Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

QUESTIONABLE PRACTICES INVOLVING NEBULIZER DRUG THERAPY

JUNE GIBBS BROWN
Inspector General

MARCH 1997
OEI-03-94-00391

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.

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

Region

Robert A. Katz, *Project Leader*
Amy Sernyak, *Lead Analyst*
Linda M. Ragone, *Program Analyst*
Cynthia Hansford, *Program Assistant*
Karen Folk, *Intern*
Ethan Shaw, *Intern*
Patti Loyack, *Intern*

Headquarters

Mary Beth Clarke, *Program Specialist*
Brian Ritchie, *Technical Support Staff*
Barbara Tedesco, *Statistician*
Linda Moscoe, *Technical Support Staff*

Office of Audit Services

David J. Graf, *Advanced Techniques Staff*, Philadelphia
Lourdes Puntonet, *Auditor*, Atlanta

EXECUTIVE SUMMARY

PURPOSE

This report identifies questionable practices relating to nebulizer drug therapy provided to Medicare beneficiaries under Part B of the Medicare program.

BACKGROUND

A nebulizer is a type of durable medical equipment (DME) through which prescription inhalation drugs are administered. Nebulizers and associated drugs are covered by Medicare "if the patient's ability to breathe is severely impaired."

Medicare allowances for nebulizer drugs remained relatively stable during the years 1990 through 1992, never exceeding about $78 million annually. In 1993, allowances increased to about $169 million and rose to about $226 million in 1994, an increase of almost 200 percent from 1990. Albuterol sulfate 0.083% is the most commonly reimbursed nebulizer drug code. This drug accounted for $150 million, or more than 65 percent, of the total dollars allowed for all nebulizer drugs in 1994. While Medicare payments for nebulizer drugs have increased in recent years, payments for nebulizer equipment have actually decreased. Allowances for nebulizer equipment dropped from $131 million in 1993 to $40 million in 1994. This may be due in part to Medicare's capped rental policy for certain types of nebulizer equipment.

To review Medicare payments for nebulizers and associated drugs, we utilized a random sample of nebulizer claims focusing on albuterol sulfate 0.083%. We also analyzed data from the Health Care Financing Administration's (HCFA) National Claims History File. We sought to determine 1) if Medicare reimbursed nebulizer equipment when a beneficiary had no corresponding nebulizer drug claims, and 2) if beneficiaries were receiving more than one type of nebulizer drug at the same time.

FINDINGS

Medicare paid for multiple inhalation drugs that when used together may be harmful to beneficiaries.

Medicare paid $8 million for multiple beta-adrenergic bronchodilator drugs that should almost never be taken during the same time period.

Medicare paid an additional $22 million for drugs that may be inappropriate when taken together.

One of HCFA's four Durable Medical Equipment Regional Carriers (DMERCs) accounted for a disproportionate share of multiple nebulizer drug allowances.

Other questionable drug provision practices may compromise beneficiaries' care.

Medicare beneficiaries received units of albuterol sulfate that differed from amounts prescribed by their physicians.

Prescribed dosage levels for some beneficiaries exceed medical guidelines.

Beneficiaries do not use all of the nebulizer drugs provided to them.

Questionable billing practices contribute to improper Medicare payments for nebulizer therapy.

Medicare allowed over $10 million for nebulizer equipment without corresponding billings for nebulizer drugs.

Suppliers billed Medicare for drug dispensing services they did not perform.

Some suppliers did not collect beneficiary coinsurance payments.

RECOMMENDATIONS

We recommend that HCFA develop a strategy to 1) eliminate the questionable and abusive billings we encountered in this inspection, and 2) ensure that beneficiaries requiring nebulizer therapy receive treatments that are appropriate.

As part of this strategy, we urge HCFA to implement a comprehensive coverage and medical review policy focusing on nebulizer equipment and inhalation drugs. In concert with these policies, the DMERCs should develop and issue guidelines to suppliers and pharmacies outlining recommended prescribing practices for inhalation drugs used with nebulizer equipment. To ensure compliance with the recent Medicare policy revision prohibiting drug payments to non-dispensing suppliers, the HCFA should take action to confirm that only appropriately licensed suppliers be permitted to dispense drugs, bill for dispensing fees, and physically handle drug products. In addition, the DMERCs could also provide suppliers with a reminder about Medicare regulations prohibiting the routine waiver of beneficiary coinsurance.

If the recommendations we just outlined had been in place during the time period of our review, Medicare could have saved up to $40 million in payments for questionable nebulizer equipment and drugs. Although this $40 million is an estimate, we believe it is credible since a more rigorous review of inhalation drug claims by one DMERC resulted in savings of nearly $20 million during only a 5 month period. The savings occurred after DMERC C implemented a review screen for claims involving both incompatible multiple inhalation drugs and overutilization. The DMERC took the initiative to implement this screen when concerns about Medicare payments for inhalation drugs in this region were raised by HCFA and the OIG after reviewing data compiled by the Statistical Analysis Durable Medical Equipment Regional Carrier.

We will refer possible abusive or fraudulent claims we encountered during our review to the fraud units responsible for handling such activities. In addition, we are planning a multi-disciplinary review, including evaluation and investigation staff, to determine the magnitude of inappropriate multiple nebulizer drug use as well as the identification of suppliers employing fraudulent or abusive practices in their Medicare billings.

AGENCY COMMENTS

The HCFA concurred with our recommendations. They have already taken steps to institute corrective actions, including revising their policies relating to nebulizer equipment and drugs which will take effect in April 1997. The revised guidelines contain more stringent requirements and are aimed at curtailing improper billings such as overutilization and billing for nebulizer equipment without corresponding billings for nebulizer drugs. To ensure that beneficiaries receive appropriate nebulizer therapy treatments, HCFA has clarified its guidelines to require that only licensed entities meeting pharmacy standards established by State Boards of Pharmacy be allowed to dispense and bill for nebulizer drugs. This change, according to HCFA, will prevent such abusive practices as supplying incompatible multiple drugs and excessive dosages of drugs. The full text of HCFA's comments may be found in Appendix B.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

This report identifies questionable practices relating to nebulizer drug therapy provided to Medicare beneficiaries under Part B of the Medicare program.

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. The HCFA designated four Durable Medical Equipment Regional Carriers (DMERCs) to process all claims for DME, prosthetics, orthotics, and medical supplies, including nebulizers and inhalation drugs. Effective October 1, 1993, the DMERCs replaced local carriers which had previously processed these claims.

Medicare Coverage of Nebulizer Therapy

A nebulizer is a type of DME through which prescription inhalation drugs are administered. 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. Nebulizer drug therapy is administered by placing a prescription inhalation drug into the reservoir of a nebulizer. The nebulizer's power source converts the drug into a fine spray which is inhaled by the patient.

The Medicare Coverage Issues Manual states that nebulizers are "covered if the patient's ability to breathe is severely impaired." While Medicare does not generally pay for outpatient prescription drugs, drugs used in conjunction with a nebulizer are covered under the program. Section 2100.5 of the Medicare Carriers Manual specifies the covered uses of outpatient prescription drugs including drugs used in conjunction with DME. In accordance with HCFA policy, if a beneficiary has a severe respiratory illness or disease, Medicare will pay for any drug that transforms 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 drug and the equipment for as long as the nebulizer drug therapy is necessary.

In 1994, the DMERCs proposed a new nebulizer medical policy which focused on specific coverage and medical necessity issues. The proposed policy outlined baseline documentation requirements to support Medicare coverage criteria for nebulizer therapy. In addition, the policy required trial use of a metered dose inhaler (MDI), a non-covered device under Medicare, before nebulizer treatment would be reimbursed.

The HCFA withdrew the policy proposal in response to concerns voiced by organizations and physicians. Primarily, these concerns centered on the possible deterioration of a patient's condition during the MDI trial period to the point where an emergency room visit or hospitalization might be required.

Medicare Allowances for Nebulizer Therapy

Between 1991 and 1993, allowances for nebulizer equipment increased from $87 million to $131 million. However, in 1994 there was a sharp reduction in Medicare allowances to $40 million. The decline was due in large part to an almost $100 million decrease between 1993 and 1994 for nebulizers with compressors (HCFA Capped Rental Code E0570). However, in contrast, allowances for portable nebulizers (Code E1375) increased more than 700 percent from $389,047 in 1993 to more than $3 million in 1994. Portable nebulizers are not capped rental items. Medicare will pay for only 15 months of rental for capped rental items if beneficiaries choose not to purchase these items.

While payments for nebulizer equipment have diminished in recent years, payments for drugs used with nebulizers have increased. Medicare allowances remained relatively stable during the years 1990 through 1992, never exceeding about $78 million annually.[1] In 1993, allowances for 21 nebulizer drug codes increased to about $169 million and rose to about $226 million in 1994, an increase of almost 200 percent from 1990. Albuterol sulfate 0.083% (Code J7620), hereafter simply referred to as albuterol sulfate, is the most commonly reimbursed nebulizer drug code. This drug accounted for $150 million, or more than 65 percent, of the total dollars allowed for all nebulizer drugs in 1994.

Pharmacies or DME suppliers use drug-specific procedure codes to claim Medicare reimbursement for nebulizer drugs. Each DMERC determines allowances for prescription drug codes in its respective region based on the guidelines stated in HCFA regulations. In addition to reimbursing for the drug product, Medicare will also pay a monthly dispensing fee of $5 when pharmacies provide drugs used in nebulizers.

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. In 1996, 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.

---

[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.

In a companion report called *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392), we found that many retail and mail-order pharmacies charge customers less for generic albuterol sulfate than Medicare's allowed price. A previously issued report, *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393), examines how much suppliers pay for albuterol sulfate. An additional report, *Appropriateness of Medicare Prescription Drug Allowances* (OEI-03-95-00420), compared Medicare drug reimbursement mechanisms with Medicaid payment mechanisms for 17 drugs and found that Medicare could achieve significant savings by adopting reimbursement strategies similar to those used by Medicaid.

The HCFA, in response to these inspections, concurred with our recommendation that it reexamine its drug reimbursement methodologies. The HCFA agreed to explore new reimbursement mechanisms to take into account actual drug costs and reduce Medicare payments.

Operation Restore Trust

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

METHODOLOGY

We reviewed pertinent background information on nebulizer therapy from a wide variety of sources including HCFA officials, medical equipment suppliers, pharmaceutical reference books, and pharmacies. In addition, we consulted with the DMERCs' medical and utilization review staffs regarding nebulizer and inhalation drug therapy coverage, medical necessity, and other technical issues such as acceptable supplier documentation and pharmaceutical practices. We received information and reports from the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC). For guidance on recommended inhalation drug dosage and administration practices, we used the *USP Drug Information for the Health Care Professional*, the *Physicians' Desk Reference*, and the product information provided in the package insert for one brand of albuterol sulfate.

We requested information from two main sources – suppliers and beneficiaries. We selected the suppliers and beneficiaries based on a sample of claims from a One Percent DME Claims File developed from HCFA's National Claims History File. Focusing on albuterol sulfate, the nebulizer drug most frequently reimbursed under Medicare, we selected a stratified random sample of albuterol sulfate claims from the 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 a 14-month period of review,

January 1, 1994 through February 28, 1995. Medicare allowances for albuterol sulfate exceeded $182 million during the 14-month period of our review, representing 68 percent of the $269 million in total allowances for nebulizer drugs. Our sample of 485 claims is statistically representative of the universe of over one million claims for albuterol sulfate which Medicare processed during the period of our review.

Supplier Information Requests

We mailed requests for information to the suppliers that billed Medicare for the 485 sample albuterol sulfate claims. In this report, we use the term "supplier" to indicate the entity which billed Medicare for the nebulizer drug provided to the beneficiary. These requests covered a variety of subjects, including 1) supplier business characteristics, 2) how the supplier obtained the nebulizer drug and delivered it 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 sample J7620 claim.

Suppliers returned completed requests for 418 of the 485 sample J7620 claims (86 percent response rate). Some suppliers 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.

Beneficiary Information Requests

We mailed information requests to the Medicare beneficiaries identified in the sample claims. We did not send information requests to deceased beneficiaries if we knew they were deceased at the time of the mailing. Questions related to five broad areas: 1) nebulizer and inhalation drug utilization patterns, 2) health condition, 3) nebulizer and inhalation drug characteristics, 4) ordering and receipt of inhalation drug, and 5) efficacy of nebulizer and inhalation drug.

Two hundred and twenty-three beneficiaries or their relatives returned completed information requests. These responses account for 307 sample albuterol sulfate claims because the sample contains more than one claim for some beneficiaries.

We analyzed supplier and beneficiary responses to the information requests. To detect inconsistencies and irregular practices in the provision of albuterol sulfate we compared supplier and beneficiary responses to related questions. We examined suppliers' documentation to identify possible questionable billing practices and inappropriate albuterol sulfate utilization. Percentage estimates and corresponding 95 percent confidence intervals for the supplier and beneficiary data were computed using standard statistical formulas for a single-stage stratified random sample. Point estimates and confidence intervals for all statistics presented in this report are provided in Appendix A.

Nebulizer Drug Review

We performed two separate analyses of data from the One Percent DME Claims File. We sought to determine 1) if Medicare had reimbursed nebulizer equipment when a beneficiary had no corresponding nebulizer drug claims, and 2) if Medicare had made payments for more than one beta-adrenergic bronchodilator drug at the same time.

To identify beneficiaries who had nebulizer equipment claims without nebulizer drug claims, we matched nebulizer equipment claims for the 14-month period (January 1, 1994 - February 28, 1995) with nebulizer drug claims. Because of possible lags in billing, we believed it would be more conservative to identify only those beneficiaries who had no matching nebulizer equipment and drug claims in the middle 8 months (April 1 - November 30, 1994) of our review period. In addition, to ensure that corresponding drug claims for these beneficiaries were not billed before or after the 8-month period, we searched the One Percent DME Claims File for drug claims billed during the 3 months prior to April 1, 1994 and the 7 months after November 30, 1994. No such claims were located.

We also verified our findings with the DMERCs which reviewed the on-line Part B service histories for a random sample of 100 of the 1,234 beneficiaries who had nebulizer equipment billings without corresponding nebulizer drug billings. The medical directors confirmed that the beneficiaries had no history of nebulizer drug billings during the period of our review. They did find drug billings for 5 beneficiaries in late 1995 and early 1996, which were subsequent to our review period.

Medicare reimburses four categories of nebulizer drugs: bronchodilators, anti-inflammatories, mucolytics, and antibiotics. Within the bronchodilator category, there are two types of drugs – beta-adrenergics and anticholinergics. For our analysis of beneficiaries receiving more than one drug at a time, we focused only on the beta-adrenergic bronchodilator type of nebulizer drug.

To determine if Medicare had made payments for more than one beta-adrenergic bronchodilator drug at the same time, we used the data from the DME Claims File for our 14-month review period. We selected 12 drug codes that represent bronchodilator drugs with beta-adrenergic stimulatory effects. Using these codes, we determined if two or more beta-adrenergic drugs were billed for a beneficiary in the same 30-day period. We then calculated the total payment for these multiple nebulizer drugs.

We did a separate analysis where we matched the 12 beta-adrenergic drug codes against drug code J7699 which represents "not otherwise classified inhalation drugs." Code J7699 can be used to bill for at least one type of beta-adrenergic bronchodilator drug which does not yet have a specific code. We then determined the total Medicare payment for these matches.

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

FINDINGS

MEDICARE PAID FOR MULTIPLE INHALATION DRUGS THAT WHEN USED TOGETHER MAY BE HARMFUL TO BENEFICIARIES.

Medicare paid $8 million for multiple beta-adrenergic bronchodilator drugs that should almost never be taken during the same time period.

Medicare made payments for two or more beta-adrenergic bronchodilator drugs for at least a 30-day period between January 1, 1994 through February 1995 for more than 10,000 beneficiaries. Medicare and its beneficiaries paid almost $8 million dollars for these drugs during this time. Beta-adrenergic bronchodilator drugs open up or dilate the lung's airways by relaxing the bronchial smooth muscle. Using two beta-adrenergic drugs during the same time period is not only ineffective but can be potentially harmful to the beneficiary.

A majority of these beneficiaries received albuterol sulfate along with another beta-adrenergic bronchodilator drug, such as metaproterenol sulfate or isoetharine hydrochloride. The product information provided in the package insert for one brand of albuterol sulfate states that "other sympathomimetic aerosol bronchodilators or epinephrine should not be used concomitantly with albuterol." According to DMERC medical personnel, beta-adrenergic bronchodilator drugs such as albuterol sulfate, metaproterenol sulfate, and isoetharine hydrochloride, when used in combination, provide no further clinical improvement beyond that obtained through the use of only one nebulizer drug in this category.

While these drug combinations provide no increased benefit, they can be harmful to the respiratory, heart, and nervous systems. Use of multiple beta-adrenergic drugs can effectively be considered an overdosage. Overutilization can lead to a loss of sensitivity to the drugs. This can eventually result in unresponsive asthma since breathing can no longer be improved with nebulizer drug therapy. In addition, overdosage can lead to irregular heart beat, anginal pain, hypertension, tremulousness, and other adverse reactions. It can even be potentially fatal, especially in a health-compromised elderly beneficiary.

Medicare paid an additional $22 million for drugs that may be inappropriate when taken together.

Along with the almost $8 million paid for multiple beta-adrenergic bronchodilator drugs, another $22 million was spent by Medicare on multiple inhalation drugs for which the level of effectiveness or harmfulness cannot be determined. The beneficiaries for whom Medicare paid these bills received multiple inhalation drugs including one beta-adrenergic drug and one drug that cannot be identified since it was billed using code J7699. Code J7699 represents "not otherwise classified inhalation drugs." Drugs billed with this code either have no procedure code or are prescribed in

amounts that do not fit the dosage of current codes. These drugs can be bronchodilators or other types of inhalation drugs.

When billing information for code J7699 was matched against other beta-adrenergic bronchodilator drug codes, 22,500 beneficiaries were found to have received multiple inhalation drugs. If the drugs billed to Medicare under code J7699 were beta-adrenergic drugs, then these beneficiaries may have received drugs that were inappropriate if used during the same time frame.

While it is possible that a beneficiary may receive multiple inhalation drugs during a single 30-day period if their doctor makes a prescription change, multiple beta-adrenergic drug claims for individual beneficiaries over successive months provide evidence that makes this an improbable explanation for such widespread multiple drug use. When individual beneficiary nebulizer drug usage was reviewed, we found instances where multiple inhalation drugs were used over a number of months. We also found claims for some beneficiaries for not just two beta-adrenergic bronchodilator drugs, but up to four different inhalation drugs during the same time period. To illustrate this point, Medicare paid over $13,000 for one beneficiary who received four inhalation drugs over a 9-month period. Three of the drugs were beta-adrenergics and the fourth drug could not be identified since it was billed using code J7699.

One DMERC accounted for a disproportionate share of multiple nebulizer drug allowances.

The DMERC for Region C paid over $20 million of the $30 million in questionable multiple nebulizer drug payments. While only 27 percent of the Medicare population resides in the area serviced by DMERC C, the region accounted for 60 percent of the beneficiaries that received multiple nebulizer drugs. The carrier paid an average of $1133.00 for each beneficiary receiving multiple nebulizer drugs during the 14-month review period. This was 30 percent more than the average dollars paid by the DMERC with the next highest average allowance per beneficiary.

The Region C DMERC not only has an unusually large share of multiple drug payments but also accounts for 60 percent of total allowances for nebulizer drugs during the 14-month review period. For five specific nebulizer drugs, DMERC C made 100 percent of the Medicare payments over the 14 months.

Region C's large share of payments appears to have continued into 1995. According to a SADMERC statistical report for the third-quarter of 1995, DMERC C accounts for 67 percent of the quarter's total national allowances of $88 million for nebulizer drugs. The report also provided evidence that while DMERC C has hundreds, sometimes thousands, of beneficiaries using certain drugs, other regions have less than 10 beneficiaries using the same drugs. Similar to what was found during the 14-month review period, DMERC C allowed 85 percent of the national payments for bitolterol; 93 percent for acetylcystein; 95 percent for metaproterenol;

99 percent for isoetharine; and 100 percent for isoproterenol in the third-quarter of 1995.

OTHER QUESTIONABLE DRUG PROVISION PRACTICES MAY COMPROMISE BENEFICIARIES' CARE.

Questionable practices involving the provision of albuterol sulfate therapy may compromise the quality of care received by Medicare beneficiaries. We are highlighting these practices because they could adversely affect the benefits of nebulizer therapy intended for Medicare beneficiaries.

Medicare beneficiaries received units of albuterol sulfate that differed from amounts prescribed by their physicians.

Twenty-six percent of claims represents billings for units of albuterol sulfate that differed from the units prescribed by beneficiaries' physicians. Thirteen percent reflects allowed units of albuterol sulfate that **exceed** prescribed units by between 9 and 819 milliliters (ml). The other thirteen percent of claims represents allowed units that were between 15 ml and 495 ml **less** than prescribed units.

Allowed units could not be compared to prescribed units of albuterol sulfate for 36 percent of claims due to two factors: "PRN" prescriptions, and billings processed by pre-DMERC carriers. A number of claims were supported with prescription documents that included a "PRN", or "as needed", direction. The "PRN" direction does not indicate a fixed amount of albuterol sulfate to be dispensed. In addition, albuterol sulfate claims were being billed to the pre-DMERC carriers as well as the four new DMERC carriers during the period of our review. Billing standards for albuterol sulfate were not uniform across the pre-DMERC carriers; therefore, suppliers were not consistently billing for units equal to the ml of albuterol sulfate dispensed.

Prescribed dosage levels for some beneficiaries exceed medical guidelines.

Approximately 13 percent of claims had physicians' orders prescribing 5 or 6 albuterol sulfate treatments per day (more than 450 ml per month). Physicians' orders for more than two-thirds of these claims prescribed monthly albuterol sulfate treatments of 540 or more mls. The product information provided by the manufacturer of one brand of albuterol sulfate advises a nebulizer dosage of 3 ml of albuterol sulfate three to four times per day. A one month prescription for albuterol sulfate at a dosage of 3 ml administered three or four times per day would result in 270 to 360 ml of the drug being dispensed. "More frequent administration or higher doses are not recommended," according to guidelines issued by manufacturers.

Drug labeling information, provided by manufacturers and approved by the Food and Drug Administration, presents clear and unmistakable warnings about the dangers of overdosage. The package insert for albuterol sulfate cautions against the overuse of

albuterol sulfate and lists a number of life-threatening conditions that could result from overdosage, including cardiovascular and central nervous system reactions.

Although the drug labeling information for albuterol sulfate currently cautions against exceeding the recommended dosage, there are conceivable occasions when a physician might escalate the dose for a patient depending on the individual's needs. However, physicians would not normally start a patient on such a high dosage scale, nor is it a common dosage regimen. Although these high dosages are not inconceivable, one out of every seven albuterol sulfate claims reviewed were based on prescriptions exceeding recommended dosages. This number of beneficiary claims for such an uncommonly high dosage seems questionable.

Nineteen percent of claims were supported with prescription documents that included a "PRN" direction. Therefore, as discussed above, we could not determine the exact number of albuterol sulfate units prescribed for comparison with the dosage recommended by manufacturers. Depending on the actual dosage the physician intended to prescribe using the "PRN" direction, our analysis may have underestimated the percentage of claims with prescriptions for six albuterol sulfate treatments per day.

Beneficiaries do not use all of the nebulizer drugs provided to them.

For twenty-four percent of albuterol sulfate claims, beneficiaries reported that they did not use all of the nebulizer medication provided to them each month. Almost 33 percent of these claims involved beneficiaries who only used half of their nebulizer medicine each month; another 44 percent of these claims represented beneficiaries who used three-quarters of their dosages. For almost half (45 percent) the claims where non-use of medication was found, beneficiaries reported discarding the unused supply each month.

While one could argue that beneficiaries were not using all of their nebulizer medication due to non-compliance, when this non-use is viewed in the context of this report's previous findings, other explanations seem more credible. Possible explanations include: 1) the lack of medical need or clinical effectiveness for the number and/or dosages of drugs prescribed, and 2) the oversupply of drug products.

QUESTIONABLE BILLING PRACTICES CONTRIBUTE TO IMPROPER MEDICARE PAYMENTS FOR NEBULIZER THERAPY.

Medicare allowed over $10 million for nebulizer equipment without corresponding billings for nebulizer drugs.

Medicare allowed over $10 million for nebulizers without corresponding billings for nebulizer drugs during the 8-month period, April 1, 1994 to November 30, 1994. This $10 million represents almost 40 percent of the $26 million that Medicare paid for nebulizer equipment during the 8 months. Two types of nebulizer equipment

accounted for 89 percent of the $10 million in improper Medicare allowances: nebulizer with compressor (code E0570) and ultrasonic nebulizer (code E0575).

According to Medicare DME coverage guidelines, nebulizers are reimbursable only when beneficiaries with severely impaired breathing use the nebulizers with albuterol sulfate or other inhalation drugs. If inhalation drugs are not being used with nebulizers, then the nebulizers should not be paid for by the Medicare program.

More than one-third of beneficiaries (123,400 of 357,000) had billings for nebulizer equipment without corresponding billings for nebulizer drugs. For 16 percent of beneficiaries, Medicare paid for 8 months of equipment billings with no corresponding claims for nebulizer drugs. About half of the beneficiaries had equipment payments for 1 or 2 months without corresponding drug claims. The remaining beneficiaries had between 3 and 7 months of claims for nebulizer equipment with no corresponding drug billings.

Suppliers billed Medicare for drug dispensing services they did not perform.

Thirty-six percent of claims for albuterol sulfate involved Medicare payments to suppliers who did not dispense the drugs to beneficiaries. Instead, these suppliers had arrangements with pharmacies who actually dispensed the drugs to beneficiaries. For 25 percent of albuterol sulfate claims, suppliers without licensed pharmacy components billed Medicare not only for the drug but also *for the $5.00 dispensing fee* even though they did not dispense the drug to beneficiaries.

Medicare paid an estimated $1.5 million for improper dispensing fee billings between January 1, 1994 and February 28, 1995. This represents one-third of the total estimated $4.7 million in albuterol sulfate dispensing fees paid for by Medicare during the review period.

The payment of both drug allowances and dispensing fees to suppliers who do not actually provide drugs to beneficiaries conflicts with HCFA's written policy and guidelines. Medicare Carriers Manual section 3060 states that "the carrier may pay assigned benefits only to the physician or other supplier who furnished the service." When the policy to pay dispensing fees was introduced, a December 1993 HCFA memorandum to Medicare administrators and carriers stated that a monthly dispensing fee for each inhalation drug would be paid "...where pharmacies provide drugs used in nebulizers."

Recent revisions to section 3060 of the Medicare Carriers Manual, as outlined in a HCFA Bureau of Policy Development memorandum dated July 30, 1996, will prohibit drug and dispensing fee payments to suppliers who do not actually provide drugs

directly to beneficiaries. The memorandum explains that the following language will be included in section 3060.D of the manual:

> In the case of drugs used in conjunction with durable medical equipment (DME) or prosthetic devices, the entity that dispenses the drug must furnish it directly to the patient for whom a prescription is written. Therefore, those drugs cannot be purchased for resale to the beneficiary by any supplier that is not the entity which dispenses the drug. Such a supplier may only bill for the DME or prosthetic devices. In order for prescription drugs that are used in conjunction with DME or prosthetic devices to be covered by Medicare, the entity that dispenses the drugs must have a Medicare supplier number, must be licensed to dispense the drug in the State in which the drug is dispensed, and must bill and receive payment in its own name.

This policy revision should prevent millions of dollars in payments to non-dispensing suppliers that Medicare has been allowing up to this point.

Some suppliers did not collect beneficiary coinsurance payments.

For 11 percent of the albuterol sulfate claims billed to Medicare, beneficiaries reported they did not pay the 20 percent coinsurance for their nebulizer medications. These beneficiaries also reported that they did not have some other form of health insurance that would cover the coinsurance payments. Since beneficiaries are required to pay (unless there is financial hardship) 20 percent of the Medicare allowed amount for services, suppliers who routinely waive this payment are not following Medicare regulations regarding beneficiary coinsurance.

Routine waiver of the coinsurance amount may constitute a violation of the Medicare and Medicaid Anti-Kickback provision (42 U.S.C. 1320a-7b(b)), if the purpose of the routine waiver is to induce Medicare or Medicaid business. A provider's routine waiver of a beneficiary's obligation to pay may also result in the filing of a Medicare or Medicaid claim that is considered false because it misrepresents the actual amount charged for the item or service. Anti-kickback violations and false claims can be actionable under criminal, civil, and administrative authorities.

RECOMMENDATIONS

We recommend that HCFA develop a strategy to 1) eliminate the questionable and abusive billings we encountered in this inspection, and 2) ensure that beneficiaries requiring nebulizer therapy receive treatments that are appropriate.

As part of this strategy, we urge HCFA to implement a comprehensive coverage and medical review policy focusing on nebulizer equipment and inhalation drugs. In concert with these policies, the DMERCs should develop and issue guidelines to suppliers and pharmacies outlining recommended prescribing practices for inhalation drugs used with nebulizer equipment. To ensure compliance with the recent Medicare policy revision prohibiting drug payments to non-dispensing suppliers, the HCFA should take action to confirm that only appropriately licensed suppliers be permitted to dispense drugs, bill for dispensing fees, and physically handle drug products. In addition, the DMERCs could also provide suppliers with a reminder about Medicare regulations prohibiting the routine waiver of beneficiary coinsurance.

If the recommendations we just outlined had been in place during the 14-month time period of our review, Medicare could have saved up to $40 million in payments for questionable nebulizer equipment and drugs. Although this $40 million is an estimate, we believe it is credible since a more rigorous review of inhalation drug claims by just one DMERC resulted in savings of nearly $20 million during only a 5-month period. The savings occurred after DMERC C implemented a review screen for claims involving both incompatible multiple inhalation drugs and overutilization. The DMERC took the initiative to implement this screen when concerns about Medicare payments for inhalation drugs in this region were raised by HCFA and the OIG after reviewing data compiled by the Statistical Analysis Durable Medical Equipment Regional Carrier.

Many of the findings presented pertain to abusive and possibly fraudulent practices. We will refer these matters to the DMERC fraud units responsible for handling such activities. In addition, we are planning a multi-disciplinary review, including evaluation and investigation staff, to determine the magnitude of inappropriate multiple nebulizer drug use as well as the identification of suppliers employing fraudulent or abusive practices in their Medicare billings.

AGENCY COMMENTS

The HCFA concurred with our recommendations. They have already taken steps to institute corrective actions, including revising their policies relating to nebulizer equipment and drugs which will take effect April 1997. The revised guidelines contain more stringent requirements and are aimed at curtailing improper billings such as overutilization and billing for nebulizer equipment without corresponding billings for nebulizer drugs. To ensure that beneficiaries receive appropriate nebulizer therapy treatments, HCFA has clarified its guidelines to require that only licensed entities

meeting pharmacy standards established by State Boards of Pharmacy be allowed to dispense and bill for nebulizer drugs. This change, according to HCFA, will prevent such abusive practices as supplying incompatible multiple drugs and excessive dosages of drugs.

APPENDIX A

POINT ESTIMATES AND CONFIDENCE INTERVALS

The tables below contain statistical estimates presented in the Findings section of this report. Point estimates and corresponding 95 percent confidence intervals based on beneficiary and supplier data were computed using standard statistical formulas for a single-stage stratified random sample. Those based on analyses of data from the HCFA One Percent DME Claims File were computed using standard statistical formulas for a simple random sample.

MEDICARE PAID FOR MULTIPLE INHALATION DRUGS THAT WHEN USED TOGETHER MAY BE HARMFUL TO BENEFICIARIES.

Medicare paid $8 million for multiple beta-adrenergic bronchodilator drugs that should not be taken during the same time period.

Point Estimate	95% Confidence Interval
$7,707,533	$6,975,119 - $8,439,946

Medicare paid an additional $22 million for drugs that may be inappropriate when taken together.

Point Estimate	95% Confidence Interval
$22,416,942	$21,615,746 - $23,218,138

One DMERC accounted for a disproportionate share of multiple nebulizer drug allowances.

	Point Estimate	95% Confidence Interval
DMERC C share of allowances	$20,395,724	$19,129,240 - $21,662,208
Total questionable payments	$30,124,480	$29,034,195 - $31,214,765
DMERC C percent of beneficiaries	59.60%	54.09% - 65.12%

OTHER QUESTIONABLE DRUG PROVISION PRACTICES MAY COMPROMISE BENEFICIARIES' CARE.

Medicare beneficiaries received units of albuterol sulfate that differed from amounts prescribed by their physicians.

	Point Estimate	95% Confidence Interval
Units differed from prescription	26.44%	18.28% - 34.60%
Units exceeded prescription	13.27%	6.72% - 19.83%
Units less than prescription	13.16%	7.00% - 19.33%
Relationship undeterminable	36.30%	28.16% - 44.45%

Prescribed dosage levels for some beneficiaries exceed medical guidelines.

	Point Estimate	95% Confidence Interval
Greater than or equal to 450 ml	13.47%	7.24% - 19.70%
Greater than or equal to 540 ml	9.38%	4.67% - 14.10%
Prescribed frequency undeterminable	18.80%	11.85% - 25.76%

Beneficiaries do not use all of the nebulizer drugs provided to them.

	Point Estimate	95% Confidence Interval
Do not use all nebulizer drugs	23.63%	14.50% - 32.75%
Use half of nebulizer medicine	32.53%	9.85% - 55.21%
Use three-quarters of drugs	43.77%	21.33% - 66.21%
Discard unused drugs	45.35%	22.87% - 67.83%

QUESTIONABLE BILLING PRACTICES CONTRIBUTE TO IMPROPER MEDICARE PAYMENTS FOR NEBULIZER THERAPY.

Medicare allowed over $10 million for nebulizer equipment without corresponding billings for nebulizer drugs.

	Point Estimate	95% Confidence Interval
Allowances for equipment without drugs	$10,382,230	$10,031,740 - $10,732,720
Total equipment allowances	$25,701,454	$25,169,154 - $26,233,753

Suppliers billed Medicare for drug dispensing services they did not perform.

	Point Estimate	95% Confidence Interval
Suppliers did not dispense drugs	36.38%	28.01% - 44.74%
Suppliers did not dispense drugs but billed dispensing fees	25.44%	17.54% - 33.33%
Medicare allowances for improper dispensing fee billings	$1,525,375	$1,051,899 - $1,998,851
Total Medicare allowances for albuterol sulfate dispensing fees	$4,688,024	$4,351,533 - $5,024,514

Some suppliers did not collect beneficiary coinsurance payments.

Point Estimate	95% Confidence Interval
10.94%	4.05% - 17.83%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: FEB 6 1997

FROM: Bruce C. Vladeck
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Questionable Practices Involving Nebulizer Drug Therapy," (OEI-03-94-00391)

TO: June Gibbs Brown
Inspector General

We reviewed the above-referenced report that identified questionable practices relating to nebulizer drug therapy provided to Medicare beneficiaries.

Our detailed comments on the report recommendations are attached for your consideration. Thank you for the opportunity to review and comment on this report.

Attachment

IG
EAIG
SAIG
PDIG
DIG-AS
DIG-EC
DIG-EI ✓
DIG-OI
DIG-MP
AIG-LC
OGC/IG ✓
ExecSec ✓
Date Sent 2-13

The Health Care Financing Administration (HCFA) Comments on
Office of Inspector General (OIG) Draft Report:
"Questionable Practices Involving Nebulizer Drug Therapy,"
(OEI-03-94-00391)

OIG Recommendation

HCFA should eliminate the questionable and abusive billings encountered in this inspection.

HCFA Response

We concur. HCFA is aware of existing problems in this area of the Medicare program and took corrective action to ensure that nebulizer drug therapy billings are appropriate. The durable medical equipment (DME) regional carriers revised the regional medical review policy (RMRP) for nebulizers and nebulizer drugs. The revised RMRP was published in the December 1996 DME Regional Carrier Advisory for distribution to all DME suppliers. The new policy, which becomes effective in April 1997, has more stringent guidelines that should reduce over-utilization and overfilling for nebulizer drug therapy equipment and services. It requires that suppliers bill Medicare for nebulizers and licensed pharmacy entities dispense and bill for nebulizer drugs. The policy also provides tightened coverage criteria for respiratory diagnoses and requires more specific coding to be used when billing Medicare for nebulizer therapy. The revised coverage criteria and coding guidelines will compel the supplier to bill Medicare for the services that are medically necessary. This will reduce the opportunity for suppliers to upcode. We anticipate significant savings will result from these actions.

OIG Recommendation

HCFA should ensure that beneficiaries requiring nebulizer therapy receive treatments that are appropriate.

HCFA Response

We concur. HCFA recently clarified the Medicare Carriers Manual at section 3060.D. That section places the dispensing and billing for nebulizer drugs under the jurisdiction of licensed pharmacies that must meet the strict pharmacy practice standards established by state boards of pharmacy regulations and professional association ethics. We believe pharmacists' involvement will ensure appropriate dispensing and prevent overuse of nebulizer drugs.