Memorandum

Date OCT - 4 2001

From Janet Rehnquist
Inspector General

Subject Review of Payments for Inhalation Drugs Made by Region C Durable Medical Equipment Regional Carrier (A-06-00-00053)

To Thomas Scully
Administrator
Centers for Medicare & Medicaid Services

Attached are two copies of the Department of Health and Human Services, Office of Inspector General's final report entitled, "Review of Payments for Inhalation Drugs Made by Region C Durable Medical Equipment Regional Carrier." The objective of this review was to determine whether claims for inhalation drugs submitted by suppliers to Region C Durable Medical Equipment Regional Carrier (DMERC) were billed for and paid in accordance with Medicare coverage and reimbursement requirements.

This review was a joint project conducted by review teams from the Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS). The CMS Region IV, including the manager and staff of the Miami, Florida satellite office, played an integral role in designing, planning, and conducting this review. We are very grateful for the tremendous assistance provided to OIG by the highly professional CMS staff.

In order to evaluate payments for inhalation drugs, we selected a statistical sample of 100 beneficiaries for whom payments for inhalation drugs were made by Region C DMERC. We then reviewed all inhalation drug payments made during the 12-month period October 1, 1998 through September 30, 1999 for the 100 beneficiaries selected.

We estimate that for the 12-month period ended September 30, 1999, the Region C DMERC paid suppliers approximately $134 million for inhalation drugs which were unallowable ($46 million) or for which there was insufficient documentation to determine their allowability ($88 million). During this period, Region C DMERC paid $224 million for inhalation drugs.

Our review showed that $52,550 of inhalation drug payments contained on 392 of 702 claims for 52 beneficiaries (3 beneficiaries had errors in more than 1 category) did not meet the Medicare coverage and reimbursement requirements. Of the 392 claims with errors, we found that 105 claims for 18 beneficiaries with payments totaling $17,955 were unallowable because the payments were for: (1) noncovered items or supplies (drugs billed without a prescription) or (2) the items or supplies were not reasonable and necessary for the beneficiary's condition.

For the remaining 287 claims for 36 beneficiaries**,** totaling $34,595, there was insufficient documentation in the suppliers' records or physicians' medical records to determine whether the payments were made in accordance with Medicare requirements. These included claims for which: (1) supplier records did not contain adequate documentation to support proof of delivery, and/or (2) physician records did not contain sufficient documentation to determine whether he/she considered the use of a metered dose inhaler prior to prescribing inhalation drugs.

We believe that Region C DMERC made payments to suppliers for inhalation drugs which were unallowable or for which there was insufficient documentation to determine their allowability because, in part, they had no procedures in place except for specific situations to "look behind" the claim at the beneficiary's medical record or at the documentation maintained by the suppliers.

Accordingly, we recommended that CMS:

1. Reevaluate Region C DMERC policies and require the DMERC to focus on prepayment reviews of claims, as well as post-payment reviews of suppliers;

2. Require Region C DMERC to establish procedures to ensure that all suppliers of inhalation drugs maintain documentation supporting the services billed and that they bill only for services that are medically necessary; and

3. Require Region C DMERC to recover the specific unallowable payments we identified as part of our sample and review all other claims submitted by the suppliers for the beneficiaries in our sample to identify and recover any additional unallowable payments.

The CMS responded to our draft report in a memorandum dated August 21, 2001. The CMS concurred with our recommendations regarding inappropriate payments for inhalation drugs. Specifically, CMS stated that they would explore the need to modify their prepayment efforts to address the unique problems associated with inhalation drugs in Region C. They also noted that CMS already requires DMERCs to use data analysis to identify possible abusive billing and contraindicated medication usage. The CMS also stated that they would work with the Region C DMERC to explore options for improving the documentation of services billed by its suppliers of inhalation drugs. With regard to unallowable payments, CMS stated that the overpayments identified have been turned over to Region C DMERC for recovery. The full text of CMS's comments is included as APPENDIX C.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

To facilitate identification, please refer to Common Identification Number A-06-00-00053 in all correspondence relating to this report.

Attachments

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF PAYMENTS FOR INHALATION DRUGS MADE BY REGION D DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER

OCTOBER 2001
A-06-00-00053

EXECUTIVE SUMMARY

Title XVIII of the Social Security Act (Act) provides for reimbursement of durable medical equipment (DME) under Part B (voluntary supplementary medical insurance) of the Medicare program. Medicare Part B provides for reimbursement of supplies that are necessary for the effective use of DME. Such supplies include those drugs and biologicals that must be put directly into DME in order to achieve the therapeutic benefit of the equipment or to assure the proper functioning of the equipment. The Medicare program is administered by the Centers for Medicare & Medicaid Services (CMS).

The Act authorizes the Secretary to designate durable medical equipment regional carriers (DMERC) to process claims for the DME benefit. In this regard, using the State in which the beneficiary established permanent residence to determine claims jurisdiction, the Secretary designated four DMERCs – Regions A, B, C, and D. The Region C DMERC pays the claims for beneficiaries who reside in 14 States, Puerto Rico, and the Virgin Islands. The DMERCs pay DME claims on behalf of Medicare, following Medicare reimbursement principles and CMS instructions.

Effective for claims with dates of service on or after December 1, 1996, only suppliers (pharmacies) licensed to dispense drugs may submit claims to DMERCs for prescription drugs used in conjunction with DME. To be covered and reimbursed by Medicare, all DME and related supplies, including prescription drugs, must be ordered by the beneficiary's treating physician. A narrative diagnosis and corresponding International Classification of Diseases 9th Edition (ICD-9) code describing the beneficiary's condition must be present on each physician's order. The supplier must include an ICD-9 code describing the condition that necessitates inhalation drug therapy on claims submitted for reimbursement for inhalation drugs and related supplies.

In addition, the ordering physician's medical records must contain information that supports the medical necessity for all DME and related supplies ordered. The information contained in the medical record does not have to be submitted with the claim, but must be made available, upon request, to the DMERC.

This multi-state review was a joint effort conducted by review teams from the Office of Inspector General and CMS. The objective of this review was to determine whether claims for inhalation drugs submitted by suppliers to Region C DMERC were billed for and paid in accordance with Medicare coverage and reimbursement requirements. In order to evaluate payments for inhalation drugs, we selected a statistical sample of 100 beneficiaries for whom payments for inhalation drugs were made by Region C DMERC. Our sample was selected from a population of beneficiaries for whom claims were paid by Region C DMERC for inhalation drug procedure codes (K0503 through K0528) with dates of service during the 12-month period ended September 30, 1999. We then reviewed all inhalation drug payments made during the 12-month period for the 100 beneficiaries selected.

We estimate that for the 12-month period ended September 30, 1999, the Region C DMERC paid suppliers approximately $134 million for inhalation drugs which were unallowable ($46 million) or for which there was insufficient documentation to determine their allowability ($88 million). During this period, Region C DMERC paid $224 million for inhalation drugs. Accordingly, about 60 percent of the payments made by Region C DMERC for inhalation drugs were either unallowable (21 percent) or not sufficiently documented to determine their allowability in accordance with Medicare requirements (39 percent).

Our review showed that $52,550 of inhalation drug payments contained on 392 of 702 claims for 52 beneficiaries (3 beneficiaries had errors in more than 1 category) did not meet the Medicare coverage and reimbursement requirements. Of the 392 claims with errors, we found that 105 claims for 18 beneficiaries with payments totaling $17,955 were unallowable because the payments were for (1) noncovered items or supplies (drugs billed without a prescription) or (2) items or supplies that were not reasonable and necessary for the beneficiary's condition.

For the remaining 287 claims for 36 beneficiaries, totaling $34,595, there was insufficient documentation in the suppliers' records or the physicians' medical records to determine whether the payments were made in accordance with Medicare requirements. These included claims for which: (1) supplier records did not contain adequate documentation to support proof of delivery, and/or (2) physician records did not contain sufficient documentation to determine whether he/she considered the use of a metered dose inhaler prior to prescribing inhalation drugs.

The Region C DMERC made payments to suppliers for inhalation drugs which were unallowable or for which there was insufficient documentation to determine their allowability. We believe this occurred primarily because the DMERC had inadequate prepayment review procedures in place to evaluate claims for inhalation drugs to ensure they were properly ordered, medically necessary, and used by beneficiaries as prescribed.

Accordingly, we recommended that CMS:

1. Reevaluate Region C DMERC policies and require the DMERC to focus on prepayment reviews of claims, as well as post-payment reviews of suppliers;

2. Require Region C DMERC to establish procedures to ensure that all suppliers of inhalation drugs maintain documentation supporting the services billed and that they bill only for services that are medically necessary; and

3. Require Region C DMERC to recover the specific unallowable payments we identified as part of our sample and review all other claims submitted by the suppliers for the beneficiaries in our sample to identify and recover any additional unallowable payments.

The CMS responded to our draft report in a memorandum dated August 21, 2001. The CMS concurred with our recommendations regarding inappropriate payments for inhalation drugs. Specifically, CMS stated that they would explore the need to modify their prepayment efforts to

address the unique problems associated with inhalation drugs in Region C. They also noted that CMS already requires DMERCs to use data analysis to identify possible abusive billing and contraindicated medication usage. The CMS also stated that they would work with the Region C DMERC to explore options for improving the documentation of services billed by its suppliers of inhalation drugs. With regard to unallowable payments, CMS stated that the overpayments identified have been turned over to Region C DMERC for recovery. The full text of CMS's comments is included as APPENDIX C.

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INTRODUCTION

BACKGROUND

Title XVIII of the Social Security Act (Act) provides for reimbursement of durable medical equipment (DME) under Part B (voluntary supplementary medical insurance) of the Medicare program. Medicare Part B provides for reimbursement of supplies that are necessary for the effective use of DME. Such supplies include those drugs and biologicals that must be put directly into DME in order to achieve the therapeutic benefit of the equipment or to assure the proper functioning of the equipment. The Medicare program is administered by the Centers for Medicare & Medicaid Services (CMS).

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Effective for claims with dates of service on or after December 1, 1996, only suppliers (pharmacies) licensed to dispense drugs may submit claims to DMERCs for prescription drugs used in conjunction with DME. To be covered and reimbursed by Medicare, all DME and related supplies, including prescription drugs, must be ordered by the beneficiary's treating physician. A narrative diagnosis and corresponding International Classification of Diseases 9th Edition (ICD-9) code describing the beneficiary's condition must be present on each physician's order. The supplier must include an ICD-9 code describing the condition that necessitates inhalation drug therapy on claims submitted for reimbursement for inhalation drugs and related supplies.

In addition, the ordering physician's medical records must contain information that supports the medical necessity for all DME and related supplies ordered. The information contained in the medical record does not have to be submitted with the claim, but must be made available, upon request, to the DMERC.

Based on CMS payment data, Region C DMERC made Medicare payments for inhalation drugs totaling $224,079,332 for 254,921 beneficiaries during the 12-month period ended September 30, 1999. These payments were exclusive of the beneficiary deductible and coinsurance.

Historically, Region C DMERC accounted for an inordinate proportion of inhalation drug payments. For example, in Calendar Year 1998, Region C DMERC had 34.6 percent of the nation's fee for service beneficiaries, but accounted for 47.1 percent of the beneficiaries receiving inhalation drugs and 56 percent of the total payments for inhalation drugs.

OBJECTIVE, SCOPE, AND METHODOLOGY

This multi-state review was a joint effort conducted by review teams from the Office of Inspector General (OIG) and CMS. The objective of this review was to determine whether claims for inhalation drugs submitted by suppliers to Region C DMERC were billed for and paid in accordance with Medicare coverage and reimbursement requirements. Because our audit objectives did not require an understanding or assessment of the complete internal control structures of CMS or the Region C DMERC, we limited our consideration of internal controls to those applicable to claims submission for inhalation drugs used with DME.

In order to evaluate payments for inhalation drugs, we selected a statistical sample of 100 beneficiaries for whom payments for inhalation drugs were made by Region C DMERC. Our sample was selected from a population of beneficiaries for whom claims were paid by Region C DMERC for inhalation drug procedure codes (K0503 through K0528) with dates of service during the 12-month period ended September 30, 1999. We then reviewed all inhalation drug payments made during the 12-month period for the 100 beneficiaries selected. The value of our sample was $87,901. APPENDIX A contains the details of our sampling methodology. APPENDIX B contains the results and projections of our sample.

To determine whether services were rendered in accordance with Medicare coverage and reimbursement requirements, review teams from OIG and CMS generally conducted three site visits for each beneficiary in our sample as follows:

1. The beneficiary was interviewed to learn about his/her medical history, to determine his/her use of the inhalation drugs, and to learn about his/her relationship with the ordering physician;

2. The supplier was visited to obtain records supporting all claims paid for inhalation drugs by Region C DMERC for the beneficiaries in our sample; and

3. The ordering physician was interviewed concerning the beneficiary's medical condition and treatment rendered by him/her. The review teams also obtained copies of the beneficiary's medical records for the period June 1998 through September 1999.

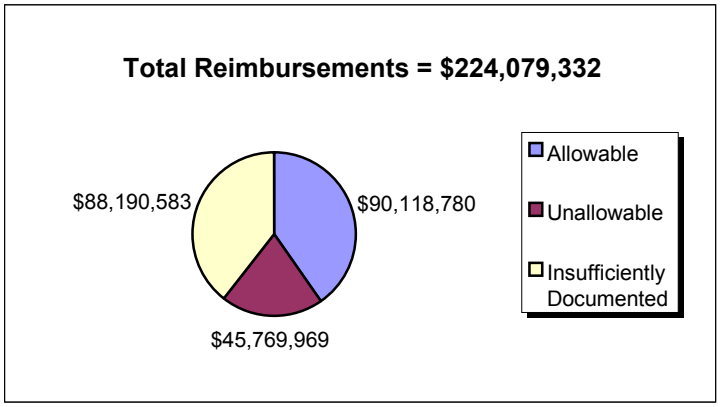
The information obtained from these interviews, as well as the medical records, were provided to CMS's program safeguard contractor (PSC) for review. The PSC was retained by CMS for the

purpose of reviewing all of the information collected in the interviews, as well as the records of the suppliers and physicians, in order to determine the appropriateness of Medicare payments. In order to meet applicable standards, we reviewed the work performed by CMS review teams and the PSC.

Our audit was performed in accordance with generally accepted government auditing standards. The field work was performed by staff from: OIG□s offices in Atlanta, Georgia; Miami, Florida; Tallahassee, Florida; San Juan, Puerto Rico; and Little Rock, Arkansas; at CMS's PSC in Springfield, Virginia; at CMS regional offices in Atlanta, Georgia and Dallas, Texas; at CMS satellite offices in Miami, Florida and New Orleans, Louisiana.

FINDINGS AND RECOMMENDATIONS

We estimate that for the 12-month period ended September 30, 1999, the Region C DMERC paid suppliers approximately $134 million for inhalation drugs which were unallowable ($46 million), or for which there was insufficient documentation to determine their allowability ($88 million). During this period, Region C DMERC paid $224 million for inhalation drugs.



Accordingly, about 60 percent of the payments made by Region C DMERC for inhalation drugs were either unallowable (21 percent), or not sufficiently documented to determine their allowability in accordance with Medicare requirements (39 percent).

Our review showed that $52,550 of inhalation drug payments contained on 392 of 702 claims for 52 beneficiaries (3 beneficiaries had errors in more than 1 category) did not meet the Medicare coverage and reimbursement requirements. Of the 392 claims with errors, we found that 105 claims for 18 beneficiaries with payments totaling $17,955 were unallowable because the payments were for (1) noncovered items or supplies (drugs billed without a prescription) or (2) items or supplies that were not reasonable and necessary for the beneficiary's condition.

For the remaining 287 claims for 36 beneficiaries, totaling $34,595, there was insufficient documentation in the suppliers' records or the physicians' medical records to determine whether the payments were made in accordance with Medicare requirements. These included claims for which: (1) supplier records did not contain adequate documentation to support proof of delivery, and/or (2) physician records did not contain sufficient documentation to determine whether he/she considered the use of a metered dose inhaler (MDI) prior to prescribing inhalation drugs.

UNALLOWABLE NEBULIZER DRUG PAYMENTS

We determined that 105 of the 702 claims in our sample, totaling $17,955 for 18 beneficiaries, were unallowable because they did not meet the Medicare coverage or reimbursement requirements. As a result, we estimate that suppliers were overpaid approximately $46 million by Region C DMERC for inhalation drugs. The payments on these claims were unallowable because they were for:

- noncovered items or supplies; or

- items or supplies that were not reasonable and necessary for the beneficiaries' condition.

Noncovered Items or Supplies

We found that suppliers billed Medicare for inhalation drugs totaling $3,425 for which they did not have a proper prescription signed and dated by the treating physician. These inhalation drugs were contained on 36 claims, billed on behalf of 9 beneficiaries.

Chapter 5 of CMS's Program Integrity Manual (PIM), section 1.1.1, requires that the supplier for all DME and related supplies is required to keep on file a physician prescription (order). The treating physician must sign and date the prescription and the supplier must have a prescription from the treating physician before dispensing the DME item or supplies to a beneficiary. In section 1.1.2, the PIM further states that, "If the supplier does not have a faxed or original order that has been both signed and dated by the treating physician, the item is noncovered, and the supplier must not submit a claim for the item to the DMERC."

During the review of supplier records, we found:

- One supplier, which had no prescriptions from the treating physician, was paid $258 for 3 claims containing 900 units of inhalation drugs on behalf of 1 beneficiary.

- Another supplier was paid $1,165 for 12 claims containing 2,712 units of inhalation drugs on behalf of 1 beneficiary. Although the supplier had a prescription for the inhalation drugs, it was written on the pharmacies own letterhead and had a stamped signature of the physician.

Items or Supplies Not Reasonable or Necessary for the Beneficiaries' Condition

The medical reviewers determined that inhalation drugs billed for 9 beneficiaries on 69 claims, totaling $14,530, were not medically necessary. For example:

- A supplier was paid $273 for 2 claims containing 360 units of inhalation drugs on behalf of 1 beneficiary who did not need inhalation drug treatments. The beneficiary's medical record did not contain documentation to show that the beneficiary had pulmonary disease, even though the physician had been treating the beneficiary for several years.

- Another supplier was paid $4,695 for 18 claims containing 1,215 units of inhalation drugs on behalf of 1 beneficiary for whom the treating physician had no medical records. The physician had closed his office in December 1998. He worked from his residence, made house calls, and wrote prescriptions for inhalation medication (about 99 percent of the physician's practice was prescribing refills for inhalation drugs). The physician had no medical records to support the treatments provided to the beneficiaries.[1]

Section 1862(a)(1)(A) of the Social Security Act states that no payment may be made by Medicare for items or services which are not reasonable and necessary for the diagnosis or treatment of the beneficiary's illness or injury. The CMS's PIM, chapter 5, section 2, requires that the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the type and quantity of the items ordered. The documentation in the medical record does not have to be routinely sent to the supplier or DMERC. However, the DMERC may request this information in selected cases. If the DMERC does not receive the information when requested, or if the information in the patient's medical record does not adequately support the medical necessity for the item or supply, the claim is not covered. For assigned claims, the

[1]The physician's total Medicare claims are currently under review by CMS.

supplier is liable for the dollar amount involved unless a properly executed advance beneficiary notice of possible denial has been obtained.

INSUFFICIENT DOCUMENTATION TO DETERMINE ALLOWABILITY OF NEBULIZER DRUG PAYMENTS

We found that 287 of 702 claims, totaling $34,595 for 36 beneficiaries (claims for 1 beneficiary had multiple errors), did not contain sufficient evidence to determine whether Region C DMERC payments to suppliers for inhalation drugs were made in accordance with Medicare requirements. We estimate that these errors could impact the Medicare program by as much as $88,190,583. These payments were made to suppliers for items or supplies for which the documentation did not meet the requirements for reimbursement. We found:

- Supplier records which did not contain sufficient documentation to support that the inhalation drugs contained on the claims in our sample were actually received by the beneficiary; and

- Physician medical records obtained and reviewed did not contain sufficient documentation to determine whether he/she considered the use of an MDI prior to prescribing inhalation drugs.

Supplier Records Did Not Adequately Document Proof of Delivery

We found that Medicare paid 152 claims totaling $20,170 for 18 beneficiaries for which the suppliers did not have adequate documentation to support proof of delivery. The required documentation was not always maintained in the suppliers' records. Instead, the suppliers relied on the delivery shipping service to maintain proof of delivery. We found, however, that delivery shipping services generally limited their retention of records to 18 months and did not require a signature confirming receipt on items delivered directly to a beneficiary.

We found 152 claims with inadequate documentation:

- 79 claims for which the shipping/delivery records were missing tracking numbers;

- 54 claims for which the delivery records included inappropriate or missing signatures for items or supplies that were delivered directly to the beneficiary; and

- 19 claims for which the shipping/delivery records were missing a detailed description of the quantity or amount delivered.

In accordance with the DMERC supplier manual, Region C DMERC can deny claims and issue overpayment demand letters to suppliers that do not maintain sufficient documentation to support proof of delivery. Where a supplier consistently fails to provide such documentation, the supplier can be subjected to civil monetary penalties or administrative sanctions.

The Region C DMERC's policies and procedures require suppliers to maintain proof of delivery documentation in the beneficiary's record. These procedures specify that: (1) the supplier maintain a signed delivery slip when the supplier delivers directly to the beneficiary; (2) when the supplier uses a delivery service, acceptable proof of delivery would include the delivery service's tracking slip and shipping invoice; and (3) delivery to nursing facilities be subject to strict inventory control. The suppliers are not required to submit proof of delivery with their claim for reimbursement under the Medicare program. They are, however, required to retain proof of delivery documentation and furnish the documentation to the Region C DMERC upon request.

Physician Did Not Consider Use of an MDI

We found that Medicare paid $14,425 for 135 claims for 19 beneficiaries when the medical records did not contain sufficient documentation to support that the physician considered the use of an MDI prior to the start of inhalation drug treatment.

To be medically necessary, inhalation drugs must be dispensed in accordance with coverage and payment rules set forth in the Region C DMERC supplier manual. Under these rules "...the physician must have considered use of a metered dose inhaler (MDI) with and without a reservoir or spacer device and decided that, for medical reasons, it was not sufficient for the administration of needed inhalation drugs. The reason for requiring a small volume nebulizer and related compressor/generator, instead of or in addition to a MDI must be documented in the patient's medical record and be available to the DMERC on request."

REGION C DMERC MONITORING EFFORTS

The Region C DMERC made payments to suppliers for inhalation drugs which were unallowable or for which there was insufficient documentation to determine their allowability. We believe this occurred primarily because the DMERC had inadequate prepayment and post-payment review procedures in place to evaluate claims for inhalation drugs to ensure they were properly ordered, medically necessary, and delivered to the beneficiaries as prescribed.

Instead, when reviewing claims for inhalation drugs, Region C DMERC focused mainly on whether or not there was aberrant activity. For example, the system identified and issued reports when: (1) excessive drug usage was detected; (2) the drugs billed were not in conformance with

unit dose coding guidelines; and (3) more than one inhalation drug was billed during the same month. Any item identified in these situations caused Region C DMERC to investigate and take corrective action. There were no procedures in place, however, to identify at the supplier level that the inhalation drugs billed were medically necessary, supported by a prescription, or that the beneficiary received the drug. Under Region C DMERC procedures, the documentation for inhalation drug payments must be maintained by the prescribing physician and by the pharmacy supplying the drug. Additionally, since inhalation drug prescriptions were generally issued for a 1-year duration, and because there were no requirements to perform reviews at the physician and supplier except for certain situations, Region C DMERC could not be sure that its payments for inhalation drugs were made in accordance with Medicare program requirements.

CONCLUSIONS AND RECOMMENDATIONS

The Region C DMERC made payments to suppliers for inhalation drugs that were unallowable or not sufficiently documented to determine their allowability in accordance with Medicare requirements. We believe that these payments occurred because it was Region C DMERC policy to rely on the prescribing physician and supplier to retain all documentation for the medications billed. There were no procedures in place, except for specific situations, to "look behind" the claim at the beneficiary's medical record or at the documentation maintained by the supplier.

More importantly, Region C DMERC's current posture of focusing on individual aberrant suppliers through post-payment review and fraud investigations does little to address the fundamental findings of our review. Our review, which was based on a statistical sample of beneficiaries/claims, not individual suppliers, demonstrates the need for DMERCs to focus on prepayment reviews of claims to prevent inappropriate payments, thereby minimizing potential losses to the Medicare Trust Funds.

As a result, in our statistical sample of 100 beneficiaries, we found that 392 of the 702 claims paid included inhalation drugs that were unallowable or insufficiently documented in the supporting medical records to determine their allowability in accordance with Medicare requirements. Extrapolating the results of the statistical sample over the population from Region C DMERC using standard statistical methods, we estimate that the suppliers claimed a total of $133,960,552 for potentially unallowable or insufficiently documented inhalation drug payments.

Accordingly, we recommended that CMS:

1. Reevaluate Region C DMERC policies and require the DMERC to focus on prepayment reviews of claims, as well as post-payment reviews of suppliers;

2. Require Region C DMERC to establish procedures to ensure that all suppliers of inhalation drugs maintain documentation supporting the services billed and that they bill only for services that are medically necessary; and

3. Require Region C DMERC to recover the specific unallowable payments we identified as part of our sample and review all other claims submitted by the suppliers for the beneficiaries in our sample to identify and recover any additional unallowable payments.

CMS COMMENTS

The CMS responded to our draft report in a memorandum dated August 21, 2001. The CMS concurred with our recommendations regarding inappropriate payments for inhalation drugs. Specifically, CMS stated that they would explore the need to modify their prepayment efforts to address the unique problems associated with inhalation drugs in Region C. They also noted that CMS already requires DMERCs to use data analysis to identify possible abusive billing and contraindicated medication usage. Further, CMS stated that they would work with the Region C DMERC to explore options for improving the documentation of services billed by its suppliers of inhalation drugs. With regard to unallowable payments, CMS stated that the overpayments identified have been turned over to Region C DMERC for recovery. The full text of CMS's comments is included as APPENDIX C.

OIG RESPONSE

The OIG is very grateful for the tremendous assistance provided by CMS staff, as well as staff from Palmetto, the Region C DMERC, and Lifecare, the program safeguard contractor. The CMS Region IV, including the manager and staff of the Miami, Florida satellite office, played an integral role in designing, planning, and conducting this review. In addition, staff from Palmetto used data analysis to identify possible problems and worked in conjunction with CMS and OIG in the past to control nebulizer drug payments.

APPENDICES

APPENDIX A

SAMPLING METHODOLOGY

OBJECTIVE

The objective of our review was to determine whether claims for inhalation drugs submitted by suppliers to Region C Durable Medical Equipment Regional Carrier (DMERC) were billed for and paid in accordance with Medicare coverage and reimbursement requirements.

POPULATION

We used the universe of all beneficiaries who received services paid by Region C DMERC with the procedure codes K0503 through K0528 (these codes represent 24 drug products used with nebulizer equipment) for the year ended September 30, 1999.

The universe included the following data:

Total Beneficiaries	254,921
Total Estimated Medicare Payments	$224,079,332

SAMPLE UNITS

The sample unit was a beneficiary who received one or more services with the procedure codes K0503 through K0528.

SAMPLE DESIGN

Unrestricted random sample

SAMPLE SIZE

100 Beneficiaries

ESTIMATION METHODOLOGY

Using the Office of Audit Services statistical software for unrestricted variable appraisal sampling, we projected the error amount for unallowable and non-documented services.

APPENDIX B

PROJECTIONS

RESULTS OF SAMPLE

No. of Benes in Sample	Value of Sample	Beneficiary Errors[1]	Value of Errors	Number of Claims in Sample	Number of Claims in Error
100	$87,901	52	$52,550	702	392

Projections	
Errors Identified in Sample (52 Beneficiaries)	392
Value of Errors in Sample	52,550
Point Estimate	**$133,960,552**
At the 90% Confidence Level:	
Lower Limit	$ 88,550,121
Upper Limit	$179,370,983

Projections	
Unallowable Errors in Sample (18 Beneficiaries)	105
Value of Unallowable Errors in Sample	$ 17,955
Point Estimate	**$ 45,769,969**
At the 90% Confidence Level:	
Lower Limit	$ 11,940,714
Upper Limit	$ 79,599,225

Projections	
Non-documented Errors in Sample (36 Beneficiaries)	287
Value of Non-documented Errors in Sample	$ 34,595
Point Estimate	**$ 88,190,583**
At the 90% Confidence Level:	
Lower Limit	$ 54,521,930
Upper Limit	$121,859,236

[1] Three beneficiaries in our sample had errors in more than one category.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

DATE: AUG 21 2001

TO: Janet Rehnquist
Inspector General
Office of Inspector General

FROM: Ruben J. King-Shaw, Jr.
Deputy Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Review of Payments for Inhalation Drugs Made by Region C Durable Medical Equipment Regional Carrier* (A-06-00-00053)

Thank you for the opportunity to review and comment on the above-referenced draft report. The Centers for Medicare & Medicaid Services (CMS) would like to thank the OIG for sponsoring this joint CMS/OIG project to further explore the Medicare program vulnerabilities associated with the inhalation drug benefit. The project team, composed of CMS Miami satellite office staff, program safeguard contractor (PSC) staff, and OIG, were able to use a coordinated, cross-agency approach to develop a number of recommendations that will further safeguard this Medicare benefit. Further, CMS was pleased to utilize the expertise of one of our PSCs, LifeCare Management Partners, in this effort. We hope to be able to work more closely with OIG on these types of coordinated studies in the future.

We share the concerns expressed by OIG regarding inappropriate payments for inhalation drugs, and would like to provide the following comments on the specific recommendations included in the draft report:

OIG Recommendation

Re-evaluate Region C durable medical equipment regional carrier (DMERC) policies and require the DMERC to focus on pre-payment reviews of claims, as well as post-payment reviews of suppliers.

CMS Response

We concur. We understand the unique circumstances surrounding payments for inhalation drugs in Region C and the potential need to focus pre-payment review for these services on claims versus providers. Currently, CMS's fiscal year 2002 Budget and Performance Requirements document places added emphasis on pre-payment review of claims, and

The Health Care Financing Administration (HCFA) was renamed to the Centers for Medicare & Medicaid Services (CMS). We are exercising fiscal restraint by exhausting our stock of stationery.

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DMERCs are required to implement their regional medical review policy (RMRP) and CMS's national coverage policies through automated pre-payment edits wherever feasible. In addition to these efforts, we will further explore the need to modify our pre-payment efforts to address the unique problems associated with inhalation drugs in Region C.

OIG Recommendation
Require Region C DMERC to establish procedures to ensure that all suppliers of inhalation drugs maintain documentation supporting the services billed and that they bill only for services that are medically necessary.

CMS Response
We concur. The DMERCs currently devote a portion of their routine supplier bulletins to provider education and outreach efforts. All DMERCs RMRPs include documentation requirements. The DMERCs will continue to pursue these communication channels and CMS will work with the Region C DMERC to explore further options for enhancing education to providers supplying inhalation drugs. It is important to note that CMS continually strives to balance the burden placed on physicians and suppliers by documentation requirements, with the ability to efficiently safeguard the Medicare Trust Fund.

OIG Recommendation
Require Region C DMERC to recover the specific unallowable payments we identified as part of our sample and review all other claims submitted by the suppliers for the beneficiares in our sample to identify and recover any additional unallowable payments.

CMS Response
We concur. It is our understanding that the overpayments identified in this report have already been turned over to the DMERC, Palmetto, for recovery.

In addition, we have the following general comments:

The CMS asks that OIG recognize in its report the importance of data analysis as a method for focusing review on specific services, benefits, or providers. The CMS requires the DMERCs to use data analysis and other active techniques to identify sources of possible abusive billing and to act based on these findings. Data analysis not only helps to identify possible problems, but also assists the DMERC in prioritizing its medical review workload in order to ensure the greatest savings to the program.

To date, data analysis remains our most efficient tool in selecting services and providers for pre-payment review, post-payment review, and proactive benefit integrity case development. Many different parameters are used in the data analysis to include: geographic variables, utilization rates, identification of outliers or aberrancies in reimbursement figures, codes billed, and ordering physician/supplier associations.

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In Palmetto's case, data analysis has contributed substantially to reductions in improper nebulizer charges.

Additionally, we would like OIG to recognize in its report the work that Palmetto has done, in conjunction with CMS and OIG in the past, to control nebulizer drug payments. For example, Palmetto conducted audits and investigations with CMS and the OIG that resulted in the identification of beneficiaries who were receiving as many as 8 different nebulizer medications. This Drug Anomaly Project resulted in numerous referrals to law enforcement. It also led to the development of an edit for the contraindicated medications. The edit is designed to deny claims based on medical necessity in situations where the quantities of medications are determined to be higher than medically reasonable and where contraindicated medications, as identified from a beneficiary's claims history, are billed.

Attachment

Page 4- Janet Rehnquist

Technical Comments

- On page 4 of the report, first paragraph, first sentence, OIG states that its review showed that certain inhalation drug payments did not meet Medicare coverage and reimbursement "requirements." Since it seems that the basis for OIG's determination rests primarily on a Program Integrity Manual (PIM), as opposed to the statute or regulations, we recommend that the word "requirements" be changed to "standards."

- We also recommend that the characterization of the PIM be revised. Specifically, we suggest that in the first sentence of the last paragraph on page 4, the word "requires" be changed to "provides."

- Similarly, we recommend that the characterization of the PIM at the bottom of page 5 be revised. In the second sentence of the last paragraph, the word "requires" should be changed to "provides."