Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PAYMENTS FOR NEBULIZER DRUGS

JUNE GIBBS BROWN
Inspector General

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OEI-03-94-00390

OFFICE OF INSPECTOR GENERAL

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This report was prepared in the Philadelphia Regional Office, under the direction of Thomas J. Robertson, Regional Inspector General for Audit Services, and Robert A. Vito, Regional Inspector General for Evaluation and Inspections. Project Staff included:

Philadelphia Region

David Graf, *Project Leader, OAS*
Robert A. Katz, *Program Analyst*
Cynthia R. Hansford, *Program Assistant*
Neil Montavani, *Intern*

Headquarters

Mary Beth Clarke, *Program Analyst*

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EXECUTIVE SUMMARY

PURPOSE

This report examines differences in the reimbursement methodologies used by the Medicare and Medicaid programs to pay for prescription drugs, focusing on three inhalation drugs used in nebulizers.

BACKGROUND

Medicare does not generally pay for outpatient prescription drugs. However, there are several exceptions to this general rule, including payment for drugs used in conjunction with medical equipment. For such drugs, Medicare computes an allowed amount 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, price is based on the lower of the EAC or the median of the national AWP for all generic sources.

The Medicaid program provides coverage for outpatient prescription drugs as an optional benefit. Currently, all States provide coverage for outpatient prescription drugs. Medicaid payment policies for such drugs vary across States, within guidelines established by the Health Care Financing Administration (HCFA). Many States discount the AWP to set drug prices. The Medicaid program, in addition, uses a rebate program to obtain discounts from pharmaceutical manufacturers.

In this report, we compare Medicare and Medicaid costs in 17 States for three drugs used in conjunction with nebulizers by Medicare beneficiaries from January 1994 through February 1995. A nebulizer is a medical device which administers drugs for inhalation therapy for patients with respiratory conditions such as asthma or emphysema. Medicare allowed amounts (which include 20 percent copayments by beneficiaries) for nebulizer drugs remained relatively stable between 1990 and 1992, never exceeding $74 million. Allowed amounts increased to $170 million in 1993 and $226 million in 1994, more than a 200 percent increase from 1990.

FINDINGS

Medicare and its beneficiaries paid about $37 million more for three nebulizer drugs in 17 States than the amount that Medicaid would have paid for equivalent drugs.

> We found that over $11.7 million of the higher costs are attributable to the method Medicare employs to determine prices paid to drug suppliers, and about $25.3 million is due to the lack of a manufacturers' rebate program, similar to Medicaid's.

Potential Medicare savings are not restricted to the three nebulizer drugs and 17 States reviewed.

Because of inherent differences in the reimbursement methodologies followed by Medicare and Medicaid, the potential cost savings available to Medicare are not, in our opinion, restricted to either the three drugs or the 17 States included in our review. For instance, if Medicare had revised its drug pricing methodology and implemented a manufacturers' rebate program, it and its beneficiaries could have saved about $58 million of the $226 million allowed for nebulizer drugs (excluding administrative costs) in 1994.

Medicare also allowed more than $1 billion for other drugs in 1994. We estimate that Medicare and its beneficiaries could have saved about $83 million for these drugs had Medicare's drug pricing methodology been revised. Furthermore, had there been a drug rebate program in effect, the estimated savings could have increased even more substantially.

RECOMMENDATIONS

We recommend that HCFA reexamine its Medicare drug reimbursement methodologies with a goal of reducing payments as appropriate.

Our study demonstrated that Medicare could have saved millions by discounting the wholesale price and establishing a rebate program. We recognize, however, that other cost saving options are available. One or more of the following options should be aggressively pursued to save Medicare funds and to place this program on par with Medicaid and other payers in obtaining competitive pricing 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 Durable Medical Equipment Regional Carriers (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.

Our work regarding drugs reimbursed by Medicare is continuing. We will explore reasons for the sharp increase in reimbursement for nebulizer drugs that occurred in 1993 and 1994. We will also determine the actual prices drug suppliers pay for nebulizer drugs. Finally, we will examine other drugs Medicare reimburses to ensure that they are properly priced, and to validate our premise that the differences inherent in the reimbursement methodologies of Medicare and Medicaid cause Medicare to pay more for drugs than Medicaid, regardless of the type of drug or where Medicare beneficiaries reside.

AGENCY COMMENTS

The HCFA concurred with our recommendation and is currently examining available options in an effort to make appropriate drug payment reductions. The HCFA expects by early 1996 to reach a decision on whether to proceed with a legislative proposal or to revise current regulations. The full text of HCFA's comments can be found in Appendix B.

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INTRODUCTION

PURPOSE

This report examines differences in the reimbursement methodologies used by the Medicare and Medicaid programs to pay for prescription drugs, focusing on three inhalation drugs 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 respiratory 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.

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. 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.

In June 1992, the Health Care Financing Administration (HCFA) issued a final rule designating 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 more than 50 area carriers which had previously processed DME claims. The geographical areas formerly serviced by the carriers were phased in under the DMERCs on a staggered basis. The DMERCs issue identical coverage policies to ensure consistency in Medicare guidelines. The four DMERCs are:

- MetraHealth in Wilkes-Barre, Pennsylvania (hereafter referred to as DMERC A). This DMERC processes claims for nebulizer drugs for Medicare beneficiaries residing in 10 States.

- AdminaStar Federal Inc. in Indianapolis, Indiana (hereafter referred to as DMERC B). This DMERC processes claims for Medicare beneficiaries in nine States and the District of Columbia.

- Palmetto Government Benefits Administrators in Columbia, South Carolina (hereafter referred to as DMERC C). This DMERC processes claims for Medicare beneficiaries in 14 States, Puerto Rico, and the Virgin Islands.

- Connecticut General Life in Nashville, Tennessee (hereafter referred to as DMERC D). This DMERC processes claims for Medicare beneficiaries in 17 States and three territories.

According to 42 Code of Federal Regulations 405.517, Medicare prices drugs based on the lower of an Estimated Acquisition Cost (EAC) or a national Average Wholesale Price (AWP). The resulting allowed amount is the price that Medicare and its beneficiaries pay a drug supplier. If a drug has multiple sources (as do the three nebulizer drugs included in this review), 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.

Pharmacies or DME suppliers (hereafter referred to as drug suppliers) generally bill Medicare for nebulizer drugs using 20 "J" procedure codes which were implemented in late 1993. The "J" codes identify the product, but not the manufacturer and, therefore, not whether the dispensed drug is a brand-name drug or generic equivalent. Prior to the use of "J" codes, procedure code A4610--defined as "medical supplies"--was used.

According to HCFA Part B data, Medicare allowed amounts[1] for nebulizer drugs remained relatively stable during Calendar Years (CYs) 1990 through 1992, never exceeding about $74 million annually. In CY 1993 the allowed amounts jumped to about $170 million, and rose to about $226 million in CY 1994--an increase of over 200 percent from CY 1990. During the 14-month period of our review--January 1, 1994 through February 28, 1995, the allowed amounts for nebulizer drugs totaled about $269 million.

Medicaid Program

State Medicaid agencies generally reimburse drug suppliers per prescription with the amount of reimbursement varying by drug. Each State agency has the authority to develop its own reimbursement formula for prescription drugs, including recipient copayments, subject to upper payment limits established by HCFA. For the drugs that

[1] The allowed amount represents the total amount of the payment for the drug. Medicare pays 80 percent of the allowed amount and the beneficiaries pay the remaining 20 percent.

we reviewed, the State Medicaid Manual, Section 6305.1 B states that payments for drugs must not exceed, in the aggregate, prices determined by applying the lower of the EAC, plus a reasonable dispensing fee, or the provider's usual and customary charges to the public. Many States also use a discounted AWP to set drug prices.

Drug suppliers bill prescription drugs to the State Medicaid agency using a national drug code (NDC). The NDC identifies the firm that manufactures or distributes the drug along with the drug's characteristics. The NDC also indicates if a drug is a brand name or a generic equivalent. Thus, unlike a State Medicaid agency, a DMERC cannot differentiate between brand and generic drugs.

With the enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), Public Law 101-508, enacted November 5, 1990, pharmaceutical manufacturers are required to enter into and have rebate agreements in effect with all State Medicaid agencies for drugs dispensed to Medicaid recipients. Manufacturers must have a completed rebate agreement in effect for their products to be eligible for inclusion in the Medicaid program. For CY 1994, quarterly rebates for innovator multiple source drugs (that is, brand name drugs) were based on the greater of 15.4 percent of Average Manufacturer Price (AMP)[2] or the difference between the AMP and Best Price.[3] For non-innovator (generic) multiple source drugs, the rebate was 11 percent for CY 1994. The Medicare program does not use rebate agreements to reduce the cost of covered drugs dispensed to Medicare beneficiaries.

Related Work by the Office of Inspector General

We recently issued a report entitled, *Medicare Part B--Reimbursement To Providers For Drugs Used In Conjunction With Durable Medical Equipment* (CIN-A-06-92-00079). In this study, we found that HCFA lacked clear legislative authority to cover self-administered outpatient prescription drugs. Additionally, we concluded there was no assurance that substantial amounts of drugs were properly priced and paid because HCFA did not require carriers to obtain detailed pricing information. We recommended HCFA seek legislation to expressly authorize the coverage of drugs used with DME and implement policies and procedures to ensure that carriers properly price and pay prescription drugs.

METHODOLOGY AND SCOPE

Our objectives for this review were to identify differences in the reimbursement methodologies used by the Medicare and Medicaid programs to pay for prescription

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[2] AMP is the average price paid by wholesalers for products distributed to the retail class or trade.

[3] Best Price is the lowest price paid by any purchaser (exclusive of depot prices and single-award contract prices as defined by any Federal agency) and includes products with special packaging, labeling, or identifiers.

drugs, and to estimate the additional costs incurred by the Medicare program and its beneficiaries for three selected nebulizer drugs. Our review includes Medicare and Medicaid payments for nebulizer drugs for the period January 1, 1994 through February 28, 1995.

We reviewed HCFA's policies and procedures concerning Medicare and Medicaid reimbursement for drugs. We obtained the Medicare information we needed to achieve our objectives from HCFA's National Claims History (NCH) One Percent Sample file and the DMERCs responsible for processing nebulizer drug claims. Using the NCH, we obtained drug claims for 20 "J" codes used for nebulizer drugs. We grouped the claims by "J" code and by the State of beneficiary residence. We then selected the three nebulizer drugs with the highest allowed amounts: (1) Albuterol Sulfate, 0.083%, hereafter referred to as Albuterol Sulfate; (2) Metaproterenol Sulfate, 0.4%; and (3) Metaproterenol Sulfate, 0.6%. Projecting the allowed amounts obtained from the NCH to the universe of nebulizer drugs, we determined that the three selected drugs totaled about $211.7 million, or about 79 percent of the $269 million allowed for all nebulizer drugs. Albuterol Sulfate accounted for $182.3 million of the allowed amounts.

We then selected 17 States[4] (based on the beneficiaries' States of residence) with the highest allowed amounts for nebulizer drugs, and grouped these States under their servicing DMERC, as shown below:

STATES AND SERVICING DMERCs INCLUDED IN REVIEW				
DMERC A	DMERC B	DMERC C		DMERC D
New York	Illinois	Alabama	Louisiana	California
Pennsylvania	Michigan	Arkansas	Mississippi	Missouri
	Ohio	Florida	North Carolina	Washington
		Georgia	Texas	
		Kentucky		

[4] Puerto Rico, Tennessee, and Arizona were originally included in the top States for review. However, reimbursement information was not available for Puerto Rico from HCFA's Medicaid Drug Rebate Initiative (MDRI) system, and Arizona and Tennessee's Medicaid programs are operated by several managed care programs. The MDRI system assists HCFA in monitoring the manufacturers' rebate program. The system calculates rebate amounts for individual drugs, and transmits these amounts to the Medicaid agencies for use in invoicing drug manufacturers. Each managed care program operates independently and sets their own fees and payments. Therefore, Puerto Rico, Tennessee, and Arizona were excluded from our review.

We projected that the Medicare beneficiaries in the 17 selected States accounted for about $146.9 million or about 69 percent of the $211.7 million in allowed amounts for the three nebulizer drugs from January 1, 1994 through February 28, 1995. We obtained actual allowed prices per milliliter (ml) for the three selected nebulizer drugs throughout the period of our review from the DMERCs. We used these prices, which include the beneficiary copayments, in our comparisons to Medicaid.

We obtained the Medicaid information we needed to achieve our objectives from the MDRI system, and from contacts with the 17 State Medicaid agencies concerning their dispensing fees and recipient copayment amounts. We factored the dispensing fees and copayment amounts into our computations of the Medicaid price per ml. For information on how we compared the costs of the three selected nebulizer drugs for the Medicare and Medicaid programs, see Appendix A.

This review is part of Operation Restore Trust, an initiative combining the forces of multiple agencies to combat Medicare and Medicaid fraud, waste, and abuse in California, Florida, Illinois, New York, and Texas. Together, these States account for 40 percent of the nation's Medicare and Medicaid beneficiaries.

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

MEDICARE AND ITS BENEFICIARIES PAID ABOUT $37 MILLION MORE FOR THREE NEBULIZER DRUGS IN 17 STATES THAN THE AMOUNT MEDICAID WOULD HAVE PAID FOR EQUIVALENT DRUGS.

During the period under review, January 1, 1994 through February 28, 1995, Medicare and its beneficiaries paid about $37 million more for three nebulizer drugs in 17 States than the amount Medicaid would have paid for equivalent drugs.

Two significant differences in the drug reimbursement methodologies used by the Medicare and Medicaid programs caused Medicare and its beneficiaries to pay more for the nebulizer drugs. One, Medicare allowed a higher price to drug suppliers for two of the three drugs reviewed because of the manner in which it used the AWP to determine the drug price. This resulted in increased costs to the Medicare program of over $11.7 million. Because Medicare beneficiaries are required to make a copayment of 20 percent for services received under Medicare, beneficiaries also had to absorb a portion of the higher drug prices. Second, Medicare does not have a manufacturers' rebate program similar to Medicaid's. This resulted in increased costs to the Medicare program of about $25.3 million. The following table illustrates the higher costs of the three nebulizer drugs to the Medicare program resulting from differences in the drug reimbursement methodologies.

SUMMARY OF MEDICARE'S HIGHER DRUG COSTS

Nebulizer Drugs Reviewed	Higher Cost of Medicare Drugs Due To:		Total
	Higher Prices Paid to Drug Suppliers	Lack of Manufacturers' Rebate Program	
Albuterol Sulfate	$11,265,556	$22,870,051	$34,135,607
Metaproterenol Sulfate 0.4%	(6,341)	1,614,042	1,607,701
Metaproterenol Sulfate 0.6%	447,731	816,856	1,264,587
Totals	$11,706,946	$25,300,949	$37,007,895
Percentage	32%	68%	100%

Nebulizer drug reimbursements could be reduced by allowing DMERCs the option of basing prices on the lower of either a discounted AWP for the drug dispensed or the median of the AWP for all generic sources.

Medicare and its beneficiaries paid drug suppliers over $11.7 million more than the amount that Medicaid would have paid for equivalent drugs. The higher payments to the drug suppliers were caused by Medicare using the median of the national AWP for all generic sources versus Medicaid's method of discounting the AWP.

The State Medicaid Manual, Section 6305.1 B states that payments for drugs must not exceed, in the aggregate, payment levels determined by applying the lower of the EAC, plus a reasonable dispensing fee, or the provider's usual and customary charges to the public. The Manual further states that in the past many States based the EAC upon the AWP, but that a number of studies have shown that:

> "*...there is a preponderance of evidence that demonstrates that such AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20 percent because they do not reflect discounts, premiums, special offers or incentives, etc. Consequently, without valid documentation to the contrary, a published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by providers.*"

In general, the four DMERCs developed Medicare drug prices using the median AWP for the generic drug equivalent of the drugs being purchased. Thirteen of 17 State Medicaid agencies discounted the AWP an average of 9.6 percent in pricing drugs as suggested by the State Medicaid Manual. Two other State agencies used the Wholesale Acquisition Cost (WAC) plus a percentage of the WAC as the basis for pricing drugs. Only two State Medicaid agencies based drug prices on the AWP. These differences in computing drug prices resulted in Medicare and its beneficiaries paying over $11.7 million more than the 17 State Medicaid agencies included in our review, as shown on the following page.

POTENTIAL MEDICARE SAVINGS BY DMERCs DUE TO PRICE REDUCTION					
Nebulizer Drugs Reviewed	DMERCs				Total
	A	B	C	D	
Albuterol Sulfate	($115,086)	$1,627,822	$8,929,695	$823,125	$11,265,556
Metaproterenol Sulfate, 0.4%	(23,595)	$ 6,750	$ 10,504	0	(6,341)
Metaproterenol Sulfate, 0.6%	(90,432)	$ 41,887	$ 419,539	$ 76,737	447,731
Totals	($229,113)	$1,676,459	$9,359,738	$899,862	$11,706,946

The above table shows that pricing drugs in a manner similar to the 17 State Medicaid agencies would not always result in a savings for each DMERC or for each drug. DMERC A would actually have allowed $229,113 more than its two State Medicaid agency counterparts because both State agencies based their prices on the AWP of the drugs dispensed rather than on a discounted AWP as indicated in the State Medicaid Manual. We also noted that some of the other State Medicaid agencies paid more for Metaproterenol Sulfate, 0.4%, (six State agencies) and Metaproterenol Sulfate, 0.6%, (seven State agencies) primarily because of the number of brand name drugs dispensed (the discounted AWP in these cases was higher than the median of the national AWP for all generic sources).

Because the practice of basing Medicare drug prices on Medicaid drug prices paid to drug suppliers does not always result in a lower price than Medicare's current method of using the median of the national AWP for all generic sources, we believe the optimum approach to revising Medicare's pricing methodology would allow DMERCs the option of using either of the two pricing methods that would result in lower costs to the Medicare program and its beneficiaries. Had this option been available to the four DMERCs, we estimate that Medicare and its beneficiaries could have saved an additional $400,000 bringing the total savings to $12.1 million.

The cost of nebulizer drugs to the Medicare program could be further reduced by establishing a manufacturers' rebate program similar to Medicaid's.

The lack of a manufacturers' rebate program caused Medicare to pay about $25.3 million more for the three drugs than the amount that Medicaid would have paid for equivalent drugs.

We reviewed data contained in the MDRI system for the 17 State Medicaid agencies included in our review. This data is grouped by manufacturer and product code and includes information on the rebate amount per unit, total units dispensed, and total rebate amounts claimed. Using this data, we were able to determine the amount of the rebate per ml that each State agency received for the three nebulizer drugs reviewed. We applied the rebate amount to the number of mls paid for by Medicare. As shown below, all four DMERCs would have reduced their drug costs had a manufacturers' rebate program been in effect for Medicare.

POTENTIAL MEDICARE SAVINGS BY DMERCs DUE TO REBATE PROGRAM

Nebulizer Drugs Reviewed	DMERCs				Total
	A	B	C	D	
Albuterol Sulfate	$1,899,860	$4,060,684	$11,905,347	$5,004,160	$22,870,051
Metaproterenol Sulfate, 0.4%	78,650	8,250	1,527,115	27	1,614,042
Metaproterenol Sulfate, 0.6%	199,426	79,300	412,527	125,603	816,856
Totals	$2,177,936	$4,148,234	$13,844,989	$5,129,790	$25,300,949

POTENTIAL MEDICARE SAVINGS ARE NOT RESTRICTED TO THE THREE NEBULIZER DRUGS AND 17 STATES REVIEWED.

This review showed that Medicare and its beneficiaries paid a net of about $37 million more for three nebulizer drugs than the amount that the 17 State Medicaid agencies would have paid for equivalent drugs because of the manner in which Medicare priced drugs and the absence of a manufacturers' rebate program. Because these two differences are inherent in the reimbursement methodologies followed by Medicare and Medicaid, the potential cost savings available to Medicare are not, in our opinion, restricted to the three drugs or the 17 States included in our review.

For example, 26 State Medicaid agencies not in our review reported that they discount the AWP an average of about 9 percent in determining drug prices. Only three State agencies not in our review reported using the AWP as the basis for determining drug prices. Thus, allowing DMERCs the option of using a discounted AWP like their State Medicaid agency counterparts could result in cost savings in many of the 26 States that base prices on a discounted AWP.

As noted earlier, Medicare allowed about $226 million for the 20 nebulizer drugs in 1994. If Medicare had revised its drug pricing methodology and implemented a manufacturers' rebate program, about $58 million of the $226 million allowed for nebulizer drugs (excluding administrative costs) in 1994 could have been saved.

Medicare also allowed more than $1 billion for other drugs in 1994. We estimate that Medicare and its beneficiaries could have saved about $83 million had Medicare's drug pricing methodology been revised. Furthermore, had there been a drug rebate program in effect, the estimated savings could have increased even more substantially.

RECOMMENDATIONS

We recommend that HCFA reexamine its Medicare drug reimbursement methodologies with a goal of reducing payments as appropriate.

Our report demonstrates that Medicare could have saved millions by discounting the wholesale price and establishing a rebate program. We recognize, however, that other cost saving options are available. One or more of the following options should be aggressively pursued to save Medicare funds and to place this program on par with Medicaid and other payers in obtaining competitive pricing 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 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.

AGENCY COMMENTS

The HCFA concurred with our recommendation and is currently examining available options in an effort to make appropriate drug payment reductions. The HCFA expects by early 1996 to reach a decision on whether to proceed with a legislative proposal or to revise current regulations. The full text of HCFA's comments may be found in Appendix B.

APPENDIX A

COST COMPARISON NOTES

The objectives of this review were to identify differences in the reimbursement methodologies used by the Medicare and Medicaid programs to pay for three nebulizer drugs. In estimating the costs incurred as a result of the different reimbursement methodologies, we considered: (1) the difference in the price of a drug paid to drug suppliers, and (2) manufacturers' rebates received by the State agencies which lower the overall cost of the drug to the Medicaid program. We also computed potential cost savings if: (1) DMERCs had the option of basing the price paid to a drug supplier on a discounted AWP, and (2) a manufacturers' rebate program had been in effect.

We used HCFA's NCH to select the three drugs paid by Medicare, and the 17 States (based on the State where the beneficiaries dispensed the drugs resided) included in this review. The selections were based on allowed amounts. We did not, however, use the allowed amounts on the NCH to determine the drug price per ml paid by the four DMERCs. The allowed amounts on the NCH were high because carriers continued to pay claims as DMERC operations were being phased in. Rather than use the higher prices paid by the carriers in comparing Medicare to Medicaid, we obtained allowed amounts per ml from the DMERCs for each of the selected nebulizer drugs during the period of our review. We used the allowed amounts, which is the price paid by Medicare and its beneficiaries, in making our program comparisons.

To determine the prices paid to drug suppliers by the 17 State Medicaid agencies, we first identified all Medicaid NDCs for the three nebulizer drugs in our review from the 1994 edition of a published national drug compendium (for example, there were 19 NDCs listed in the compendium for Albuterol Sulfate). We then used two basic sources to compute Medicaid drug prices. From the MDRI system, we obtained: (1) the total amount that the 17 State Medicaid agencies reimbursed drug suppliers for each of the three selected nebulizer drugs; (2) total drug mls dispensed for each drug; and (3) total number of prescriptions for each drug. (Typically, nebulizer drugs are dispensed in vials which contain three mls of the product.) From contacts with the State Medicaid agencies, we identified: (1) the dispensing fee per prescription that the State agencies included in their payments to drug suppliers for the period of our review; and (2) copayment amounts that each recipient must pay drug suppliers for nebulizer drugs.

Using this information, we calculated the price that each of the 17 State Medicaid agencies would have paid to drug suppliers for the three nebulizer drugs, as shown below.

1. We recorded the total reimbursable amount paid to drug suppliers by a State agency for a NDC as shown on the MDRI system.

2. We subtracted from the total reimbursable amount the total dispensing fees paid to the drug suppliers. We computed the total dispensing fees by multiplying the number of prescriptions per NDC as shown on the MDRI system by the State Medicaid agency's dispensing fee per prescription. This step was needed to separate the cost of the drug from the professional dispensing fee, both of which were lumped together in the State agency payment to the drug supplier.

3. We added to the total reimbursable amount the total copayments that were the responsibility of the Medicaid recipients. We computed this total by multiplying the number of prescriptions as shown on the MDRI system by the copayment amount provided by each State agency. This step was necessary to arrive at total reimbursable amounts paid to drug suppliers by both the State agencies and the recipients who shared in the payments.

4. We divided total reimbursable amounts paid to drug suppliers as computed above by the total mls dispensed as shown on the MDRI system to arrive at the price paid to drug suppliers per ml. We consider this the total price of the drug per ml paid to the drug supplier by a State Medicaid agency.

We then applied the difference between the Medicare price per ml paid by the four DMERCs and the Medicaid price per ml paid by the 17 State Medicaid agencies to the volume of drugs reimbursed by Medicare, per the NCH. The comparison showed that Medicare paid over $11.7 million more than the amount that the 17 State Medicaid agencies would have paid. In making the above computations, we had pricing data for the entire 14-month period of our review for Medicare, but only 9 months for Medicaid. We, therefore, compared the 9-month Medicaid data against Medicare data for both a 9-month and 14-month period, and used the most conservative results (that is, the lowest Medicare price regardless of the time period).

The actual cost of a drug to the Medicaid program is lessened by quarterly rebates provided by drug manufacturers. To arrive at this cost to the Medicaid program, we subtracted from the total price per ml paid to drug suppliers by a State agency (as computed in step 4 above) the rebate amount per ml as shown in the MDRI system. We then compared this amount to the Medicare price per ml paid to drug suppliers to determine the total amount that Medicare paid in excess of the cost of the drugs to the Medicaid program after the rebate was factored in.

We determined that the Medicare program and its beneficiaries paid about $37 million more for the three nebulizer drugs than the amount that Medicaid would have paid for the drugs. This excess cost could have been avoided had: (1) the four

Comments of the Health Care Financing Administration (HCFA) on Office of Inspector General (OIG) Draft Report "Medicare Payments for Nebulizer Drugs," (OEI-03-94-00390)

OIG Recommendation

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

HCFA Response

We appreciate the list of options furnished by OIG and are currently examining all options available in an effort to make appropriate drug payment reductions. The list of options furnished by OIG focuses on legislative and regulatory changes to our current drug payment policy. We are currently focusing on a number of options and expect to reach a decision early next year on whether to proceed with a legislative proposal or to develop a revision to our current regulations.

Discounted Wholesale Price

We examined ways of reducing payments for many drugs, including nebulizers. As an initial step toward this option, we are developing a crosswalk between the current HCFA common procedure coding system and the National Drug Code (NDC). In the near future, this development will enable HCFA operations to process claims using the NDC, which identifies the drug, manufacturer, and packaging. By using this additional information provided by the NDC, we can reduce drug payments by basing them on the lower of a discounted Average Wholesale Price (AWP) or the median of the AWP for all generic sources.

Manufacturers' Rebates/Competitive Bidding

These options involve proposing legislation to mandate a "Manufacturers' Rebate Program" similar to Medicaid's rebate program and to allow for "competitive bidding." As part of the Medicare drug benefit proposed in the Administration's health care reform bill, we put forward both a manufacturers' rebate program and discounted wholesale pricing. All drugs covered under Medicare Part B would have been affected by these new payment rules. We are currently examining the issues involved in adopting the drug prices available to Medicaid through its rebate program. We are also developing a competitive bidding demonstration for certain durable medical equipment, prosthetics, and orthotics (DMEPOS) including nebulizers and bronchodilator drugs.

Inherent Reasonableness

We agree that the Secretary's authority to make "inherent reasonableness" payment changes for DMEPOS should be simplified. Under current law, only the Secretary can determine whether Medicare payments for DMEPOS are "grossly excessive or deficient" and propose the necessary payment changes. Prior to the Omnibus Budget Reconciliation Act of 1987, Medicare carriers had the authority to propose inherent reasonableness payment changes for DMEPOS. In this regard, we believe that inherent reasonableness authority should be restored to Medicare's

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE

TO June Gibbs Brown
Inspector General

FROM Bruce C. Vladeck
Administrator

SUBJECT Office of Inspector General Draft Report: "Medicare Payments for Nebulizer Drugs," (OEI-03-94-00390)

We reviewed the above-referenced report which examines the differences in the reimbursement methodologies used by the Medicare and Medicaid programs to pay for nebulizer drugs. Attached are our comments on the report recommendation.

Thank you for the opportunity to review and comment on this draft report.

Attachment

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DMERCs been able to adopt the same drug pricing methods as their 17 State Medicaid agency counterparts, and (2) a manufacturers' rebate program been in effect for Medicare.

As shown in this report, however, although Medicaid's pricing methods resulted in a net savings of over $11.7 million, there were instances where Medicare's current method of pricing resulted in a lower price. This had the effect of lowering the potential savings to Medicare. Because of this we recommended that HCFA allow DMERCs the option of using Medicaid's method of discounting the AWP or Medicare's method of using the median of the national AWP for all generic sources, whichever results in the lower cost to Medicare and its beneficiaries.

Had the DMERCs been allowed this option, they could have saved the Medicare program and its beneficiaries $12,136,321 on the price paid to drug suppliers. The increase is due to the fact that whenever the Medicaid price per ml was higher then Medicare's price, we used Medicare's price. This had the effect of increasing the cost savings available to Medicare by $429,375. Adding the cost savings attributed to the manufacturers' rebate program, the total potential cost savings is $37,437,270.

APPENDIX B

HCFA COMMENTS

carriers. Because inherent reasonableness is the only tool we have, HCFA has already started doing the pricing studies necessary to determine if lowering prices of nebulizers is appropriate.

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. The survey was found to be too burdensome to pursue because of the large number of physicians and drugs that would be included. We are currently examining a way to reduce or eliminate the survey burden by using a percentage of the AWP similar to that used by Medicaid.