



January 4, 2010

TO: Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /John Hapchuk/ for
Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Review of Medicare Payments for Selected Durable Medical Equipment Claims
With the KX Modifier for Calendar Year 2006 (A-04-08-04020)

Attached is an advance copy of our final report on Medicare payments for selected durable medical equipment claims with the KX modifier for calendar year 2006. We will issue this report to CIGNA Government Services (CGS), the durable medical equipment Medicare administrative contractor (DME MAC) for Jurisdiction C, within 5 business days.

Pursuant to sections 1832(a)(1) and 1861(n) of the Social Security Act (the Act), Medicare Part B provides for the coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Centers for Medicare & Medicaid Services (CMS) contracted with four DME MACs to process and pay Medicare Part B claims for DMEPOS. These DME MACs replaced the Durable Medical Equipment Regional Carriers. Also, CMS contracts with Palmetto Governmental Benefits Administrators, LLC (Palmetto GBA), to serve as the National Supplier Clearinghouse. The National Supplier Clearinghouse is responsible for enrolling and reenrolling DMEPOS suppliers.

For certain DMEPOS, suppliers must use the KX modifier on filed claims. The KX modifier indicates that the supplier has the required documentation on file. While suppliers must have a written physician's order and proof of delivery for all DMEPOS, suppliers must have additional documentation on file for items requiring the KX modifier. For example, respiratory assist devices also require documentation that a sleep study was performed before the date on the physician's order.

Our objective was to determine whether the KX modifier was effective in ensuring that suppliers of DMEPOS who submitted claims to Palmetto GBA had the required supporting documentation on file.

The KX modifier was not effective in ensuring that suppliers of DMEPOS who submitted claims to Palmetto GBA had the required supporting documentation on file. Of the 100 items in our sample, totaling \$8,809, suppliers had the required documentation on file for 46. However, suppliers did not have the required documentation on file for the remaining 54, totaling \$4,574. As a result, Palmetto GBA made unallowable payments totaling \$4,574 for 54 of the 100 sampled items. Based on our sample, we estimated that Palmetto GBA paid approximately \$127 million to suppliers who did not have the required documentation on file to support the DMEPOS items with calendar year 2006 dates of service.

The types of missing documentation included the following: proof of delivery (23 of 100 items), physician's order (20 of 100 items), use or compliant use follow-up documentation (19 of 72 applicable items), and physician's statement (5 of 28 applicable items). For 10 of the 54 items, suppliers were missing multiple required documents.

These errors occurred because Palmetto GBA's electronic edits in place were not effective for determining whether suppliers had the required documentation on file when they used the KX modifier on claims. The edits could only determine whether the required KX modifier was on the claim.

We recommend that CGS, as the current DME MAC, recover the \$4,420 (\$154 was repaid during fieldwork) in payments for specific DMEPOS items claimed for which the suppliers did not have the required documentation; review other payments for DMEPOS related to our unallowable sample items and recover any additional unallowable payments; notify CMS of the 23 suppliers who did not meet the supplier standard for maintaining proof of delivery so CMS can take appropriate action; and develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$127 million.

In written comments to the draft report, CGS acknowledged the facts presented in the report and described the actions it intends to take in response to our recommendations.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at George.Reeb@oig.hhs.gov or Peter J. Barbera, Regional Inspector General for Audit Services, Region IV, at (404) 562-7800 or through email at Peter.Barbera@oig.hhs.gov. Please refer to report number A-04-08-04020.

Attachment



Office of Audit Services, Region IV
61 Forsyth Street, SW., Suite 3T41
Atlanta, GA 30303

January 11, 2010

Ms. Jean Rush
President, CIGNA Government Services
2 Vantage Way
Nashville, Tennessee 37228

Dear Ms. Rush:

Enclosed is the Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Medicare Payments for Selected Durable Medical Equipment Claims With the KX Modifier for Calendar Year 2006." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me at (404) 562-7800, or contact Mark Wimple, Audit Manager, at (919) 790-2765, extension 24, or through email at Mark.Wimple@oig.hhs.gov. Please refer to report number A-04-08-04020 in all correspondence.

Sincerely,

/Peter J. Barbera/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Nanette Foster Reilly, Consortium Administrator
Consortium for Financial Management & Fee for Service Operations
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 235
Kansas City, Missouri 64106

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF MEDICARE
PAYMENTS FOR SELECTED
DURABLE MEDICAL EQUIPMENT
CLAIMS WITH THE KX MODIFIER FOR
CALENDAR YEAR 2006**



Daniel R. Levinson
Inspector General

January 2010
A-04-08-04020

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <http://oig.hhs.gov>

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to sections 1832(a)(1) and 1861(n) of the Social Security Act (the Act), Medicare Part B provides for the coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Centers for Medicare & Medicaid Services (CMS) contracted with four durable medical equipment Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims for DMEPOS. These DME MACs replaced the Durable Medical Equipment Regional Carriers (DMERC). Also, CMS contracts with Palmetto Governmental Benefits Administrators, LLC (Palmetto GBA), to serve as the National Supplier Clearinghouse. The National Supplier Clearinghouse is responsible for enrolling and reenrolling DMEPOS suppliers.

Under the statutory and policy framework of the Act, the “Medicare National Coverage Determinations Manual” defines DME as equipment that can withstand repeated use, serves a medical purpose, is generally not useful to a person in the absence of illness or injury, and is appropriate for use in a patient’s home. For certain DMEPOS, suppliers must use the KX modifier on filed claims. The KX modifier indicates that the supplier has the required documentation on file. While suppliers must have a written physician’s order and proof of delivery for all DMEPOS, suppliers must have additional documentation on file for items requiring the KX modifier. For example, respiratory assist devices also require documentation that a sleep study was performed before the date on the physician’s order.

On January 16, 2007, CMS awarded the DME MAC contract for Jurisdiction C to CIGNA Government Services (CGS). CGS assumed full responsibility for administering the DME MAC work and began processing DMEPOS claims for Jurisdiction C as of June 1, 2007. Palmetto GBA was the Region C DMERC and processed the DMEPOS claims through May 31, 2007. (CMS refers to the DMERCs’ coverage areas as “regions” and the DME MACs’ coverage areas as “jurisdictions.”)

Palmetto GBA processed approximately \$4 billion in Medicare DMEPOS claims with calendar year 2006 dates of service. This audit focused on \$257,925,264 of Medicare paid claims processed by Palmetto GBA for therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure reducing support surfaces (groups 1 and 2) that included the KX modifier.

OBJECTIVE

Our objective was to determine whether the KX modifier was effective in ensuring that suppliers of DMEPOS who submitted claims to Palmetto GBA had the required supporting documentation on file.

SUMMARY OF FINDINGS

The KX modifier was not effective in ensuring that suppliers of DMEPOS who submitted claims to Palmetto GBA had the required supporting documentation on file. Of the 100 items in our sample, totaling \$8,809, suppliers had the required documentation on file for 46. However, suppliers did not have the required documentation on file for the remaining 54, totaling \$4,574. As a result, Palmetto GBA made unallowable payments totaling \$4,574 for 54 of the 100 sampled items. Based on our sample, we estimated that Palmetto GBA paid approximately \$127 million to suppliers who did not have the required documentation on file to support the DMEPOS items with calendar year 2006 dates of service.

The types of missing documentation included:

- proof of delivery (23 of 100 items),
- physician's order (20 of 100 items),
- use or compliant use follow-up documentation (19 of 72 applicable items), and
- physician's statement (5 of 28 applicable items).

For 10 of the 54 items, suppliers were missing multiple required documents.

These errors occurred because Palmetto GBA's electronic edits in place were not effective for determining whether suppliers had the required documentation on file when they used the KX modifier on claims. The edits could only determine whether the required KX modifier was on the claim.

RECOMMENDATIONS

We recommend that CGS, as the current DME MAC:

- recover the \$4,420 (\$154 was repaid during fieldwork) in payments for specific DMEPOS items claimed for which the suppliers did not have the required documentation;
- review other payments for DMEPOS related to our unallowable sample items and recover any additional unallowable payments;
- notify CMS of the 23 suppliers who did not meet the supplier standard for maintaining proof of delivery so CMS can take appropriate action; and
- develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$127 million.

AUDITEE COMMENTS

In written comments to the draft report, CGS acknowledged the facts presented in the report and listed actions it intends to take in response to our recommendations. CGS's comments are included in their entirety as Appendix D.

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
BACKGROUND	1
Contracts for Processing Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Claims	1
KX Modifier Used for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Claims Processing	2
OBJECTIVE, SCOPE, AND METHODOLOGY	3
Objective	3
Scope.....	3
Methodology	4
FINDINGS AND RECOMMENDATIONS	5
MISSING REQUIRED DOCUMENTATION	5
Proof of Delivery	5
Physician’s Order.....	6
Use or Compliant Use Follow-Up Documentation.....	6
Physician’s Statement	7
KX MODIFIER SYSTEM EDITS	7
EFFECT OF UNALLOWABLE PAYMENTS	7
RECOMMENDATIONS	8
AUDITEE COMMENTS	8
 APPENDIXES	
A – SAMPLE DESIGN AND METHODOLOGY	
B – SAMPLE RESULTS AND ESTIMATES	
C – ERROR DETAILS	
D – AUDITEE COMMENTS	

INTRODUCTION

BACKGROUND

The Medicare program, established by Title XVIII of the Social Security Act (the Act) in 1965 provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. Pursuant to sections 1832(a)(1) and 1861(n) of the Act, Medicare Part B provides for the coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS contracted with four durable medical equipment Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims for DMEPOS. These DME MACs replaced the Durable Medical Equipment Regional Carriers (DMERC). Also, CMS contracts with Palmetto Governmental Benefits Administrators, LLC (Palmetto GBA), to serve as the National Supplier Clearinghouse. The National Supplier Clearinghouse is responsible for enrolling and reenrolling DMEPOS suppliers. CMS will revoke a supplier's billing privileges if it finds that the supplier does not meet the supplier standards (42 CFR § 424.57(c) and (d)).¹

Contracts for Processing Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Claims

On January 16, 2007, CMS awarded the DME MAC contract for Jurisdiction C to CIGNA Government Services, LLC (CGS). CGS assumed full responsibility for administering the DME MAC work and began processing DMEPOS claims for Jurisdiction C as of June 1, 2007. CGS processes DMEPOS claims for Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, U.S. Virgin Islands, Virginia, and West Virginia.

Palmetto GBA was the Region C DMERC and processed the DMEPOS claims through May 31, 2007.² Palmetto GBA transferred its DMEPOS files to CGS after CMS awarded CGS the DME MAC contract for Jurisdiction C.

¹Federal requirements referenced in this document are the ones that were in effect during our audit period.

²CMS refers to the DMERCs' coverage areas as "regions" and the DME MACs' coverage areas as "jurisdictions." The Region C DMERC's coverage area also included Kentucky but did not include Virginia or West Virginia.

KX Modifier Used for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Claims Processing

National Coverage Determinations (NCD) describe the circumstances for Medicare coverage nationwide for specific medical service procedures or devices, including DMEPOS, and generally outline the conditions under which a service or device is considered covered. The “Medicare National Coverage Determinations Manual” (Pub. No. 100-03, chapter 1, section 280.1) defines DMEPOS as equipment that can withstand repeated use, serves a medical purpose, is generally not useful to a person in the absence of illness or injury, and is appropriate for use in a patient’s home.

Contractors develop Local Coverage Determinations (LCD) for some covered DMEPOS items. LCDs specify under what clinical circumstances the DMEPOS item is considered to be reasonable and necessary. For covered DMEPOS items (including therapeutic shoes for diabetics (therapeutic shoes), continuous positive airway pressure systems (CPAP), respiratory assist devices (RAD), and pressure reducing support surfaces (groups 1 and 2) (PRSS)³), the LCDs require a KX modifier be added to the claims before they can be paid. By adding the KX modifier, the supplier attests that the specific required documentation, which varies based on the DMEPOS item, is on file at the supplier before submitting the claim to the DME MAC. This documentation requirement includes the written physician’s order and proof of delivery that are required for all DMEPOS, as well as additional documentation such as a sleep study for a RAD claim.

Through LCDs and Internet postings, the contractors instructed the suppliers to use the KX modifier only if the suppliers have the required documentation on file. However, if the KX modifier is not used with claims for DMEPOS that require it, the claims will be denied.

This audit focused on claims paid by Palmetto GBA for therapeutic shoes, CPAPs, RADs, and PRSS.

³These DMEPOS are included in the Level II Healthcare Common Procedure Coding System, which is a comprehensive, standardized system that classifies similar medical products into categories for efficient claims processing. It is the standardized coding system used for describing, identifying, and preparing claims for DMEPOS.

Documentation Requirements for Selected Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Requiring the KX Modifier

Documentation Required To Be on File at Supplier	Required by	Therapeutic Shoes	CPAP	RAD	PRSS
Physician's Order (written, signed, and dated)	-“Program Integrity Manual” (PIM), Pub. No. 100-08, chapter 5 -LCD	X	X	X	X
Proof of Delivery	-42 CFR § 424.57(c)(12) -PIM, chapter 4	X	X	X	X
Statement of Treating/ Ordering Physician Before Delivery	-The Act, § 1861(s)(12) (A-C) -LCD	X			X
Polysomnography (sleep study) Before Physician's Order	-NCD -LCD		X	X	
Use or Compliant Use Follow-up Statement of Physician and/or Beneficiary	-LCD		X	X	

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the KX modifier was effective in ensuring that suppliers of DMEPOS who submitted claims to Palmetto GBA had the required supporting documentation on file.

Scope

Palmetto GBA processed approximately \$4 billion in Medicare DMEPOS claims with calendar year 2006 dates of service. This audit focused on \$257,925,264 of Medicare paid claims for therapeutic shoes, CPAPs, RADs, and PRSS that included the KX modifier. The Region C DMERC (Palmetto GBA) processed the claims. However, in connection with the transition to

DME MACs, the DMERC transferred its workload to the current Jurisdiction C DME MAC (CGS).⁴

We limited our review of internal controls to gaining an understanding of the contractors' processing of selected DMEPOS claims that were submitted with the KX modifier.

From December 2007 through October 2008, we conducted fieldwork at CGS offices in Nashville, Tennessee; at the National Supplier Clearinghouse offices in Columbia, South Carolina; and at supplier offices in 14 States and Puerto Rico.

Methodology

To accomplish our audit objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CGS officials concerning the manual and electronic claims processing procedures for claims for therapeutic shoes, CPAPs, RADs, and PRSS with the KX modifier and CGS's and Palmetto GBA's edits in the claims processing system to ensure that claims were adjudicated;
- interviewed CGS officials concerning the education and training specific to the KX modifier that CGS and Palmetto GBA provided to the suppliers of therapeutic shoes, CPAPs, RADs, and PRSS;
- selected a simple random sample of 100 items from four categories of DMEPOS (Appendix A);
- made unannounced visits to the 94 suppliers⁵ to obtain their documentation supporting the use of the KX modifier;
- reviewed the suppliers' applications and/or renewals to dispense DMEPOS;
- reviewed the suppliers' documentation for the sample items to determine whether it met the requirements for using the KX modifier; and
- requested CGS's medical review staff review the documentation provided by the suppliers for those sample items that we determined did not meet the documentation requirements for use of the KX modifier.

⁴Kentucky was part of the Region C DMERC's coverage area. However, CMS made certain coverage area realignments during the transition to DME MACs, including making Kentucky part of DME MAC Jurisdiction B. Thus, according to CMS's DME MAC Workload Implementation Handbook, the DMERC should have transferred the Kentucky workload to the Jurisdiction B DME MAC.

⁵Six of the ninety-four suppliers had two items in the sample.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

The KX modifier was not effective in ensuring that suppliers of DMEPOS who submitted claims to Palmetto GBA had the required supporting documentation on file. Of the 100 sampled items, suppliers had the required documentation on file for 46 items.⁶ Suppliers did not have the required documentation on file for the remaining 54 items. As a result, Palmetto GBA made unallowable payments totaling \$4,574 for 54 of the 100 sampled items. Based on our sample, we estimated that Medicare paid approximately \$127 million to suppliers who did not have the required documentation on file to support the DMEPOS items with 2006 dates of service.

The types of missing documentation included:

- proof of delivery (23 of 100 items),
- physician's order (20 of 100 items),
- use or compliant use follow-up documentation (19 of 72 applicable items), and
- physician's statement (5 of 28 applicable items).⁷

Additional details on the results of the sampled items are provided in Appendixes B and C.

These errors occurred because Palmetto GBA's electronic edits in place were not effective for determining whether suppliers had the required documentation on file when they used the KX modifier on claims. The edits could only determine whether the required KX modifier was on the claim.

MISSING REQUIRED DOCUMENTATION

Proof of Delivery

Pursuant to the supplier standard (42 CFR § 424.57(c)(12)), the supplier "[m]ust be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery." Also, the PIM, chapter 4, section 4.26, requires suppliers to maintain proof of delivery documentation in their files for 7 years. Section 4.26.1 outlines proof of delivery requirements for different methods of delivery. Section 4.26 also states that, for "any services, which do not

⁶Five of these forty-six sampled items were from suppliers who were no longer active.

⁷For 10 of the 54 sampled items, suppliers were missing multiple required documents.

have proof of delivery from the supplier, such claimed items and services shall be denied and overpayments recovered.”

For 23 of the 100 items, suppliers did not have proof of delivery documentation on file to support billing for the DMEPOS. In all 23 instances, at least one of the following deficiencies occurred: the delivery ticket was missing, the delivery ticket was not signed and dated by the beneficiary or his or her designee, or the documentation for shipped items such as tracking numbers or the supplier’s invoice was missing.

Physician’s Order

The PIM, chapter 5, section 5.1.1,⁸ states that all DMEPOS suppliers are required to keep on file a physician’s order. The treating physician must sign and date the order. Section 5.1.1.2⁹ states that if the supplier does not have a written order signed and dated by the treating physician before billing Medicare, the item will be denied.

For 20 of the 100 items, suppliers did not have a physician’s order on file to support billing for the DMEPOS. In all 20 instances, at least one of the following deficiencies occurred: the order was missing, the order was not signed and dated by the physician, or the DMEPOS item was not listed on the order.

Use or Compliant Use Follow-Up Documentation

The LCDs for the CPAP, effective January 1 and March 1, 2006, and the LCDs for the RAD effective January 1, March 1, and April 1, 2006, state that, for an E0601 (CPAP) and an E0470 (RAD) to be covered beyond the first 3 months of therapy, the supplier must ascertain no sooner than the 61st day after initiating therapy that the CPAP is being used and that the RAD is being compliantly used. For the CPAP, either the beneficiary or the treating physician must confirm that the beneficiary is continuing to use the CPAP, and the supplier must maintain documentation that the requirement has been met. For the RAD, the supplier must obtain signed statements from both the treating physician and the beneficiary stating that the RAD is being compliantly used.¹⁰ The LCDs state that continued coverage of the device will be denied if the requirements are not met.

For 19 of the 72 applicable items in our sample, suppliers did not have the use or compliant use follow-up documentation on file to support billing for the DMEPOS. In all 19 instances, at least one of the following deficiencies occurred: the use or compliant use follow-up documentation was missing, the use or compliant use follow-up was done within 60 days after initiating therapy, the statement(s) required to be completed by the treating physician and/or the beneficiary were

⁸Section 5.2.1 in the October 1, 2006, revision.

⁹Section 5.2.3 in the October 1, 2006, revision.

¹⁰The LCD defines “compliantly used” for a RAD as an average usage of 4 hours out of 24 hours.

missing for the RAD, or the item was billed after the first 3 months but before the supplier obtained use or compliant use follow-up documentation.

Physician's Statement

Pursuant to the Act, § 1861(s)(12)(A), the physician must certify that the patient meets specific criteria for therapeutic shoes. The LCD for therapeutic shoes, effective January 1 and March 1, 2006, and the LCDs, effective October 1, 2005, and March 1, 2006, for PRSS state that DMEPOS items are covered if the supplier obtains a signed and dated statement from the certifying or treating physician¹¹ saying the patient meets specific criteria. The physician's statement must be signed and dated some time during the year before the date of service for therapeutic shoes. The LCDs state that the item will be denied if the requirements are not met.

For 5 of the 28 items in our sample requiring a physician's statement, suppliers did not have the physicians' statements on file to support billing for the DMEPOS. In all five instances, at least one of the following deficiencies occurred: the physician's statement of medical need was missing, was incomplete, or was not timely.

KX MODIFIER SYSTEM EDITS

The LCDs require DMEPOS suppliers to include the KX modifier on claims submitted for therapeutic shoes, CPAPs, RADs, and PRSS when the "specific required documentation is on file." Use of the KX modifier constitutes a statement that the suppliers have the documentation on file that the policy requires for the particular item or service.

Palmetto GBA established electronic edits to evaluate the claims submitted by the DMEPOS suppliers. However, the edits were not effective for determining whether suppliers had the required documentation on file when they used the KX modifier on claims. The edits could only determine whether the required KX modifier was on the claim.

EFFECT OF UNALLOWABLE PAYMENTS

For 54 of the 100 items in our sample, suppliers who did not have the required documentation on file to support their use of the KX modifier received \$4,574 in payments. Based on our sample, we estimated that Palmetto GBA paid approximately \$127 million in unallowable Medicare payments to DMEPOS suppliers with 2006 dates of service.

Before we completed our fieldwork, 1 of the 54 suppliers voluntarily repaid \$154 for one of the sampled items.

¹¹The certifying or treating physician is the physician who treats the underlying condition that requires the use of the DMEPOS.

RECOMMENDATIONS

We recommend that CGS, as the current DME MAC:

- recover the \$4,420 in payments for specific DMEPOS items claimed for which the suppliers did not have the required documentation;
- review other payments for DMEPOS related to our unallowable sample items and recover any additional unallowable payments;
- notify CMS of the 23 suppliers who did not meet the supplier standard for maintaining proof of delivery so CMS can take appropriate action; and
- develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$127 million.

AUDITEE COMMENTS

In written comments to the draft report, CGS acknowledged the facts presented in the report and described actions it intends to take in response to our recommendations.

CGS's comments are included in their entirety as Appendix D.

APPENDIXES

APPENDIX A: SAMPLE DESIGN AND METHODOLOGY

Population

The population consisted of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items for the year ending December 31, 2006, that DMEPOS suppliers claimed for payment using the KX modifier under Medicare Part B.

Sampling Frame

The sampling frame consisted of 2,775,403 items totaling \$257,925,264 for the year ending December 31, 2006. These items were for specific categories of DMEPOS (therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure reducing support surfaces (groups 1 and 2)) claimed for payment using the KX modifier under Medicare Part B.

Sample Unit

The sample unit was a line item payment made to a DMEPOS supplier, based on the use of the KX modifier, for DMEPOS in one of the categories above.

Sample Design

We used a simple random sample.

Sample Size

We selected a sample of 100 DMEPOS line items.

Source of Random Numbers

We generated the random numbers with the Office of the Inspector General (OIG), Office of Audit Services (OAS), statistical software.

Estimation Methodology

We used OIG/OAS statistical software to estimate the amount of unallowable payments and potentially unallowable payments.

APPENDIX B: SAMPLE RESULTS AND ESTIMATES

SAMPLE RESULTS

Frame Size	Frame Value	Sample Size	Value of Sample	Number With Unallowable Payments	Value of Unallowable Payments
2,775,403	\$257,925,264	100	\$8,809	54	\$4,574

ESTIMATES OF UNALLOWABLE PAYMENTS

(Limits Calculated for a 90-Percent Confidence Interval)

	Total Estimated Unallowable Payments
Point estimate	\$126,938,885
Lower limit	96,770,147
Upper limit	157,107,622

APPENDIX C: ERROR DETAILS

TYPES OF MISSING DOCUMENTATION	DMEPOS Required For	Total In Sample	Number of Errors					Line Items with Only One Error
			Total	CPAP	TS *	RAD	PRSS	
Proof of Delivery	All	100	23	15	7	1	0	15
Physician's Prescription/Order	All	100	20	9	9	2	0	12
Use or Compliant Use Follow-up Documentation	CPAP, RAD	72	19	12	0	7	0	15
Physician's Certifying Statement	TS, PRSS	28	5	0	4	0	1	2
Total Errors (Duplicated Count)			67	36	20	10	1	44

CATEGORIES OF DME	Dollars Tested	Items Tested	Items Allowed †	Items Errors	Dollars in Error	1 Error	2 Errors	3 Errors	Multiple Errors ‡
Continuous Positive Airway Pressure Systems	\$3,486.72	58	29	29	\$1,648.44	24	3	2	5
Therapeutic Shoes for Diabetics	2,625.26	26	11	15	1,547.02	11	3	1	4
Respiratory Assist Devices	1,872.87	14	5	9	971.09	8	1	0	1
Pressure Reducing Support Surfaces (groups 1 and 2)	824.21	2	1	1	407.16	1	0	0	0
Totals	\$8,809.06	100	46	54	\$4,573.71	44	7	3	10

* Therapeutic shoes are a one-time purchase.

† Five of these forty-six sampled items were for suppliers who were no longer active and were considered non-errors.

‡ Ten of the fifty-four unallowable sampled items had multiple errors.

DMEPOS = durable medical equipment, prosthetics, orthotics, and supplies

CPAP = continuous positive airway pressure systems

TS = therapeutic shoes for diabetics

RAD = respiratory assist devices

PRSS = pressure reducing support surfaces (groups 1 and 2)

APPENDIX D: AUDITEE COMMENTS

Jean Rush
President



**CIGNA Government
Services**

Two Vantage Way
Nashville, TN 37228
Telephone 615.252.3657
Facsimile 615.782.4695
Jean.Rush@CIGNA.com

November 17, 2009

Peter J. Barbera
Regional Inspector General for Audit Services
DHHS/OIG/OAS/Region IV
61 Forsyth Street, S.W., Ste. 3T41
Atlanta, GA 30303

Dear Mr. Barbera,

On October 21, 2009, CIGNA Government Services (CGS) received Draft Report A-04-08-04020: "Review of Medicare Payments for Selected Durable Medical Equipment Claims With the KX Modifier for Calendar Year 2006." CGS has reviewed the report and acknowledges the facts presented in the report. CGS will take the following actions in response to the recommendations:

- Adjust the identified provider claims with insufficient documentation and begin recovery efforts for the \$4,420 in identified overpayments.
- Review the unallowable sample items to determine if additional overpayments can be identified and recovered.
- Report to the appropriate CMS staff, as well as the National Supplier Clearinghouse Medicare Administrative Contractor (NSC-MAC), the suppliers identified who violated the supplier standards for maintaining proof of delivery.
- Partner with CMS on the effectiveness of the KX modifier and take appropriate actions to protect the Medicare Trust Fund

In addition, CGS has provided training on the use of the KX modifier through onsite workshops, individual education, teleconferences, webinars, and online education, since assuming the DME MAC Jurisdiction C contract in 2007. CGS will continue to include the KX modifier in its future supplier training.

If you have any questions or additional requests related to this review, please contact Jennifer Ullig, Compliance Senior Specialist at 615-252-6532.

Sincerely,

Jean Rush
President
CIGNA Government Services

RECEIVED

NOV 19 2009

Office of Audit Svcs.

