medicaid agency has the authority to develop its own drug reimbursement methodology subject to upper limits set by HCFA. Additionally, Medicaid receives rebates from drug manufacturers as required by Federal law. Unlike Medicare and Medicaid, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system 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 obtained reimbursement amounts for albuterol from Medicare, Medicaid, and the VA. We also determined retail prices for albuterol by contacting chain and Internet pharmacies. We compared Medicare's current reimbursement amount for albuterol to amounts reimbursed by Medicaid and the VA, and prices available at pharmacies.

FINDINGS

Medicare and its beneficiaries would save \$120 million or \$209 million a year if albuterol was reimbursed at amounts available through other Federal sources

The Medicare reimbursement amount for albuterol is almost seven times greater than the VA price. The VA purchases generic albuterol through the Federal Supply Schedule for only \$0.07 per milligram (mg), while Medicare reimburses at \$0.47 per mg. We estimate

	1	
Medicare Reimbursement of Albuterol	l	OEI-03-00-00311

that Medicare and its beneficiaries would save \$209 million a year if reimbursement for albuterol was set at the amount available to the VA under the Federal Supply Schedule. Medicare's reimbursement amount for albuterol is almost double Medicaid's upper limit of \$0.24 per mg. We estimate that Medicare and its beneficiaries would save \$120 million if Medicare's reimbursement amount for albuterol equaled Medicaid's upper limit amount.

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

Customers walking into nearly all of the chain pharmacies we contacted would pay less than the Medicare reimbursement amount for albuterol. Prices at these pharmacies ranged from a low of \$0.24 cents per mg to a high of \$0.48 per mg for a single box supply. If Medicare reimbursement was set at the pharmacies' median price of \$0.38 per mg, Medicare and its beneficiaries could save \$47 million a year on albuterol. Some pharmacies offered even lower prices for larger quantity purchases. Prices for albuterol at the Internet pharmacies we visited ranged from \$0.21 to \$0.31 per mg for a single box supply. Medicare would save almost \$115 million a year if its reimbursement amount for albuterol equaled the median Internet pharmacy price of \$0.25 per mg. As with the chain pharmacies, discounts for larger quantity purchases were sometimes available.

RECOMMENDATION

The information in this report adds to the evidence which shows that Medicare pays too much for albuterol. The finding that Medicare pays more than the VA for albuterol is not surprising since the VA acts as a purchaser of drugs while Medicare reimburses suppliers after-the-fact. Even allowing for this difference in payment methods, Medicare's reimbursement amount for albuterol — almost seven times higher than the cost of the drug to the VA — seems excessive. It also seems excessive that Medicare beneficiaries pay more in just monthly copayments for albuterol than the VA pays for a whole month's supply of the drug. Medicaid, which reimburses for drugs in a manner similar to Medicare, has a federally-mandated upper limit for albuterol. The upper limit amount established by HCFA is about half of the Medicare amount. In addition, anyone with a prescription can walk into a retail chain pharmacy or visit an Internet pharmacy and pay a price for albuterol which is usually below the Medicare reimbursement amount. These findings raise serious doubts about the accuracy and efficacy of Medicare's payment policy.

This report found that Medicare would save between \$47 million and \$209 million by lowering its reimbursement amount for albuterol to prices available through other sources. It is important to note that 20 percent of these savings would directly benefit Medicare beneficiaries through reduced copayments.

We continue to support the need for lower albuterol prices for the Medicare program and its beneficiaries. We realize, however, that HCFA's power to lower drug prices through the use of its inherent reasonableness authority was recently limited by a provision of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. In past reports, we recommended a number of other options for lowering albuterol payments. These recommendations included (1) greater discounting of AWPs, (2) basing payments on supplier acquisition costs, (3) establishing manufacturers' rebates, and (4) using competitive bidding. We continue to strongly believe that action needs to be taken to lower unreasonable drug reimbursement amounts.

Agency Comments

The HCFA concurred with our recommendation, noting that basing reimbursement on acquisition cost is probably the best way to ensure that Medicare pays fair prices for covered drugs. Additionally, HCFA gave a detailed account of their numerous attempts to lower unreasonable drug reimbursement amounts in the Medicare program. Currently, HCFA plans to utilize a number of more accurate drug prices developed by First Databank, publisher of a pricing compendium used by the pharmaceutical industry. HCFA requested that Medicare contractors use these prices when calculating their drug reimbursement amounts. The HCFA also commented that they are working to develop a comprehensive electronic file on the pricing of Medicare covered drugs, and are continuing a competitive bidding demonstration project for albuterol in Texas. In addition, HCFA is consulting with the Department of Justice and the Office of Inspector General on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare reimbursement rates. The full text of HCFA's comments is presented in Appendix E.

We commend HCFA's efforts to lower Medicare drug reimbursement rates. We fully support attempts to obtain more accurate prices for the Medicare program. We believe that HCFA's request that Medicare contractors use the more accurate prices supplied by First Databank is a significant first step towards reimbursing drugs in a more appropriate manner.

TABLE OF CONTENTS

PAGE
EXECUTIVE SUMMARY 1
INTRODUCTION5
FINDINGS
Medicare Reimbursement Compared to VA and Medicaid
Medicare Reimbursement Compared to Chain and Internet Pharmacies
RECOMMENDATION
APPENDICES
A. Previous OIG Reports on Albuterol Reimbursement
B. Calculation of Potential Savings for Albuterol
C. Albuterol Prices Available at Chain Pharmacies
D. Albuterol Prices Available at Internet Pharmacies
E. Health Care Financing Administration Comments

INTRODUCTION

PURPOSE

This report compares the amount Medicare reimburses for albuterol with (1) the amounts reimbursed by Medicaid and the Department of Veterans Affairs, and (2) prices available at pharmacies.

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 which are necessary for the effective use of durable medical equipment (DME). One such drug, albuterol, is commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Medicare allowed approximately \$246 million for albuterol in 1999, which represents nearly half of the \$545 million allowed for all nebulizer drugs that year.

Medicare Drug Reimbursement

The Health Care Financing Administration (HCFA), which administers the Medicare program, contracts with four DME regional carriers (DMERCs) to process all claims for durable medical equipment and associated supplies, including nebulizer drugs. Each DMERC is responsible for determining the reimbursement amount for equipment and supplies 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 DMERCs base their reimbursement amount for a covered drug on its average wholesale price (AWP) as published in *Drug Topics Red Book* or similar pricing publications used by the pharmaceutical industry. If a drug is available only in brand form, reimbursement is calculated by taking 95 percent of the drug's AWP. For drugs like albuterol that have both brand and generic sources available, reimbursement is based on 95 percent of the median AWP for generic sources. However, if a brand name product's AWP is lower than the median generic price, Medicare reimburses 95 percent of the lowest brand price.

Section 4316 of the Balanced Budget Act of 1997 allows HCFA to diverge from the statutorily-defined payment method if the method results in payment amounts which are not inherently reasonable. However, HCFA's ability to use its inherent reasonableness authority was recently limited by a provision of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. This provision requires the General

Accounting Office (GAO) to complete a study on the potential effects of using inherent reasonableness measures before HCFA can invoke the authority. The Department of Health and Human Services must then publish a notice of final rule-making concerning inherent reasonableness in the *Federal Register*. This notice must respond to both the GAO study and any comments received on the interim inherent reasonableness regulation. The Act also requires that the Department reevaluate the appropriateness of the criteria used to identify unreasonable payments, and take steps to ensure the use of valid and reliable data when exercising the inherent reasonableness authority.

Medicaid Drug Reimbursement

Each State Medicaid agency has the authority to develop its own drug reimbursement methodology subject to upper limits set by HCFA. Like Medicare, most Medicaid agencies use a discounted AWP as the basis for calculating drug reimbursement amounts. Medicaid agencies generally use a more deeply-discounted AWP than does Medicare. However, HCFA has established a Medicaid upper limit for albuterol. The payments for albuterol and other drugs with Federal upper limits must not exceed, in the aggregate, the established upper limit amounts. The HCFA sets the upper limit for a drug at 150 percent of the lowest price listed in any of the drug pricing compendia.

Additionally, Medicaid receives rebates from drug manufacturers as required by Federal law. In 1999, the quarterly rebate for brand-name drugs was based on either 15.1 percent of the average manufacturer price (AMP) or the difference between the AMP and the best price, whichever was greater. The AMP is the average price paid by wholesalers for products distributed for retail trade. The best price is the lowest price paid by any purchaser with the exception of Federal agencies and State pharmaceutical assistance programs. The rebate amount for generic drugs was 11 percent of AMP.

Department of Veterans Affairs Drug Reimbursement

Unlike Medicare and Medicaid, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system 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.

The Federal Supply Schedule provides agencies like the VA with a simple process for purchasing commonly-used products in various quantities while still obtaining the discounts associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide services and supplies at the Federal Supply Schedule price over a given period of time. Agencies are not required to use the Federal Supply Schedule, however, and are sometimes able to negotiate prices lower than the Federal Supply Schedule price.

Related Work by the Office of Inspector General

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

METHODOLOGY

Medicare Reimbursement Amounts

Medicare identifies covered drugs using codes in HCFA's Common Procedure Coding System (HCPCS). The HCPCS codes define the type of drug and, in most cases, a dosage amount. There are currently two HCPCS 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 solution of 0.083 percent albuterol.

As of January 2000, the HCPCS code for the unit dose form of albuterol is J7619. This code is defined as, "albuterol, inhalation solution administered through DME, unit dose form, per milligram." In 1999, HCPCS code K0505 was used to bill for the unit dose form of albuterol. The HCPCS code definition of K0505 is identical to J7619.

We obtained current fee schedule reimbursement amounts for HCPCS code J7619 from the four DMERCs. The reimbursement amount for albuterol was the same for each of the four DMERCs. For the purpose of this report, Medicare's reimbursement amount includes both the 80 percent Medicare payment and the 20 percent beneficiary copayment.

Matching HCPCS Codes to National Drug Codes

Unlike Medicare, Medicaid and the VA use national drug codes (NDCs) rather than HCPCS codes to identify drugs products. Because of these coding differences, we used the January 2000 CD-ROM edition of *Drug Topics Red Book* to identify the specific NDCs that would match the HCPCS code definition for albuterol. Each drug manufactured or distributed in the United States has a unique NDC. The NDCs identify the manufacturer of the drug, the product dosage form, and the package size. From the NDCs, the drugs can be identified as either brand or generic. Because Medicare uses generic products to determine its reimbursement amount for albuterol, we only selected generic albuterol NDCs. We found 17 NDCs for generic albuterol which matched the HCPCS definition of J7619.

Medicaid Reimbursement Amounts

We obtained from HCFA the Medicaid upper limit amount for albuterol as of April 1, 2000. We also accessed the Medicaid Drug Rebate Initiative system to determine the Medicaid rebate amounts for albuterol. We used the most recent rebate amounts available for each NDC code, which in most cases was the fourth quarter of 1999. Four of the 17 NDCs reviewed did not have any rebate information available. We calculated the median milliliter (ml) rebate amount for the remaining 13 NDCs in order to determine a single Medicaid rebate amount.

VA Pricing

To determine the VA's fourth quarter 1999 costs for albuterol, we obtained a file from the VA containing their contracted prices. The VA pricing file contained Federal Supply Schedule prices for 7 of the 17 matching albuterol NDCs. To determine a single VA price, we calculated the median price per ml for these seven NDCs.

Pharmacy Pricing

We contacted three chain pharmacies in each of eight cities (Atlanta, Boston, Chicago, Dallas, Kansas City, New York, Philadelphia, and San Francisco). We also visited the websites of three Internet pharmacies. Our review of the applicable NDCs indicates that the smallest amount of unit dose albuterol available for purchase is 75 ml, which is usually supplied in one box of twenty-five 3 ml vials. Therefore, we requested that the pharmacies provide their price for this amount of the drug. To determine if there were volume discounts available, we asked for the price of four boxes of albuterol (300 ml), which is a typical monthly usage amount for the drug. We then calculated the median price per ml of a single box supply for both chain and Internet pharmacies.

Conversion of Prices

The HCPCS code for the unit dose form of albuterol, J7619, is reimbursed per milligram (mg). Medicaid's upper limit is based on 1 ml of 0.083 percent albuterol solution. The NDCs used to determine the Medicaid rebates, VA prices, and pharmacy prices were all based on 3 ml vials of 0.083 percent albuterol solution. Consequently, we needed to convert milliliter prices of albuterol into milligram 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). After determining a per ml price for albuterol from each of the sources, we converted this to a per mg price simply by dividing the per ml price by 0.833. For example, by dividing the Medicaid upper limit price of \$0.20 per ml by 0.833, we calculated that the Medicaid upper limit price equals \$0.24 per milligram.

Calculating Potential Medicare Savings

To calculate potential Medicare savings, we compared Medicare's reimbursement amount for albuterol to amounts available at the VA, Medicaid, chain pharmacies, and Internet pharmacies. We determined the percentage difference in prices by subtracting the 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 was based on prices provided by other sources. We then multiplied these percentages by Medicare's 1999 allowed charges for albuterol in order to calculate dollar savings. A table showing the data used to calculate potential savings is presented in Appendix B.

FINDINGS

Medicare and its beneficiaries would save \$120 million or \$209 million a year if albuterol was reimbursed at amounts available through other Federal sources

The Medicare reimbursement amount for albuterol is almost seven times greater than the VA price

The median Federal Supply Schedule price available to the VA for generic albuterol is only \$0.07 per mg, compared to \$0.47 per mg for Medicare. We estimate that Medicare and its beneficiaries would save \$209 million a year if reimbursement for albuterol was set at the amount available to the VA under the Federal Supply Schedule. This savings represents 85 percent of the \$246 million in Medicare allowed charges for albuterol in 1999. A Medicare beneficiary using 250 mg of albuterol per month would pay more in just the Medicare copayment (\$23.50) than the VA would pay (\$17.50) to purchase the drug outright. Table 1 below compares the Medicare reimbursement amount to prices available through other sources. It also provides potential Medicare savings and beneficiary copayments based on various reimbursement levels.

TABLE 1: COMPARISON OF ALBUTEROL PRICES

Pricing Source	Price per mg	Cost of Typical Individual Monthly Usage (250 mg)	Monthly Beneficiary Copayment Based on Source Price	Potential Annual Medicare and Beneficiary Savings
Medicare Reimbursement Amount	\$0.47	\$117.50	\$23.50	N/A
Department of Veterans Affairs Median Cost	\$0.07	\$17.50	\$3.50	\$209,478,193
Medicaid Upper Limit Amount	\$0.24	\$60.00	\$12.00	\$120,449,961
Chain Pharmacy Median Price	\$0.38	\$95.00	\$19.00	\$47,132,593
Internet Pharmacy Median Price	\$0.25	\$62.50	\$12.50	\$115,213,006

The Medicare reimbursement amount for albuterol is nearly twice the Medicaid reimbursement amount

The HCFA has set Medicaid's upper limit for a	lbuterol at \$0.24 per mg, yet Medicare
DMERCs reimburse albuterol at \$0.47 per mg.	We estimate that Medicare and its

Medicare Reimbursement of Albuterol	10	OEI-03-00-00311

beneficiaries would save \$120 million a year if Medicare's reimbursement amount for albuterol equaled Medicaid's upper limit amount. These potential savings represent almost one-half of Medicare allowed charges for albuterol in 1999.

In addition to the lower reimbursement amount, Medicaid also receives a rebate for generic albuterol of approximately \$0.01 per mg. This would create an additional \$5.2 million in savings a year for Medicare.

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

Customers walking into nearly all of the chain pharmacies we contacted would pay less than the Medicare reimbursement amount for albuterol

Twenty-two of the 24 pharmacies we contacted charge customers less than the Medicare reimbursement amount for albuterol. Prices at the 24 chain pharmacies ranged from a low of \$0.25 cents per mg to a high of \$0.48 per mg for a single box supply. Based on the 24 pharmacies' median price of \$0.38 per mg, Medicare and its beneficiaries would save \$47 million a year on albuterol.

Some pharmacies offered even lower prices for larger quantities of the drug. For example, one chain pharmacy offered four boxes of albuterol (a typical monthly supply) for \$35.94, a cost of only \$0.14 per mg. Medicare would have reimbursed \$117.50 for the same amount. If Medicare reimbursed albuterol at \$0.14 per mg, it would save 70 percent of current albuterol payments. The prices for albuterol available at the chain pharmacies we contacted are presented in Appendix C.

Customers purchasing albuterol at Internet pharmacies would pay lower prices than Medicare

Prices for albuterol at the Internet pharmacies we visited ranged from \$0.21 to \$0.31 per mg for a single box supply. Medicare would save almost \$115 million a year if its reimbursement amount for albuterol equaled the median Internet pharmacy price of \$0.25 per mg. As with the chain pharmacies, discounts for larger quantity purchases were sometimes available. The lowest price found for a four-box supply of albuterol was \$41.94, a cost of \$0.17 per mg. If Medicare reimbursed albuterol at \$0.17 per mg, it would save 64 percent of current albuterol payments. The prices for albuterol at each of the Internet pharmacies we contacted are presented in Appendix D.

RECOMMENDATION

The information in this report adds to the evidence which shows that Medicare pays too much for albuterol. The finding that Medicare pays more than the VA for albuterol is not surprising since the VA acts as a purchaser of drugs while Medicare reimburses suppliers after-the-fact. Even allowing for this difference in payment methods, Medicare's reimbursement amount for albuterol — almost seven times higher than the cost of the drug to the VA — seems excessive. It also seems excessive that Medicare beneficiaries pay more in just monthly copayments for albuterol than the VA pays for a whole month's supply of the drug. Medicaid, which reimburses for drugs in a manner similar to Medicare, has a federally-mandated upper limit for albuterol. The upper limit amount established by HCFA is about half of the Medicare amount. In addition, anyone with a prescription can walk into a retail chain pharmacy or visit an Internet pharmacy and pay a price for albuterol which is usually below the Medicare reimbursement amount. These findings raise serious doubts about the accuracy and efficacy of Medicare's payment policy.

This report found that Medicare would save between \$47 million and \$209 million by lowering its reimbursement amount for albuterol to prices available through other sources. It is important to note that 20 percent of these savings would directly benefit Medicare beneficiaries through reduced copayments.

We continue to support the need for lower albuterol prices for the Medicare program and its beneficiaries. We realize, however, that HCFA's power to lower drug prices through the use of its inherent reasonableness authority was recently limited by a provision of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999. In past reports, we recommended a number of other options for lowering albuterol payments. These recommendations included (1) greater discounting of AWPs, (2) basing payments on supplier acquisition costs, (3) establishing manufacturers' rebates, and (4) using competitive bidding. We continue to strongly believe that action needs to be taken to lower unreasonable drug reimbursement amounts.

Agency Comments

The HCFA concurred with our recommendation, noting that basing reimbursement on acquisition cost is probably the best way to ensure that Medicare pays fair prices for covered drugs. Additionally, HCFA gave a detailed account of their numerous attempts to lower unreasonable drug reimbursement amounts in the Medicare program. Currently, HCFA plans to utilize a number of more accurate drug prices developed by First Databank, publisher of a pricing compendium used by the pharmaceutical industry. HCFA requested that Medicare contractors use these prices when calculating their drug reimbursement amounts. The HCFA also commented that they are working to develop a

Medicare Reimbursement of Albuterol	<u> 12</u>	OEI-03-00-00311

comprehensive electronic file on the pricing of Medicare covered drugs, and are continuing a competitive bidding demonstration project for albuterol in Texas. In addition, HCFA is consulting with the Department of Justice and the Office of Inspector General on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare reimbursement rates. The full text of HCFA's comments is presented in Appendix E.

OIG Response

We commend HCFA's efforts to lower Medicare drug reimbursement rates. We fully support attempts to obtain more accurate prices for the Medicare program. We believe that HCFA's request that Medicare contractors use the more accurate prices supplied by First Databank is a significant first step towards reimbursing drugs in a more appropriate manner.

Previous OIG Reports on Albuterol Reimbursement

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.

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.

Medicare Payments for Nebulizer Drugs (OEI-03-94-00390), February 1996. We found that Medicare and its beneficiaries paid about \$37 million more for three nebulizer drugs in 17 States than Medicaid would have paid for equivalent drugs. In addition, we found that the potential savings were not limited to the three nebulizer drugs and 17 states which were reviewed.

Medicare Reimbursement of Albuterol 14 OEI-03-00-00311

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 1999 allowed charges for albuterol by the percentage difference in price.

Price Source	Price per mg	Medicare Price per mg	Percentage Difference in Price*	1999 Medicare Allowed Charges	Potential Medicare and Beneficiary Savings
VA Median Cost	\$0.07	\$0.47	85.1%	\$246,136,877	\$209,478,193
Medicaid Upper Limit Amount	\$0.24	\$0.47	48.9%	\$246,136,877	\$120,449,961
Chain Pharmacy Median Price	\$0.38	\$0.47	19.1%	\$246,136,877	\$47,132,593
Internet Pharmacy Median Price	\$0.25	\$0.47	46.8%	\$246,136,877	\$115,213,006

^{*} Percentage rounded to nearest tenth

Albuterol Prices Available at Chain Pharmacies

City	Pharmacy	Price of 1 Box (75ml)	1 Box per mg Price	Price of 4 Boxes (300 ml)	
Atlanta	CVS	\$22.99	\$0.37	\$91.99	\$0.37
Atlanta	Drug Emporium	\$28.95	\$0.46	\$102.95	\$0.41
Atlanta	Walmart	\$20.54	\$0.33	\$52.68	\$0.21
Boston	CVS	\$29.29	\$0.47	\$117.99	\$0.47
Boston	K Mart	\$27.99	\$0.45	\$86.59	\$0.35
Boston	Walgreens	\$26.99	\$0.43	\$106.89	\$0.43
Chicago	K Mart	\$21.99	\$0.35	\$80.59	\$0.32
Chicago	Osco	\$27.69	\$0.44	\$110.76	\$0.44
Chicago	Walgreens	\$28.19	\$0.45	\$112.76	\$0.45
Dallas	Drug Emporium	\$15.44	\$0.25	\$35.94	\$0.14
Dallas	Walgreens	\$23.89	\$0.38	\$94.99	\$0.38
Dallas	Walmart	\$21.54	\$0.34	\$52.68	\$0.21
Kansas City	K Mart	\$27.99*	\$0.37	\$99.19*	\$0.33
Kansas City	Walgreens	\$23.99	\$0.38	\$95.79	\$0.38
Kansas City	Walmart	\$21.54	\$0.34	\$52.98	\$0.21
New York	CVS	\$22.99	\$0.37	\$91.99	\$0.37
New York	K Mart	\$26.89*	\$0.36	\$98.00*	\$0.33
New York	Walgreens	\$27.39	\$0.44	\$108.69	\$0.43
Philadelphia	Drug Emporium	\$28.95	\$0.46	\$102.95	\$0.41
Philadelphia	Walgreens	\$26.99	\$0.43	\$107.96	\$0.43
Philadelphia	Walmart	\$20.54	\$0.33	\$52.68	\$0.21
San Francisco	Rite Aid	\$21.98	\$0.35	\$57.69	\$0.23
San Francisco	Safeway	\$26.99	\$0.43	\$81.49	\$0.33
San Francisco	Walgreens	\$29.89	\$0.48	\$117.49	\$0.47

^{*} Price of product is for box of 90 ml rather than 75 ml.

Medicare Reimbursement of Albuterol

Albuterol Prices Available at Internet Pharmacies

Pharmacy	Price of 1 Box (75 ml)	1 Box per mg Price	Price of 4 Boxes (300 ml)	
Drugstore.com	\$15.78	\$0.25	\$62.50	\$0.25
Pharmor.com	\$19.29	\$0.31	\$76.89	\$0.31
Planetrx.com	\$13.23	\$0.21	\$41.94	\$0.17

Health Care Financing Administration Comments

In this appendix, we present, in full, comments from the Health Care Financing Administration.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

RECEIVED

TO:

June Gibbs Brown

Inspector General

OFFICE OF INSPECTOR

GENE

JUN | 3 2002000 JUN 15 AM 10: 43

FROM:

Nancy-Ann Min DeParle

Administrator

SUBJECT: Office of Inspector General (OIG) Draft Reports: "Medicare Reimbursement of

End Stage Renal Disease Drugs," (OEI-03-00-00020) and "Medicare

Reimbursement of Albuterol," (OEI-03-00-00311)

Thank you for your recent reports about the Administration's efforts to obtain fair prices for the limited number of drugs that Medicare currently covers and for your efforts to assist us in addressing the need to ensure that both Medicare and Medicaid pay appropriately for prescription drugs.

We have closely monitored the investigations of drug pricing conducted by the Department of Justice, the HHS Inspector General, and the State Medicaid Fraud Control Units (MFCUs). The reports echo our own concerns about the significant discrepancies between the prices that Medicare must pay by law and the significantly lower prices at which physicians may obtain certain drugs. I appreciate the opportunity to explain what we have done and the challenges we face in ensuring that Medicare pays fair prices.

The Health Care Financing Administration (HCFA) has been actively working to address this issue, both legislatively and through administrative actions, for many years. In 1991, the agency issued regulations to pay for these drugs based on the lower of the estimated acquisition cost or the average wholesale price. To implement this policy, HCFA developed a survey to get the necessary information from physicians. However, because of the wide range of drugs used in different amounts at different frequencies by different types of physicians in different geographic areas of the country, we would have had to survey virtually all physicians in order to get a statistically valid estimate of acquisition costs. Because that would have been burdensome and unfeasible, the Administration therefore determined that it would rely instead on the average wholesale price.

Because the estimated acquisition cost approach had proved unworkable, in 1997, the President proposed legislation to pay physicians their actual acquisition costs. Physicians would tell Medicare what they pay for drugs and be reimbursed that amount, rather than the Administration developing an estimate of acquisition costs and basing payment on the estimate. Unfortunately, Congress did not adopt the Administration's proposal. Instead, the Balanced Budget Act reduced Medicare payment for covered drugs from 100 percent to 95 percent of average wholesale price. This recaptures only a fraction of the excessive Medicare payment amounts because, until recently, available average wholesale price data did not correlate to actual wholesale prices for certain Medicare-covered drugs.

Page 2 - June Gibbs Brown

In 1998, the President again proposed paying physicians their actual acquisition cost to "ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients." However, no Congressional action was taken.

Because Congress failed to act on the Administration's 1997 and 1998 proposals, in 1999 and again this year, the President proposed a different legislative approach to achieve a similar result -- paying 83 percent of the average wholesale price instead of the 95 percent allowed by the Balanced Budget Act. We estimate that this would substantially reduce the pricing discrepancy, as well as any administrative burden associated with surveying vast numbers of physicians to estimate acquisition costs. The HCFA actuaries project that this legislative proposal would save Medicare \$2.9 billion over 10 years.

On May 31, 2000, we announced that we are now moving administratively to take advantage of the newly available, more accurate data on average wholesale prices developed for Medicaid as a result of Department of Justice investigations. These data are from catalogs of drug wholesalers, which the Department of Justice says account for a significant portion of the wholesale market. The Department of Justice and MFCUs have compiled data for about 400 national drug codes, representing about 50 different chemical compounds. The Department of Justice provided this information to First Data Bank, a company specializing in the compilation of drug pricing data (formerly known as the "Blue Book") that is used to determine prices paid by State Medicaid programs. These drugs represent about one-third of Medicare spending for drugs.

To obtain the benefits of this new information in Medicare right away, we will provide to Medicare carriers the average of the wholesale catalog prices, as has been calculated by First Data Bank for Medicaid. In June, we will send this information to Medicare carriers so they can use it when they determine average wholesale prices for their next quarterly update of Medicare drug allowances, which will become effective on October 1, 2000. According to the General Counsel at the Department of Health and Human Services, this is the most immediate action we can take without going through the formal rule-making process.

We also are consulting with the Department of Justice and your office on the feasibility of developing additional means to ensure that accurate drug pricing data is used in setting Medicare rates. To monitor carrier activities, we are requiring carriers to send to HCFA, by September 15, 2000, a written explanation of the data sources used for determining payment allowances for these drugs. In addition, we have met with the company that publishes the "Red Book," which is the source of average wholesale price data that most carriers have used to date, to discuss recent developments and the need for accurate data. Furthermore, we are considering whether to change our current legislative proposal for paying 83 percent of average wholesale prices to instead propose paying physicians their actual acquisition costs.

Page 3 - June Gibbs Brown

Based on our recent discussions with the Department of Justice and your office, we believe that the Administration's original approach -- to base Medicare's payment for drugs on the physician's actual acquisition costs -- is probably the most effective means to ensure that Medicare is paying fairly. As part of this effort, we plan to work with physician groups to review the physician's ability to provide acquisition cost data, and to review payment rates for chemotherapy administration to ensure that they are adequate as we reduce payments for the drugs themselves to the prices that physicians pay.

In addition to the proposed legislation and administrative activity discussed above, we are taking several other steps to try to address Medicare drug pricing inequities.

• We are developing an electronic file of prices for Medicare covered drugs, as recommended in your December 1997 report. A contractor has been working on numerous technical issues, including the components necessary for appropriate drug pricing (e.g., route of administration, drug strength concentrations, available package size and most commonly used dosage ranges). We are hopeful that a report on this first phase of the project will be available by this summer.

A report on a second phase of work on issues relating to mapping between codes Medicare currently uses (the HCFA Common Procedure Coding System) and national drug codes, compatibility with the Health Insurance Portability and Accountability Act administrative simplification standards that are being developed, generic and brand name mapping, new drug entries, drug deletions, and updates, is expected by the end of the year. We believe this work will help us ensure that all carriers across the country have access to the most accurate average wholesale price data and will reimburse a uniform allowed amount for each drug code.

- We are using market forces and competition to set fairer prices for one drug -- Albuterol sulfate -- as part of a competitive bidding demonstration for durable medical equipment supplies in Texas. A similar demonstration in Florida, while not including drugs, is saving an average of 17 percent for beneficiaries and Medicare through the bidding process. We hope to be able to use the results from these demonstrations more generally in the Medicare program.
- Finally, we are awaiting a final General Accounting Office report on using the "inherent reasonableness" authority contained in the Balanced Budget Act of 1997. In September 1998, we proposed reducing excessive charges on several items, including Albuterol sulfate. Our contractors who process durable medical equipment claims surveyed retailers in 16 states and found that Medicare was paying substantially more than other payers.

Page 4 - June Gibbs Brown

Congress, however, in the Balanced Budget Refinement Act of 1999, mandated that we not take action to finalize the proposed rule until a GAO study of our use of the inherent reasonableness authority is published. We just received the draft final report from the GAO and look forward to its final report so we can move forward to reduce these payments to reasonable levels.

We have also taken actions to help State Medicaid programs obtain fair prices for drugs.

- We have proposed sharing average manufacturer price data with States so they can
 accurately set Medicaid reimbursement rates. Current law requires drug manufacturers to
 report average manufacturer price data to HHS.
- We have proposed applying the consumer price index-urban (CPI-U) adjustment to generic drugs. Brand name drug manufacturers must pay an additional dollar-for-dollar rebate to Medicaid if they increase prices in excess of CPI-U. But, it is now clear that generic drug prices also sometimes increase faster than inflation.
- We plan to work with all State Medicaid programs regarding First Data Bank's
 announcement that it will revise the way it collects and reports average wholesale price
 data to them, based on information in wholesaler catalogs. This should create immediate
 benefits for all State Medicaid programs.

Finally, as you may know, the President has proposed a voluntary, comprehensive Medicare outpatient drug benefit available to all Medicare beneficiaries. A critical element of this proposal is the use of private pharmacy benefit managers who will negotiate prices with pharmaceutical companies, as they do now for most private insurance plans. This will help keep the benefit affordable without any statutory price setting, and avoid the types of concerns addressed in this response.

Thank you again for your time and effort on these important issues.

Attachment

Comments of the Health Care Financing Administration on the

Office of Inspector General Reports: "Medicare Reimbursement of End State Renal Disease

Drugs," (OEI-03-00-00020) and "Medicare Reimbursement of Albuterol." (OEI-03-00-00311)

OIG Recommended Options

HCFA should examine its Medicare drug reimbursement methodologies with the goal of reducing payments as appropriate. Options include (1) greater discounting of published average wholesale prices, (2) basing payment on acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, and (4) using competitive bidding.

HCFA Response

HCFA concurs with this recommendation and believes that our administrative action is an important step in assuring that Medicare pays fair and accurate prices for currently covered drugs. In addition, we also believe that the Administration's original approach -- to base Medicare's payment for drugs on the physician's actual acquisition costs -- is probably the most effective mean to ensure that Medicare is paying fairly. As part of this effort, we plan to work with the physician groups to review physician's ability to provide acquisition cost data, and to review payment rates for chemotherapy administration to ensure that they are adequate as we reduce payments for the drugs to the prices that physicians pay.