DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

April 5, 2012

TO: Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Claim Modifier Did Not Prevent Medicare From Paying Millions in Unallowable Claims for Selected Durable Medical Equipment (A-04-10-04004)

The attached final report provides the results of our reviews of suppliers of selected durable medical equipment claims with the KX modifier for calendar year 2007.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (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, or your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-04-10-04004 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CLAIM MODIFIER DID NOT PREVENT MEDICARE FROM PAYING MILLIONS IN UNALLOWABLE CLAIMS FOR SELECTED DURABLE MEDICAL EQUIPMENT

Daniel R. Levinson
Inspector General

April 2012
A-04-10-04004

Office of Inspector General

http://oig.hhs.gov

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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 (contractors) to process and pay Medicare Part B claims for DMEPOS. Also, CMS contracts with Palmetto GBA, LLC, to serve as the National Supplier Clearinghouse for the enrollment and reenrollment of DMEPOS suppliers.

Under the statutory and policy framework of the Act, the *Medicare National Coverage Determinations Manual* 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. For certain DMEPOS, suppliers must use the KX modifier on filed claims. The KX modifier indicates that the claim meets Medicare coverage criteria and 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, therapeutic shoes also require that a certifying physician's statement be on file before the supplier bills Medicare.

This report summarizes the results of individual reviews of the 4 contractors that processed the DMEPOS claims for Jurisdictions A through D (which included all 50 States, 5 territories, and the District of Columbia). The contractors processed approximately $9.3 billion in DMEPOS claims with calendar year 2007 dates of service. This audit focused on $570,693,352 in paid claims processed by the contractors 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 summarize the results of the individual reviews of the four contractors that processed the DMEPOS claims for Jurisdictions A through D for claims with 2007 dates of service. The objective of those reviews was to determine whether the KX modifier was effective in ensuring that suppliers of DMEPOS that submitted Medicare claims had the required supporting documentation on file.

SUMMARY OF FINDINGS

The KX modifier was not effective in ensuring that suppliers of DMEPOS that submitted Medicare claims had the required supporting documentation on file. Of the 400 sampled items, suppliers had the required documentation on file for 163 items. Suppliers did not have the required documentation on file for the remaining 237 items. As a result, the contractors made unallowable payments totaling $19,767 for 237 of the 400 sampled items. Based on our sample,

we estimated the contractors paid approximately $316.4 million in unallowable Medicare payments to suppliers.

The types of missing or incomplete documentation were:

- physician orders (147 of 400, 37 percent);
- proof of delivery (84 of 400, 21 percent);
- use or compliant use followup statements (78 of 312, 25 percent);
- physician statements (25 of 88, 28 percent); and
- sleep studies (7 of 312, 2 percent).

These errors occurred because the contractors did not supplement their electronic edits with sufficient prepayment and postpayment review to ensure that suppliers maintained required documentation. The edits could determine only whether the required KX modifier was on the claims and did not prevent payments for unallowable claims. Also, one contractor, at the request of the suppliers, would add the KX modifier to claims when the suppliers had neglected to insert it.

RECOMMENDATIONS

We recommend that CMS:

- ensure that contractors recover the overpayments identified in our individual reports to contractors for specific DMEPOS items claimed for which the suppliers did not have the required documentation,
- develop an alternative mechanism such as having contractors perform additional prepay and postpay reviews to ensure that suppliers maintain the required documentation for the specific DMEPOS items included in this review that currently use the KX modifier,
- take appropriate action for suppliers that did not meet the supplier standard for maintaining proof of delivery, and
- issue a special alert emphasizing the documentation that suppliers must have in their files to support the use of the KX modifier before billing Medicare.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and listed actions it intends to take in response to them, consistent with its policies and procedures. In response to our first recommendation, CMS raised concerns about the cost of reviewing DMEPOS claims. CMS's comments are included in their entirety as Appendix F.

OFFICE OF INSPECTOR GENERAL RESPONSE

In response to the actions CMS plans to take related to our first recommendation, we agree that CMS needs to consider the return on investment when conducting medical review activities. Our recommendation addressed only the overpayments we identified for the sampled items.

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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).

Contractors for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS contracted with four durable medical equipment Medicare administrative contractors (contractors) to process and pay Medicare Part B claims for DMEPOS. In addition, CMS contracts with Palmetto GBA, LLC, to serve as the National Supplier Clearinghouse (NSC) for the enrollment and reenrollment of 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]

This report summarizes the results of individual reviews of the 4 contractors that processed the DMEPOS claims for Jurisdictions A through D (which included all 50 States, 5 territories, and the District of Columbia).[2] The contractors processed approximately $9.3 billion in Medicare DMEPOS claims with calendar year 2007 dates of service.

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 developed supplier manuals, Local Coverage Determinations (LCD), and Policy Articles covering DMEPOS items. These materials specify the clinical circumstances under which a DMEPOS item is considered reasonable and necessary. For covered DMEPOS items, including therapeutic shoes for diabetics (therapeutic shoes), continuous positive airway pressure

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

[2] We issued these reports under report numbers A-01-09-00528, A-04-09-04039, A-05-09-00094, and A-09-09-00111.

systems (CPAP), respiratory assist devices (RAD), and pressure reducing support surfaces (groups 1 and 2) (PRSS), LCDs require that a KX modifier be added to claims before they are paid. By adding the KX modifier, the supplier attests that the claim meets the Medicare coverage criteria and that the specific required documentation, which varies based on the DMEPOS item, is on file at the supplier before submitting the claim to the contractor. This documentation required a written physician's order and proof of delivery for all DMEPOS, as well as additional documentation, such as a certifying physician's statement for therapeutic shoe claims.

Our previous audits focused on claims paid by the contractors for therapeutic shoes, CPAPs, RADs, and PRSSs. The LCDs for all four contractors required suppliers to have the same documentation on file for the categories of DMEPOS and dates of service included in our audit.

Through contractor-issued supplier manuals, LCDs, Policy Articles, and Internet postings, the contractors instructed suppliers to use the KX modifier only if the claim meets the Medicare coverage criteria and 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.

Table 1 lists the documentation required by Medicare regulations for each of the four DMEPOS categories in our review. Details and examples for each are in Appendix A.

Table 1: 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 Order (written, signed, and dated)	-Program Integrity Manual (PIM), Pub. No. 100-08, ch. 5 -LCDs	X	X	X	X
Proof of Delivery	-42 CFR § 424.57(c)(12) -PIM, ch. 4	X	X	X	X
Statement of Treating/Certifying Physician Before Billing	-The Act, § 1861(s)(12) (A-C) -LCDs and Policy Articles	X			X
Polysomnography (Sleep Study) Before Physician Order	-NCD -LCDs and Policy Articles		X	X	
Use or Compliant Use Followup Statement of Physician and/or Beneficiary	-LCDs		X	X	

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to summarize the results of the individual reviews of the four contractors that processed the DMEPOS claims for Jurisdictions A through D. The objective of those reviews was to determine whether the KX modifier was effective in ensuring that suppliers of DMEPOS that submitted Medicare claims had the required supporting documentation on file.

Scope

Of the approximately $9.3 billion in Medicare DMEPOS claims with calendar year 2007 dates of service, we focused on $570,693,352 in paid claims for therapeutic shoes, CPAPs, RADs, and PRSSs that included the KX modifier.

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.

We conducted fieldwork at the four contractors' offices and at suppliers' locations throughout the United States.

Methodology

To accomplish our audit objective, we reviewed applicable laws, regulations, and manuals and interviewed contractor officials concerning both manual and electronic processing procedures for claims with the KX modifier for therapeutic shoes, CPAPs, RADs, and PRSSs. We also discussed the KX modifier with CMS officials.

We selected a simple random sample of 100 line items from each of the 4 contractors' paid claims, made unannounced visits to the 362 suppliers associated with the 400 sample line items, and reviewed the suppliers' files for compliance with documentation requirements. (See Appendix B.) Also, we requested that the contractors' staffs review the documentation provided by the suppliers. We issued individual reports to each of the four contractors in which we analyzed the sampled items by contractor and analyzed the errors by both type of missing documentation and category of DMEPOS.

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 that submitted Medicare claims had the required supporting documentation on file. Of the 400 sampled line

items, suppliers had the required documentation on file for 163 line items. Suppliers did not have the required documentation on file for the remaining 237 line items. As a result, the contractors made unallowable payments totaling $19,767 for 237 of the 400 sampled line items. Based on our sample, we estimated that the contractors paid approximately $316.4 million to suppliers that did not have the required documentation on file to support the DMEPOS line items with 2007 dates of service.

These errors occurred because the contractors' electronic edits could not determine whether suppliers had the required documentation on file when they used the KX modifier on claims. The edits could determine only whether the required KX modifier was on the claims.

In addition, during calendar years 2007 through 2009, one contractor, at the request of the suppliers, added the KX modifier to claims when the suppliers had neglected to insert it. This action was inconsistent with the intended purpose of the KX modifier as an attestation that required documentation was on file at the supplier.

MISSING OR INCOMPLETE REQUIRED DOCUMENTATION

Medicare regulations require suppliers to have specific required documentation, as applicable, on file before billing Medicare for a DMEPOS item. The LCDs for all four jurisdictions required suppliers to have the same documentation on file before using the KX modifier on claims for the categories of DMEPOS and dates of service included in this audit.

The types of missing or incomplete documentation were:

- physician orders (147 of 400, 37 percent), which must be signed and dated and be on file with the suppliers for every DMEPOS item before billing Medicare;

- proof of delivery (84 of 400, 21 percent), which must be maintained on file with the suppliers for every DMEPOS item;

- use or compliant use followup statements (78 of 312, 25 percent), which must be obtained by the supplier no sooner than the 61st day after a beneficiary starts therapy to ensure that the CPAP is being used and that the RAD is being compliantly used;

- physician statements (25 of 88, 28 percent), which must be signed and dated by the certifying or treating physician and certify that the patient meets specific criteria for therapeutic shoes and PRSSs; and

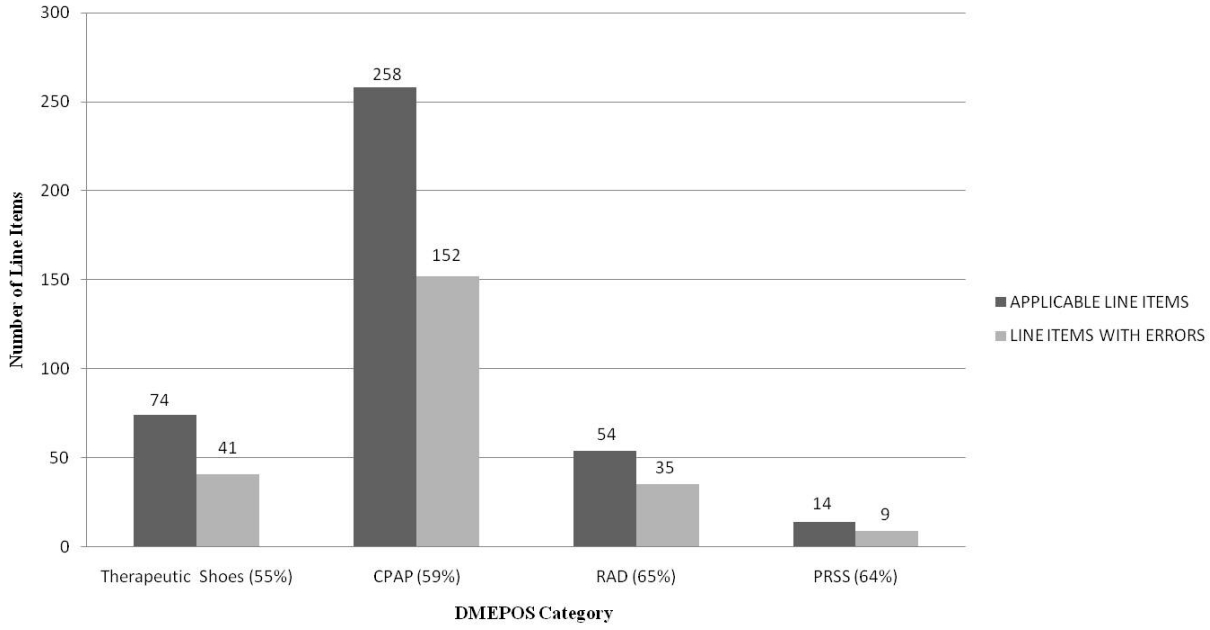
- sleep studies (7 of 312, 2 percent), which must be documented for CPAPs and RADs and must not be performed by a DMEPOS supplier.

Detailed Federal documentation requirements are provided in Appendix A.

ERRORS BY DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES CATEGORY

More than half of the 400 sampled items we reviewed had missing or incomplete required documentation. Of the 237 sampled items with missing supplier documentation, 154 were missing 1 item of documentation and 83 were missing 2 or more items. (See Appendix C.) The following chart identifies the errors by DMEPOS category.

Errors by Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Category



Therapeutic Shoes

Items related to therapeutic shoes made up 74 of the 400 line items in the sample. Of the 74 line items, 41 (55 percent) had 1 or more errors, for a total of 60 errors. (See Appendix C.)

- Missing or incomplete physician orders accounted for 28 of the 60 errors. Physician orders were missing, were not signed and/or dated by the physician, or did not include the DMEPOS item.

- Missing or incomplete certifying physician statements accounted for 18 of the 60 errors. Physician statements were missing, were not signed and/or dated by the certifying physician, or did not include all of the required certifications.

- Missing or incomplete proofs of delivery accounted for 14 of the 60 errors. Proofs of delivery were missing, were not signed and/or dated by the beneficiary or designee, or did not include the DMEPOS item.

Continuous Positive Airway Pressure Systems

Items related to CPAPs made up 258 of the 400 line items in the sample. Of the 258 line items, 152 (59 percent) had 1 or more errors, for a total of 214 errors. (See Appendix C.)

- Missing or incomplete physician orders accounted for 96 of the 214 errors. The orders were missing, were not signed and/or dated by the physician, or did not include the DMEPOS item. Also, we found suppliers that had beneficiaries sign a request to have CPAP supplies automatically shipped periodically to beneficiaries' residences, but the physician orders did not specify frequency.

- Missing or incomplete proofs of delivery accounted for 57 of the 214 errors. Proofs of delivery were missing, were not signed and/or dated by the beneficiary or designee, or did not include the DMEPOS item.

- Missing or incomplete use or followup documentation accounted for 56 of the 214 errors.

- Missing sleep studies accounted for 5 of the 214 errors.

Respiratory Assist Devices

Items related to RADs made up 54 of the 400 line items included in the sample. Of the 54 line items, 35 (65 percent) had 1 or more errors, for a total of 54 errors. (See Appendix C.)

- Missing or incomplete compliant use followup documentation accounted for 22 of the 54 errors. This documentation was missing, was not signed and/or dated by the beneficiary and/or the certifying/treating physician, or did not include all of the required certifications.

- Missing or incomplete physician orders accounted for 19 of the 54 errors. Physician orders were missing, were not signed and/or dated by the physician, or did not include the DMEPOS item.

- Missing or incomplete proofs of delivery accounted for 11 of the 54 errors. Proofs of delivery were missing, were not signed and/or dated by the beneficiary or designee, or did not include the DMEPOS item.

- Missing sleep studies accounted for 2 of the 54 errors.

Pressure Reducing Support Surfaces

Items related to PRSSs made up 14 of the 400 line items in the sample. Of the 14 line items, 9 (64 percent) had 1 or more errors, for a total of 13 errors. (See Appendix C.)

- Missing or incomplete treating physician statements accounted for 7 of the 13 errors. Physician statements were missing, were not signed and/or dated by the treating physician, or did not include all of the required certifications.

- Missing or incomplete physician orders accounted for 4 of the 13 errors. Physician orders were missing, were not signed and/or dated by the physician, or did not include the DMEPOS item.

- Missing or incomplete proofs of delivery accounted for 2 of the 13 errors. Proofs of delivery were missing, were not signed and/or dated by the beneficiary or designee, or did not include the DMEPOS item.

ERRORS BY CONTRACTOR

The error rates for the contractors ranged from 52 to 67 percent, as reflected in Table 2. The contractors had similar errors by types of missing or incomplete documentation and DMEPOS categories.

Table 2: Errors by Contractor

Contractor	Sample Items	Items With Errors	Percent With Errors
A	100	63	63%
B	100	52	52%
C	100	55	55%
D	100	67	67%
Total	**400**	**237**	**59%**

During the audit period, contractors performed some prepayment and postpayment reviews on various types of DMEPOS. However, the selected categories of DMEPOS may not have been included in these reviews.

We have provided additional details on the results of the sampled items in Appendix C. Also, Appendix D contains a map showing the locations of suppliers by contractor in our sample. The map identifies suppliers with and without the required documentation in their files.

KX MODIFIER SYSTEM EDITS

The LCDs require DMEPOS suppliers to include the KX modifier on claims submitted for therapeutic shoes, CPAPs, RADs, and PRSSs when the "specific required documentation is on file." Use of the KX modifier is an attestation by a supplier that the claim meets Medicare

coverage criteria and the supplier has the required documentation on file for the particular item or service. The contractors deny claims without the KX modifier, so it is in the suppliers' interests to insert it on their claim forms.

The contractors established electronic edits to determine whether the claims submitted by suppliers had the KX modifier. However, the contractors did not supplement these edits with sufficient prepayment and postpayment review to ensure that suppliers maintained the required documentation.

In addition, during calendar years 2007 through 2009, one contractor, at the request of the suppliers, added the KX modifier to claims when the suppliers had neglected to insert it. This action was inconsistent with the intended purpose of the KX modifier as an attestation that required documentation was on file at the supplier.

EFFECT OF UNALLOWABLE PAYMENTS

Of the 400 items in our sample, suppliers did not have the required documentation on file for 237. As a result, the contractors made unallowable payments totaling $19,767. Based on our sample, we estimated that the contractors paid approximately $316.4 million in unallowable Medicare payments to DMEPOS suppliers with 2007 dates of service.

SIGNIFICANT POLICY CHANGES RESULTING FROM AUDIT REPORTS TO CONTRACTORS

We issued individual reports to each of the four contractors. Each contractor provided written comments in response. In their comments, the contractors agreed to:

- recover the payments for specific DMEPOS items claimed for which the suppliers did not have the required documentation;

- review other payments related to these DMEPOS items and recover any additional unallowable payments; and

- notify CMS, for appropriate action, of the suppliers that did not meet the supplier standard for maintaining proof of delivery.

The contractors stated that they had worked together to strengthen controls surrounding claims submitted for payment that included the KX modifier. As a result of our reviews, the four contractors' Medical Directors stated that they jointly revised the LCDs and documentation requirements for 17 DMEPOS policies[3] for the use of the KX and other modifiers. The revised LCDs include more documentation requirements for both the suppliers and the certifying and treating physicians. This information does not have to be submitted with the claim but must be available on request. One contractor stated that these policy changes increase the effectiveness

[3] The policies were effective December 1, 2009.

of the KX modifier by requiring that the provider file an appeal to add or change the KX modifier and must provide documentation to support its use.

Also, one contractor developed a proposal that included a prepayment verification process for supplier documentation to improve the effectiveness of the KX modifier.

The contractors stated that they were aware that the suppliers' lack of documentation supporting the use of the KX modifier for the specific DMEPOS items included in this review was a widespread problem. While the contractors have described the steps that they are taking to strengthen controls surrounding claims submitted for payment that included the KX modifier, the high error rate across the country indicates the need for CMS to take additional steps.

RECOMMENDATIONS

We recommend that CMS:

- ensure that contractors recover the payments identified in our individual reports to contractors for specific DMEPOS items claimed for which the suppliers did not have the required documentation,

- develop an alternative mechanism such as having contractors perform additional prepay and postpay reviews to ensure that suppliers maintain the required documentation for the specific DMEPOS items included in this review that currently use the KX modifier,

- take appropriate action for suppliers that did not meet the supplier standard for maintaining proof of delivery, and

- issue a special alert emphasizing the documentation that suppliers must have in their files to support the use of the KX modifier before billing Medicare.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and listed actions it intends to take in response to them. CMS said that it would:

- pursue the recovery of identified overpayments in our previously issued reports to individual contractors, consistent with its policies and procedures, but raised concerns about the cost of reviewing DMEPOS claims;

- inform the Medicare administrative contractors and the reviewers of fee-for-service claims, the Recovery Auditors, to consider the report findings in prioritizing their prepayment and/or postpayment reviews;

- instruct the NSC "to further investigate allegations" that suppliers did not maintain proof of DMEPOS delivery; and

- develop an educational article that clearly explains what documentation must be maintained by suppliers in their files to support the use of the KX modifier on a Medicare claim for DMEPOS.

OFFICE OF INSPECTOR GENERAL RESPONSE

In response to the actions CMS plans to take related to our first recommendation, we agree that CMS needs to consider the return on investment when conducting medical review activities. Our recommendation addressed only the overpayments we identified for the sampled items.

APPENDIXES

APPENDIX A: DOCUMENTATION REQUIREMENTS

PHYSICIAN ORDERS

The *Program Integrity Manual* (PIM), chapter 5, sections 5.2.1 and 5.2.2, states that all durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers are required to keep on file a physician order for each item. The treating physician must sign and date the order. Section 5.2.3 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.

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

PHYSICIAN STATEMENTS

Pursuant to the Social Security Act, § 1861(s)(12)(A), the physician must certify that the patient meets specific criteria for therapeutic shoes. The Local Coverage Determinations (LCD) and Policy Articles for therapeutic shoes and pressure reducing support surfaces (groups 1 and 2) (PRSS) state that DMEPOS items are covered if the supplier obtains a signed and dated statement from the certifying or treating physician saying the patient meets specific criteria. The physician's statement must be signed and dated sometime during the year before the date of service for therapeutic shoes, and the Policy Articles state that the items will be denied if the requirements are not met.

SLEEP STUDIES

The LCDs effective during our audit period for the continuous positive airway pressure systems (CPAP) (E0601) and for the respiratory assist devices (RAD) (E0470) require that the beneficiary have a documented polysomnographic study. Additionally, polysomnographic studies must not be performed by a DMEPOS supplier.

USE OR COMPLIANT USE FOLLOWUP DOCUMENTATION

The LCDs effective during our audit period for the CPAP and for the RAD state that, for an E0601 (CPAP) and an E0470 (RAD) to be covered beyond 3 months of therapy, the supplier must determine no sooner than the 61st day after the beneficiary starts 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. The LCDs state that continued coverage of the RAD will be denied if the requirements are not met.

APPENDIX B: SAMPLING METHODOLOGY

POPULATION

The population consisted of specific categories of DMEPOS items (therapeutic shoes for diabetics, CPAPs, RADs, and PRSSs) that DMEPOS suppliers claimed for calendar year 2007 dates of service using the KX modifier under Medicare Part B.

SAMPLE FRAME

The sampling frame consisted of 6,606,197 DMEPOS line items totaling $570,693,352 for calendar year 2007.

SAMPLE UNIT

The sample unit was a line item.

SAMPLE DESIGN

We used simple random samples.

SAMPLE SIZE

We selected 4 samples of 100 line items each.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

The sampling frames were consecutively numbered. After generating 100 random numbers for each of 4 contractor jurisdictions, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

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

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	400	84	57	14	11	2	22
Physician Prescription/Order	All	400	147	96	28	19	4	82
Use or Compliant Use Followup Documentation	CPAP, RAD	312	78	56	0	22	0	38
Polysomnogram or Other Required Study	CPAP, RAD	312	7	5	0	2	0	2
Physician Certifying Statement	TS, PRSS	88	25	0	18	0	7	10
Total Errors (Duplicated Count)			**341**	**214**	**60**	**54**	**13**	**154**

CATEGORIES OF DMEPOS	Dollars Tested	Items Tested	Items in Allowed †	Items in Errors	Dollars in Error	1 Error	2 Errors	3 Errors	4 Errors	Multiple Errors ‡
CPAP	$17,546	258	106	152	$10,300	102	39	10	1	50
Therapeutic Shoes for Diabetics	7,918	74	33	41	3,935	24	15	2	0	17
RAD	6,264	54	19	35	2,968	22	8	4	1	13
PRSS	4,418	14	5	9	2,564	6	2	1	0	3
Totals	**$36,146**	**400**	**163**	**237**	**$19,767**	**154**	**64**	**17**	**2**	**83**

* Therapeutic shoes are a one-time purchase.

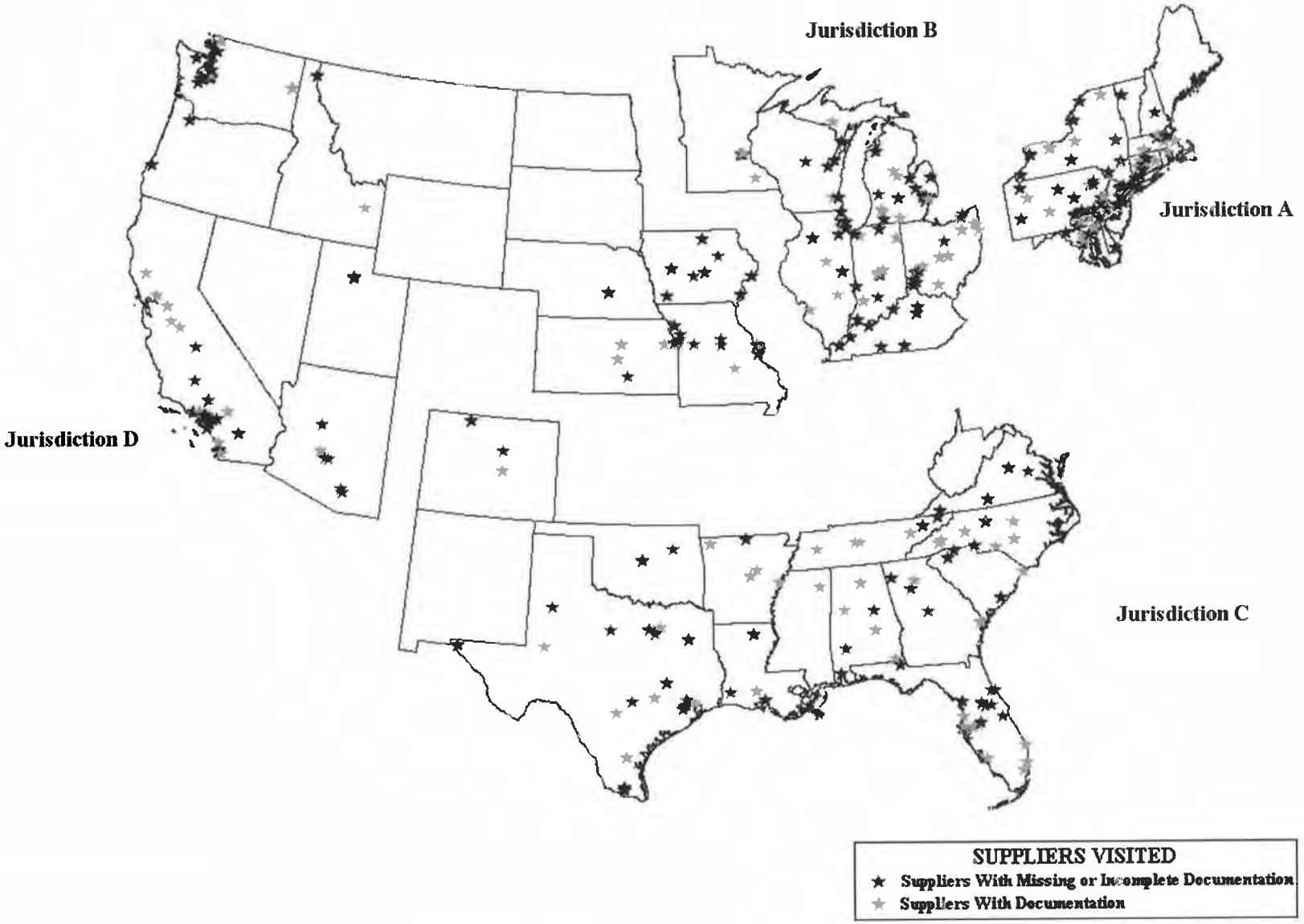
† Of these 163 sampled items, 9 were for suppliers who were no longer active or under investigation and were considered nonerrors.

‡ Of the 237 unallowable sampled items, 83 had multiple errors.

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

TS = therapeutic shoes for diabetics

APPENDIX D: SUPPLIERS WITH AND WITHOUT REQUIRED DOCUMENTATION IN THEIR FILES



[1] In our sample, there was one supplier located in Alaska and none in Hawaii. Documentation was missing for the selected item in Alaska.

APPENDIX E: JURISDICTIONS A–D SAMPLE RESULTS AND ESTIMATES

ESTIMATES OF UNALLOWABLE PAYMENTS
(Limits Calculated for a 90-Percent Confidence Interval)

JURISDICTION	POINT ESTIMATE	LOWER LIMIT	UPPER LIMIT
A	$54,040,694	$42,702,383	$65,379,005
B	55,422,915	43,750,627	67,095,204
C	137,404,646	103,735,580	171,073,712
D	69,577,013	52,575,987	86,578,040
TOTAL	**$316,445,268**		

JURISDICTION A SAMPLE RESULTS

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Payments	Value of Unallowable Payments
1,020,402	$96,722,670	100	$10,373	63	$5,296

JURISDICTION B SAMPLE RESULTS

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Payments	Value of Unallowable Payments
1,390,415	$117,042,423	100	$7,992	52	$3,986

JURISDICTION C SAMPLE RESULTS

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Payments	Value of Unallowable Payments
3,024,176	$257,266,589	100	$8,478	55	$4,544

JURISDICTION D SAMPLE RESULTS

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Payments	Value of Unallowable Payments
1,171,204	$99,661,670	100	$9,303	67	$5,941

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JAN 0 9 2012

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: *Claim Modifier Did Not Prevent Medicare from Paying Millions in Unallowable Claims for Selected Durable Medical Equipment,* (A-04-10-04004)

Thank you for the opportunity to review and comment on the OIG Draft Report titled "Claim Modifier Did Not Prevent Medicare from Paying Millions in Unallowable Claims for Selected Durable Medical Equipment (A-04-10-04004)." The Centers for Medicare & Medicaid Services (CMS) appreciates the time and resources OIG has invested to review this issue. The OIG's audit focused on paid claims with 2007 dates of service for therapeutic shoes for diabetes, continuous positive airway pressure systems, respiratory assist devices, and pressure reducing support surfaces processed by the Durable Medical Equipment Prosthetics/Orthotics and Supplies (DMEPOS) contractor for each of Jurisdictions A, B, C and D. The objective of the audit was to determine whether the KX modifier was effective in ensuring that DMEPOS suppliers that submitted these Medicare claims had the required supporting documentation on file.

The CMS understands that the lack of sufficient documentation within DMEPOS supplier files to support claims that were submitted with the KX modifier is a widespread issue. The finding of this audit that only 163 of the 400 sampled line items were supported by the required documentation on file at the supplier further validates the importance of this matter. Based on the results, OIG estimates that the Medicare program overpaid suppliers approximately $316.4 million. OIG recommends that CMS recover the overpayments; develop an alternative mechanism, such as having contractors perform additional prepay and post pay reviews, to ensure that suppliers maintain the required documentation for the DMEPOS items that currently use the KX modifier; take appropriate action against identified suppliers that did not meet the supplier standard for maintaining proof of delivery; and conduct supplier education on the documentation that suppliers must have in their files to support the use of the KX modifier.

We have reviewed the report and have responded to your recommendations.

OIG Recommendation

Ensure that contractors recover the overpayments identified in our individual reports to contractors for specific DMEPOS items claimed for which the suppliers did not have the required documentation.

CMS Response

The CMS agrees that overpayments should be recovered as appropriate. CMS is pursuing the recovery of the identified overpayments in the previously issued OIG reports to individual contractors, consistent with the agency's policies and procedures.

The CMS must always consider the return on investment when conducting medical review due to the limited resources available for medical review activities. The OIG's overpayment projection assumes if CMS reviewed additional DMEPOS claims we would identify $316.4 million in improper payments. The universe of claims in this study is greater than 6.6 million. The major claim error identified in this report is lack of required documentation. This problem can only be identified through manual review. Therefore, CMS would have to conduct review on all of the 6.6 million claims in the universe. This suggested universe is nearly 300 percent more than the universe of claims actually reviewed by CMS in FY 2011. Given the medical review and overpayment recovery costs associated with this recommendation, CMS would need over $165 million in funding to review the claims from this study alone.

Given CMS' limited resources, we attempt to focus the medical review resources on the most highly vulnerable areas as identified by sources such as the Comprehensive Error Rate Testing (CERT) program, individual contractor data analyses, and other reports, including OIG audits. Many of the items identified in this report are part of the medical review strategies of the Durable Medical Equipment Medicare Administrative Contractors for FY 2012, however given resource constraints it is impossible to review every claim with a KX modifier.

OIG Recommendation

Develop an alternative mechanism such as having contractors perform additional prepay and post pay reviews to ensure that suppliers maintain the required documentation for the specific DMEPOS items included in this review that currently use the KX modifier.

CMS Response

The CMS concurs. The CMS will provide the Medicare Administrative Contractors (MACs) with a link to the final OIG report. CMS will inform the MACs that these findings are informational and should be considered a source of data as they prioritize their prepayment and/or postpayment review workload, along with all other data they consider.

Also, Recovery Auditors review Medicare fee-for-service claims, including DMEPOS claims, on a post payment basis and are tasked with identifying overpayments and underpayments. While CMS does not mandate areas for review, we will share the final OIG report with the Recovery Auditors and encourage them to consider it as they decide what claims to review on a post-payment basis.

OIG Recommendation

Take appropriate action for suppliers that did not meet the supplier standard for maintaining proof of delivery.

CMS Response

The CMS concurs. The National Supplier Clearinghouse (NSC) is responsible for investigating suspected violations of the DMEPOS supplier standards found at 42 CFR § 424.57(c), including the requirement that suppliers maintain proof of delivery (42 CFR § 424.57(c)(12)). A sample of records is reviewed to ensure that the supplier maintains proper documentation, including delivery records and physician orders. In instances where the supplier is determined to not be in compliance with the supplier standards, the NSC can recommend that CMS revoke a supplier's Medicare billing privileges. CMS will instruct the NSC to further investigate allegations that suppliers did not maintain proof of DMEPOS delivery, as required under 42 CFR § 424.57(c)(12).

OIG Recommendation

Issue a special alert emphasizing the documentation that suppliers must have in their files to support the use of the KX modifier before billing Medicare.

CMS Response

The CMS concurs. The CMS will develop an educational article that clearly explains what documentation must be maintained by suppliers in their files to support the use of the KX modifier on a Medicare claim for DMEPOS.

The CMS appreciates the OIG's efforts and insight on this report. CMS looks forward to continually working with the OIG on issues related to waste, fraud and abuse in the Medicare program.