Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

SUPPLIERS' ACQUISITION COSTS FOR ALBUTEROL SULFATE

JUNE GIBBS BROWN
Inspector General

JUNE 1996
OEI-03-94-00393

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EXECUTIVE SUMMARY

PURPOSE

This report examines suppliers' acquisition costs and Medicare allowances for albuterol sulfate, an inhalation prescription drug used in conjunction with nebulizers.

BACKGROUND

Title XVIII of the Social Security Act prescribes coverage requirements under Part B of the Medicare program. Part B covered items and services include durable medical equipment (DME) as well as certain outpatient prescription drugs. The Health Care Financing Administration (HCFA) administers the Medicare program.

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 durable medical equipment (DME), such as a nebulizer. For such drugs, Medicare computes an allowed amount based on the lower of estimated acquisition costs (EACs) or the median of national average wholesale prices (AWPs).

Medicare allowed amounts for all inhalation drugs remained relatively stable during 1990 through 1992, never exceeding about $78 million annually. In 1993, allowances rose to about $170 million, and climbed to about $227 million in 1994, an increase of almost 200 percent since 1990. During the 14-month period of our review--January 1, 1994 through February 28, 1995--allowances for inhalation drugs totaled approximately $269 million. The subject of this study--albuterol sulfate--accounted for more than $182 million in allowances during the 14-month period.

In this report, we examine Medicare payments for albuterol sulfate compared to suppliers' acquisition costs for the drug. Albuterol sulfate is the most commonly prescribed inhalation drug used for nebulizer therapy. This report is one of a series of Office of Inspector General (OIG) inspections concerning Medicare payments for outpatient prescription drugs in general and inhalation drugs in particular.

FINDINGS

Medicare's allowances for albuterol sulfate substantially exceed suppliers' acquisition costs for the drug.

> Suppliers pay an average cost of $0.19 per milliliter (ml) to purchase albuterol sulfate, while Medicare's allowed amounts ranged from $0.40 per ml to $0.43 per ml during the period of our review. Medicare could have saved $94 million during the 14-month period of our review if albuterol sulfate allowances had been based on the average of supplier invoice costs.

Average supplier costs for albuterol sulfate ranged from $0.14 per ml to $0.23 per ml depending on the purchase source. Suppliers purchasing albuterol sulfate directly from a manufacturer paid the lowest average cost, $0.14 per ml. When purchased from wholesalers, suppliers paid an average of $0.20 per ml. Suppliers purchasing the drug from pharmacies paid the highest average cost, $0.23 per ml. Most of the albuterol sulfate billed to the Medicare program was the generic form of the drug.

RECOMMENDATIONS

The findings of this report indicate that Medicare's allowances for albuterol sulfate substantially exceed suppliers' costs for the drug. During the period of our review, Medicare reimbursed suppliers at allowed amounts ranging from $0.40 to $0.43 per ml of albuterol sulfate. These allowances were based on drug manufacturers' AWPs. Current HCFA regulations allow Medicare reimbursement to be based on the lower of EAC or median AWP. However, HCFA has been unsuccessful in obtaining the data to determine EAC.

We believe our invoice cost analysis further supports the recommendation made in an earlier OIG report entitled *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390). In that report, we suggested various options and recommended that **HCFA should reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments for prescription drugs.** Options included a discounted wholesale price, manufacturers' rebates, competitive bidding, inherent reasonableness, and acquisition cost. For our readers' convenience, we have included the full text of these options in the Recommendation section of this report.

HCFA 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 D.

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.

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INTRODUCTION

PURPOSE

This report examines suppliers' acquisition costs and Medicare allowances for albuterol sulfate, an inhalation prescription drug used in conjunction with nebulizers.

BACKGROUND

Title XVIII of the Social Security Act prescribes coverage requirements under Part B of the Medicare program. Part B covered items and services include durable medical equipment (DME) as well as certain outpatient prescription drugs. The Health Care Financing Administration (HCFA) administers the Medicare program.

Medicare Coverage of Prescription Drugs

Medicare does not generally pay for outpatient prescription drugs. However, there are several exceptions to this general rule. These exceptions are detailed in section 2100.5 of the Medicare Carriers Manual which specifies instances involving covered uses of outpatient prescription drugs, including drugs used in conjunction with DME. The Manual states that drugs are covered under Part B as long as the drugs are necessary for the effective use of the DME.

A nebulizer is a type of 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. 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.

In accordance with HCFA policy, if a beneficiary has a severe respiratory illness or disease, Medicare will pay for certain inhalation drugs that transform a nebulizer into effective therapy for that condition. Medicare guidelines stipulate that the prescribed drug must be used to deliver respiratory therapy, and the nebulizer must be the means to deliver that therapy. If these conditions are met, Medicare will reimburse both the inhalation drug and the nebulizer for as long as the drug is necessary for the effective use of the nebulizer.

According to HCFA Part B data, Medicare allowed amounts for all inhalation drugs remained relatively stable during the years 1990 through 1992, never exceeding about

$78 million annually.[1] In 1993, allowances increased to about $170 million and rose to about $227 million in 1994, an increase of almost 200 percent from 1990. During the 14-month period of our review--January 1, 1994 through February 28, 1995--allowed amounts for inhalation drugs totaled about $269 million.

Albuterol Sulfate Allowances

Albuterol sulfate 0.083%, hereafter referred to as albuterol sulfate, is the most commonly prescribed inhalation drug for nebulizer therapy. Medicare allowances for albuterol sulfate exceeded $182 million during the 14-month period of our review, representing 68 percent of total allowances for all nebulizer drugs.

Medicare determines drug allowances based on the lower of estimated acquisition costs (EAC) or national average wholesale prices (AWP) according to 42 Code of Federal Regulations 405.517. Resulting allowed amounts are the prices that Medicare and its beneficiaries pay drug suppliers or pharmacies. If a drug has multiple sources, like albuterol sulfate, the price is based on the lower of the EAC or the median of national AWPs for all generic sources. Medicare calculates the median AWP using *The Red Book* or similar sources which list the average wholesale prices pharmaceutical companies self-report for their products. An EAC is determined based on surveys of the actual invoice prices suppliers pay for drugs.

Pharmacies or DME suppliers use a drug-specific procedure code, J7620, to claim Medicare reimbursement for albuterol sulfate. This code identifies the product, but not the drug manufacturer. Therefore, it does not indicate whether the dispensed drug is a brand-name drug or generic equivalent.

The HCFA designated four Durable Medical Equipment Regional Carriers (DMERCs) to process all claims for DME, prosthetics, orthotics, and medical supplies, including nebulizer drugs. Effective October 1, 1993, the DMERCs replaced local carriers which had previously processed these claims. Each DMERC determines allowances for albuterol sulfate in its respective region based on the guidelines stated in the regulations. During the scope of our review, DMERC allowances for albuterol sulfate were based on median AWP calculations and ranged from $0.40 to $0.43 per milliliter (ml). Medicare will also pay drug suppliers a monthly dispensing fee of $5 for each drug in addition to the payment for the drug itself.

This study was conducted as part of Operation Restore Trust, an initiative combining the forces of multiple agencies to combat Medicare and Medicaid fraud, waste, and abuse in five States. The five States--California, Florida, Illinois, New York, and Texas--account for 40 percent of the nation's Medicare and Medicaid beneficiaries.

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[1]Office of Inspector General, *Medicare Part B - Reimbursement to Providers for Drugs Used in Conjunction with Durable Medical Equipment*, A-06-92-00079 (Washington, D.C.: U.S. Department of Health and Human Services, 1995), 3.

The initiative centers on services provided by DME suppliers in addition to services provided by nursing homes, hospices, and home health agencies.

Related Work by the Office of Inspector General

This report is one of a series of Office of Inspector General (OIG) inspections concerning Medicare payments for outpatient prescription drugs in general and inhalation drugs in particular. Earlier this year, we released a report entitled *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390). We found that Medicaid reimbursed albuterol sulfate and other nebulizer drugs at significantly lower prices than Medicare. In a related report called *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392), we found that many pharmacies, pharmaceutical buying groups and mail-order pharmacies charged customers less for generic albuterol sulfate than Medicare's allowed reimbursement. A forthcoming report, *Questionable Medicare Payments for Nebulizer Drugs* (OEI-03-94-00391), examines coverage, utilization, and medical necessity issues relating to the use of albuterol sulfate in nebulizers by Medicare beneficiaries.

In an earlier report, *Medicare Part B--Reimbursement to Providers for Drugs used in Conjunction with Durable Medical Equipment* (CIN-A-06-92-00079), we found that HCFA lacked clear legislative authority to cover self-administered outpatient prescription drugs. Additionally, we concluded there was no assurance that drugs were properly priced and paid because HCFA did not require carriers to obtain detailed pricing information. We recommended that 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

We obtained pertinent background information on inhalation drugs used in nebulizers from a wide variety of sources, including HCFA officials, DMERC medical directors and utilization review personnel, medical equipment suppliers, and pharmacies.

Focusing on albuterol sulfate, the inhalation drug most frequently reimbursed under Medicare, we selected a stratified random sample of 485 claims for albuterol sulfate (procedure code J7620) from a HCFA One Percent DME Claims File. Seven strata were designated in the sampling plan: one for each of the five Operation Restore Trust States, Puerto Rico, and a strata comprised of J7620 claims from all other States. Service dates were confined to the 14-month period of our review, January 1, 1994 through February 28, 1995.

We mailed requests for information to the suppliers that billed Medicare for the 485 sampled albuterol sulfate claims. (In this report, we use the term "supplier" to indicate the entity which billed Medicare for providing the nebulizer drug to the beneficiary.) These requests covered a variety of subjects, including (1) supplier business characteristics, (2) how the supplier obtained and delivered the nebulizer

drug to the beneficiary, (3) description of the drug provided, and (4) drug procurement costs and related drug costs. We asked suppliers to submit copies of documents from their files, such as physician prescriptions, invoices showing drug procurement costs, and beneficiary medical information, to support each sampled J7620 claim.

Supplier Response Rates

Suppliers returned completed requests for 418 of the 485 sampled J7620 claims (86 percent response rate). Some respondents did not, however, submit copies of all of the claim-supporting documentation that we requested. We contacted these suppliers by telephone and letter to secure missing documentation. After executing this follow-up plan, we achieved a 47 percent overall response rate for claim-supporting albuterol sulfate invoices. However, invoice response rates varied widely by strata. These strata response rates are presented in Appendix A.

Nonrespondent and Invoice Cost Analyses

As mentioned above, a 47 percent response rate for claim-supporting invoices was achieved. To address the potential bias effects that suppliers who did not provide albuterol sulfate invoices may have had on our cost estimates, we conducted a chi-square analysis of nonrespondents (a statistical method used to test a hypothesis between observed and expected results). Chi-square analysis indicates that there is a significant difference between suppliers who provided invoices and those who did not provide invoices with respect to asset size. Suppliers in our sample possessing assets in excess of $100 million were less likely to submit invoices to support their albuterol sulfate claims. The table in Appendix A shows that only 5 percent of claims billed by suppliers owning assets over $100 million were supported with invoices. In contrast, invoices were submitted for 61 percent of claims billed by suppliers owning assets under $100 million.

Cost estimates were computed based on a sample of claim-supporting invoices for albuterol sulfate submitted by supplier respondents. (Cost estimates and associated confidence intervals appear in Appendix B.) However, our calculations may overestimate average supplier invoice costs. As explained above, there is a relationship in our sample between suppliers' submission of invoices and the size of their assets. We believe large suppliers owning assets over $100 million may be able to use their market power to negotiate low costs for albuterol sulfate with drug manufacturers, wholesale outfits, and pharmacies.

The overall estimate of average supplier cost for albuterol sulfate was applied to a conservative calculation of total albuterol sulfate units reimbursed by Medicare from January 1994 through February 1995. These calculations, presented in Appendix C, illustrate the magnitude of potential program savings if Medicare allowances for albuterol sulfate were based on supplier invoice costs.

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

FINDINGS

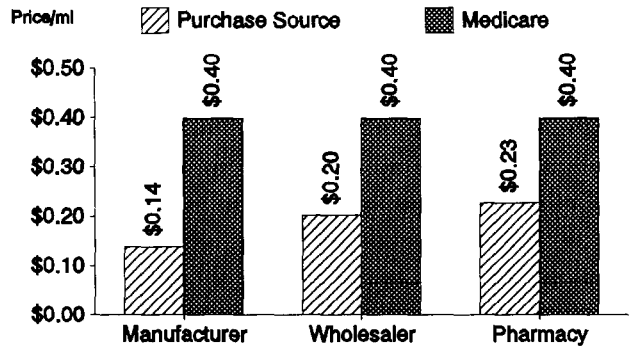
MEDICARE'S ALLOWANCES FOR ALBUTEROL SULFATE SUBSTANTIALLY EXCEED SUPPLIERS' ACQUISITION COSTS FOR THE DRUG.

- ***Suppliers are paying an average cost of $0.19 per ml for albuterol sulfate.***

During the period of our review, January 1994 through February 1995, Medicare allowed amounts for albuterol sulfate ranged from $0.40 per ml to $0.43 per ml. Clearly, nebulizer drug suppliers' acquisition costs for the drug, averaging $0.19 per ml, are significantly lower than Medicare's AWP-based reimbursements. Medicare allowances for albuterol sulfate, based on a median of national AWPs, totaled over $182 million for this period. If HCFA had based its reimbursement for albuterol sulfate on the average of supplier invoice costs, as collected in our survey, the Medicare program could have saved $94 million during the 14-month period of our review. (See Appendix C) Determination of prescription drug allowances based on EAC--requiring surveys of supplier invoices--is one of the methods presently authorized by Medicare reimbursement regulations.

We estimated an overall average supplier cost for albuterol sulfate of $0.19. Respondents submitted three distinct types of claim-supporting invoices for albuterol sulfate: manufacturer invoices, wholesale company invoices, and pharmacy invoices. These invoices reflect three different purchase sources. Therefore, supplier costs for albuterol sulfate varied widely, ranging from a low of $0.12 to a high of $0.41. To address this variability, we calculated average supplier cost estimates by invoice type. The chart below compares cost estimates per ml for each purchase type to Medicare's lowest reimbursement per ml of albuterol sulfate during the sample period.

Supplier Costs Compared to
Medicare Lowest Allowance



- ***When purchased from a drug manufacturer, the average supplier cost per ml of albuterol sulfate was $0.14.***

Thirty-two percent of sampled claims were billed by suppliers who purchased generic albuterol sulfate from a drug manufacturer. In our sample, suppliers' costs paid to the drug manufacturer ranged from $0.12 to $0.17. Medicare's lowest allowance per ml for albuterol sulfate during the sample time frame was $0.40. This allowed amount is almost three times the drug manufacturer invoice price average of $0.14.

- ***The average cost per ml of albuterol sulfate was $0.20 when suppliers purchased the drug from wholesale companies.***

Twenty-three percent of sampled claims were billed by suppliers purchasing the nebulizer drug from wholesalers. While suppliers purchasing from drug manufacturers were able to obtain albuterol sulfate at the most advantageous costs, those paying wholesale costs were reimbursed by the Medicare program at rates at least two times greater than the wholesaler costs estimate.

- ***Suppliers purchasing albuterol sulfate from pharmacies paid an average cost per ml of $0.23.***

Forty-five percent of sampled claims were billed by suppliers who purchased albuterol sulfate from pharmacies. These suppliers received Medicare reimbursements at least 1.8 times greater than the $0.23 pharmacy cost estimate.

Invoices of this type indicate the cost suppliers pay to a pharmacy, not the cost that the pharmacy incurs for the drug. Nebulizer drug suppliers buying albuterol sulfate from pharmacies may be paying for not only the drug, but also the cost of related services provided by pharmacies. These services may include dispensing, packaging and/or shipping the drug to Medicare beneficiaries. Therefore, costs paid by suppliers purchasing the drug from pharmacies were less competitive than those paid to manufacturers and wholesalers.

Only 43 percent of sample claims were billed by suppliers who provided information on their additional costs. Most suppliers did not quantify these other costs per ml of albuterol sulfate. Rather, these suppliers listed general types of additional expenses including sales, billing and support personnel, respiratory therapists, drivers, 24-hour service, home delivery, insurance, and storage. Suppliers also noted expenses such as packaging, labelling, shipping, and delivery of the drug.

- ***Most albuterol sulfate billed to the Medicare program was the generic form of the drug.***

Suppliers submit claims for albuterol sulfate to Medicare under the HCFA Common Procedure Coding System code, J7620. Suppliers bill code J7620 whether the albuterol sulfate they provided to beneficiaries was brand name or generic in form. Our analysis indicates that 90 percent of sampled claims were supported by supplier invoices for generic, non-compounded albuterol sulfate. In contrast, only six percent of sampled claims were supported by supplier invoices for brand name albuterol sulfate.

The remaining four percent of sampled claims were supported by invoices for the ingredients suppliers use to compound albuterol sulfate. Suppliers compound albuterol sulfate on an individual basis from prescribed ingredients. We could not determine unit cost per ml of albuterol sulfate from the compounding ingredient invoices. Therefore, these invoices were not included in the cost analysis.

RECOMMENDATIONS

The findings of this report indicate that Medicare's allowances for albuterol sulfate are excessive compared to suppliers' costs for the drug. During the period of our review, Medicare reimbursed suppliers at allowed amounts ranging from $0.40 to $0.43 per ml of albuterol sulfate. These allowances were based on drug manufacturer AWPs. Current HCFA regulations allow Medicare reimbursement to be based on the lower of EAC or median AWP. However, HCFA has been unsuccessful in gathering the data to determine EAC.

If the HCFA had based its reimbursement for albuterol sulfate on the average of supplier invoice costs, as illustrated in this report, the Medicare program could have saved $94 million during the 14-month period of our review. Although we recognize that suppliers of albuterol sulfate incur other costs related to inhalation therapy in addition to the cost of the drug, we believe current Medicare reimbursements more than compensate suppliers for these costs along with a reasonable profit margin.

We believe our invoice cost analysis further supports a recommendation made in an OIG report entitled *Medicare Payments for Nebulizer Drugs*. We previously recommended that HCFA reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments as appropriate.

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

Discounted Wholesale Price

Many Medicaid 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 costs.

HCFA 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 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 D.

In a technical comment, HCFA suggested that we review the proportion of albuterol sulfate actually obtained through a pharmacy as opposed to a pharmacy selling to a DME company who, in turn, sells to the Medicare patient.

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.

We discussed directly with HCFA staff the data we had available in response to their technical comment.

APPENDIX A

NONRESPONDENT ANALYSIS

An important consideration with respondent-based research is the bias that may be introduced into the results if nonrespondents differ from respondents in systematic ways. We achieved an overall response rate for claim-supporting albuterol sulfate invoices of only 47 percent. However, as shown in the table below, invoice response rates varied widely by strata.

INVOICE RESPONSE RATES BY STRATA

Strata	Population Size	Sample Size	Achieved Sample Size (Invoices)	Invoice Response Rates
California	603	75	25	33%
Florida	1789	75	40	53%
Illinois	464	75	28	37%
New York	433	75	31	41%
Puerto Rico	866	55	46	84%
Texas	1075	75	36	48%
Other States	6763	55	24	44%
TOTAL	11993	485	230	47%

In order to test for potential bias effects that suppliers who did not provide albuterol sulfate invoices may have had on our invoice price estimates, we conducted an analysis utilizing National Supplier Clearinghouse (NSC) supplier profile data. The NSC processes all supplier number applications and maintains files on these suppliers.

We inspected NSC data profiling the nebulizer drug suppliers who billed Medicare for the 485 albuterol sulfate claims in our sample. We reviewed NSC data fields providing information on supplier characteristics such as size and scope of business activity. We focused our analysis on suppliers possessing assets over $100 million. The Chi-square statistic was used to test for differences between suppliers who submitted invoices and suppliers who did not submit invoices with respect to assets.

CHI-SQUARE FOR SIZE OF ASSETS

	Invoice Submitted	Invoice Not Submitted	Total	% Invoice Submitted
Assets > $100 million	5 (2%)	95 (41%)	100	5%
Assets < $100 million	214 (98%)	138 (59%)	352	61%
Overall	219	233	452	48%

CHI-SQUARE = 97.069[2] Degrees of Freedom = 1

Chi-square results are presented in the table above. Analysis indicates that our invoice price estimates are biased with respect to size of supplier assets. We can conclude that there is a relationship in our sample between invoice submission and size of assets at the 99% confidence level.

[2]A Chi-square statistic of 6.63 or higher indicates that we can reject the null hypothesis that the invoice submissions and asset sizes are independent at the 99 percent confidence level.

APPENDIX B

COST ESTIMATES AND CONFIDENCE INTERVALS

The tables below contain estimated average supplier costs for albuterol sulfate overall and by purchase source. Also provided are estimated proportions of invoices by purchase source and drug type. These estimates and their corresponding 95 percent confidence intervals were computed using standard statistical formulas for a single-stage stratified random sample.

Supplier Costs for Albuterol Sulfate

Overall Mean Estimate	95% Confidence Interval
$0.194	$0.185 - $0.204

Supplier Costs by Invoice Type

Purchase Source	Mean	95% Confidence Interval
Manufacturer	$0.139	$0.133 - $0.145
Wholesaler	$0.203	$0.177 - $0.229
Pharmacy	$0.227	$0.207 - $0.246

Supplier Purchase Source

Purchase Source	Proportion	95% Confidence Interval
Manufacturer	32.25%	21.39% - 43.11%
Wholesaler	23.25%	13.63% - 32.88%
Pharmacy	44.50%	32.66% - 56.34%

Type of Albuterol Sulfate Provided

Drug Type	Proportion	95% Confidence Interval
Generic	90.02%	82.57% - 97.47%
Brand Name	5.93%	0 - 12.10%
Compounded	4.05%	0 - 8.62%

Other Costs

	Proportion	95% Confidence Interval
Reported Other Costs	42.80%	32.54% - 53.06%

APPENDIX C

CALCULATION OF POTENTIAL MEDICARE SAVINGS

Analysis of claim-supporting invoices indicates that suppliers are paying an average cost of $0.19 per ml for albuterol sulfate.

During the period of our review, January 1994 through February 1995, Medicare allowed amounts for albuterol sulfate ranged from $0.40 per ml to $0.43 per ml. Medicare allowances for albuterol sulfate, based on a median of national AWPs, totaled over $182 million for this period. If Medicare allowances for albuterol sulfate had been based on supplier invoice costs, however, the program could have saved an estimated $94 million.

This savings estimate was calculated by first determining the total Medicare allowance for albuterol sulfate during the study period. This figure was obtained from HCFA's National Claims History One Percent File. Total allowed services corresponding to the total Medicare allowance were calculated conservatively by dividing the total allowance by the lowest reimbursement allowed during this period: $0.40. Total allowed services were then multiplied by the overall average supplier cost of $0.194 per ml of albuterol sulfate. This estimated total Medicare allowance for albuterol sulfate was subtracted from the actual total Medicare allowance to derive potential savings. The calculation steps are outlined below.

STEP 1

Actual Total Allowance	Lowest Reimbursement per ml	Estimated Total Services
$182,313,000	/ $0.40	= 455,782,500

STEP 2

Estimated Total Services	Estimated Mean Supplier Price per ml	Estimated Total Allowance
455,782,500	X $0.194 ($0.185 - $0.204)	= $88,421,805 ($84,319,763 - $92,979,630)

STEP 3

Actual Total Allowance	Estimated Total Allowance	Potential Medicare Savings
$182,313,000	- $88,421,805 ($84,319,763 - $92,979,630)	= $93,891,195 ($89,333,370 - $97,993,237)

APPENDIX D

AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

RECEIVED
1996 MAY 13 A 11:46
OFFICE OF INSPECTOR GENERAL

DATE: MAY - 3 1996

TO: June Gibbs Brown
Administrator

FROM: Bruce C. Vladeck
Administrator

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

IG	
SAIG	
PDIG	
DIG-AS	
DIG-EI	✓
DIG-OI	
DIG-MP	
AIG-CFAA	
OGC/IG	
EXSEC	✓
DATE SENT	5/13

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.