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

FROM: Daniel R. Levinson  
Inspector General

SUBJECT: Independent Contractor’s Review of Durable Medical Equipment Claims From the  
Fiscal Year 2008 Comprehensive Error Rate Testing Program  
(A-01-09-00500)

The attached final report provides the results of our audit of an independent contractor’s review of  
durable medical equipment (DME) claims from Medicare’s fiscal year (FY) 2008 Comprehensive  
Error Rate Testing (CERT) program. We conducted our audit at the request of the Senate Committee  
on Finance.

To help determine the annual Medicare error rate, the Centers for Medicare & Medicaid Services’  
(CMS) CERT contractor conducts medical reviews of a sample of paid DME claims. CMS  
requires the CERT contractor to make medical review decisions in accordance with CMS’s  
written policies, including those in its “Program Integrity Manual.”

To provide assurance that the reported FY 2008 DME error rate was accurate, CMS contracted with  
Palmetto GBA (Palmetto) to perform a random, independent review of the CERT contractor’s  
payment determinations. Palmetto’s review consisted of a subsample of 250 paid claims from the  
sample of 14,221 claims that the CERT contractor had reviewed in determining the FY 2008 DME  
error rate. CMS’s contract required Palmetto to follow guidance in national coverage  
determinations (NCD), local coverage determinations (LCD), and CMS manuals and to use the  
same documentation that the CERT contractor had used to assess whether payments for DME items  
met Medicare medical necessity and documentation requirements.

Our objectives were to determine whether (1) Palmetto complied with the CMS contract in  
performing medical reviews of a subsample of claims from the FY 2008 CERT DME sample and  
(2) Palmetto’s results provided assurance that the FY 2008 DME error rate was accurate.

Palmetto complied with its CMS contract in performing medical reviews of a subsample of claims  
from the FY 2008 DME sample. Using the same documentation that the CERT contractor had used,  
Palmetto followed the protocols in the applicable NCDs, LCDs, and CMS manuals to determine  
whether the DME items in the subsample were medically necessary and adequately documented.
Palmetto’s results did not provide assurance that the FY 2008 DME error rate was accurate. Palmetto found that 175 of the 250 sampled claims were in error, significantly exceeding the 23 errors found by the CERT contractor. After further review, the CERT contractor agreed with 17 of Palmetto’s additional error determinations (for a total of 40 error determinations) but disagreed with the remaining 135 error determinations. Most of Palmetto’s error determinations were based on insufficient documentation to establish medical necessity.

Palmetto’s review determinations differed from those of the CERT contractor because of (1) incorrect medical necessity determinations by the CERT contractor and (2) differences in review standards and methodology. Specifically, the CERT contractor agreed that it had made incorrect determinations on 17 claims after it reviewed Palmetto’s determinations. The differences in review standards and methodology were due to the CERT contractor’s use of clinical inference to make medical necessity determinations based on its review of supplier documents, beneficiary claim histories, and limited medical records. In contrast, officials of Palmetto—as well as other DME medical review contractors—stated that they required beneficiary medical records to perform medical reviews and to make medical necessity determinations.

The CERT contractor’s acknowledgment of the additional 17 errors and its use of limited medical records to infer medical necessity, which was inconsistent with the methodology used by Palmetto and other DME medical review contractors, cast doubt on the accuracy of the FY 2008 DME error rate.

We recommend that CMS require the CERT contractor to:

- develop a corrective action plan to reduce its number of incorrect determinations and
- perform a complex medical review by obtaining and reviewing all medical records from all relevant providers to support the medical necessity of DME items.

In comments on our draft report, CMS concurred with our findings and recommendations and outlined the steps it has taken to begin implementing our recommendations.

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent the information in the report is not subject to exemptions in the Act. Accordingly, this report will be posted on the Internet at http://oig.hhs.gov.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Joseph J. Green, Assistant Inspector General for Financial Management and Regional Operations, at (202) 619-1157 or through e-mail at Joe.Green@oig.hhs.gov. Please refer to report number A-01-09-00500 in all correspondence.

Attachment
INDEPENDENT CONTRACTOR’S REVIEW OF DURABLE MEDICAL EQUIPMENT CLAIMS FROM THE FISCAL YEAR 2008 COMPREHENSIVE ERROR RATE TESTING PROGRAM
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

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act.

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

The Centers for Medicare & Medicaid Services (CMS) established the Comprehensive Error Rate Testing (CERT) program to produce a Medicare fee-for-service error rate. Using the results of the CERT program, CMS annually submits to Congress an estimate of the amount of improper payments for Medicare fee-for-service claims pursuant to the Improper Payments Information Act of 2002 (P.L. No. 107-300).

To determine the error rate, CMS’s CERT contractor conducts medical record reviews of a random sample of paid claims. CMS requires the CERT contractor to make medical review decisions in accordance with CMS’s written policies, including those in its “Program Integrity Manual.” For medical reviews of durable medical equipment (DME) claims, the “Program Integrity Manual” states that information in the beneficiary’s medical record must support the item’s medical necessity.

To strengthen its confidence in the CERT review findings and provide assurance that the reported fiscal year (FY) 2008 DME error rate was accurate, CMS contracted with Palmetto GBA (Palmetto), an independent medical review organization, to perform a random, independent review of the CERT contractor’s payment determinations. Palmetto’s review consisted of a subsample of 250 paid claims from the sample of 14,221 claims that the CERT contractor had reviewed in determining the FY 2008 DME error rate. CMS’s contract required Palmetto to follow guidance in national coverage determinations (NCD), local coverage determinations (LCD), and CMS manuals and to use the same documentation that the CERT contractor had used to assess whether payments for DME items met Medicare medical necessity and documentation requirements.

We conducted this review at the request of the Senate Committee on Finance.

OBJECTIVES

Our objectives were to determine whether (1) Palmetto complied with the CMS contract in performing medical reviews of a subsample of claims from the FY 2008 CERT DME sample and (2) Palmetto’s results provided assurance that the FY 2008 DME error rate was accurate.

SUMMARY OF FINDINGS

Palmetto complied with its CMS contract in performing medical reviews of a subsample of claims from the FY 2008 CERT DME sample. Using the same documentation that the CERT contractor had used, Palmetto followed the protocols in the applicable NCDs, LCDs, and CMS manuals to determine whether the DME items in the subsample were medically necessary and adequately documented.

Palmetto’s results did not provide assurance that the FY 2008 DME error rate was accurate. Palmetto found that 175 of the 250 sampled claims were in error, significantly exceeding the
23 errors found by the CERT contractor. After further review, the CERT contractor agreed with 17 of Palmetto’s additional error determinations (for a total of 40 error determinations) but disagreed with the remaining 135 error determinations. Most of Palmetto’s error determinations were based on insufficient documentation to establish medical necessity.

Palmetto’s review determinations differed from those of the CERT contractor because of (1) incorrect medical necessity determinations by the CERT contractor and (2) differences in review standards and methodology. Specifically, the CERT contractor agreed that it had made incorrect determinations on 17 claims after it reviewed Palmetto’s determinations. The differences in review standards and methodology were due to the CERT contractor’s use of clinical inference to make medical necessity determinations based on its review of supplier documents, beneficiary claim histories, and limited medical records. In contrast, officials of Palmetto—as well as other DME medical review contractors—stated that they required beneficiary medical records to perform medical reviews and make medical necessity determinations.

The CERT contractor’s acknowledgment of the additional 17 errors and its use of limited medical records to infer medical necessity, which was inconsistent with the methodology used by Palmetto and other DME medical review contractors, cast doubt on the accuracy of the FY 2008 DME error rate. We issued a report on the medical review of DME claims for the fiscal year (FY) 2006 CERT program that noted that the FY 2006 DME error rate likely would have been significantly higher if the CERT contractor had reviewed additional records from physicians and other health care providers and information obtained from beneficiary interviews. Conversely, Palmetto would likely have found fewer errors in the subsample of FY 2008 CERT DME claims if the CERT contractor had obtained sufficient medical records to determine medical necessity.

RECOMMENDATIONS

We recommend that CMS require the CERT contractor to:

- develop a corrective action plan to reduce its number of incorrect determinations and
- perform a complex medical review by obtaining and reviewing all medical records from all relevant providers to support the medical necessity of DME items.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In comments on our draft report, CMS concurred with our findings and recommendations and outlined the steps it has taken to begin implementing our recommendations. In a technical comment, CMS requested clarification of the number of sampled claims reviewed. We met with CMS officials and resolved their technical comment. The subsample contained 250 claims.

CMS’s comments are included in their entirety as the Appendix.
# TABLE OF CONTENTS

## INTRODUCTION

- Medicare Error Rate Program .......................................................... 1
- Durable Medical Equipment ................................................................. 1
- Claim Review Activities ...................................................................... 1
- Medical Reviews of Claims in the Comprehensive Error Rate Testing Program .......................................................... 2
- Independent Medical Review Contractor ............................................ 2
- Congressionally Requested Review .................................................... 3

## BACKGROUND

- Medicare Error Rate Program .......................................................... 1
- Durable Medical Equipment ................................................................. 1
- Claim Review Activities ...................................................................... 1
- Medical Reviews of Claims in the Comprehensive Error Rate Testing Program .......................................................... 2
- Independent Medical Review Contractor ............................................ 2
- Congressionally Requested Review .................................................... 3

## OBJECTIVES, SCOPE, AND METHODOLOGY

- Objectives ............................................................................................ 3
- Scope ...................................................................................................... 3
- Methodology ........................................................................................ 3

## FINDINGS AND RECOMMENDATIONS

- PROGRAM REQUIREMENTS ................................................................. 5
  - Medicare Payment Requirements ..................................................... 5
  - Medical Reviews of Durable Medical Equipment Claims ............... 5
- COMPLIANCE WITH CONTRACT ........................................................ 5
- ASSURANCE OF ERROR RATE ACCURACY ......................................... 5
  - Palmetto’s Error Determinations ...................................................... 5
  - Response to Palmetto’s Additional Error Determinations ............... 6
- DIFFERENCES IN REVIEW DETERMINATIONS ..................................... 7
- CONCLUSION ....................................................................................... 8
- RECOMMENDATIONS .......................................................................... 8

## CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

## APPENDIX

- CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS
INTRODUCTION

BACKGROUND

Medicare Error Rate Program

The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, established the Comprehensive Error Rate Testing (CERT) program to produce a Medicare fee-for-service error rate. An error is the difference between the amount that Medicare paid to a health care provider and the amount that it should have paid. Medicare will pay only for items and services that are medically necessary. Using the results of the CERT program, CMS annually submits to Congress an estimate of the amount of improper payments for Medicare fee-for-service claims pursuant to the Improper Payments Information Act of 2002 (P.L. No. 107-300).

Durable Medical Equipment

Durable medical equipment, prosthetics, orthotics, and supplies (DME) include items such as wheelchairs, hospital beds, oxygen, and medical and surgical supplies. Pursuant to CMS’s “Medicare Claims Processing Manual,” Pub. No. 100-04, chapter 20, section 10.1.1, Medicare Part B covers DME. CMS defines DME as equipment that can withstand repeated use, is used primarily and customarily to serve a medical purpose, generally is not useful to a person in the absence of an illness or injury, and is appropriate for use in the home.

Claim Review Activities

CMS’s “Medicare Program Integrity Manual,” Pub. No. 100-08 (Integrity Manual), chapter 3, section 3.4.5, defines three types of claim review activities: automated prepayment review (performed by computers), routine prepayment and postpayment reviews (performed by nonmedical professionals), and complex prepayment and postpayment medical reviews (performed by licensed medical professionals). Only a complex medical review requires that a licensed medical professional evaluate medical records to determine whether a service or an item is covered and medically necessary. Pursuant to the Integrity Manual, a medical reviewer who performs a complex medical review must follow national coverage determinations (NCD) and local coverage determinations (LCD) and must consider the beneficiary’s clinical condition as indicated by the beneficiary’s medical records.

To identify program vulnerabilities, four DME Medicare administrative contractors currently conduct prepayment and postpayment medical reviews based on analyses of DME claim data. In addition, three DME program safeguard contractors (PSC) conduct medical review for early detection, prevention, intervention, and investigation of potential fraud.

---

1CMS develops NCDs to describe the circumstances for nationwide Medicare coverage of specific medical services, procedures, and devices. Medicare contractors develop LCDs to specify the clinical circumstances under which services are considered reasonable and necessary in their jurisdictions.
Medical Reviews of Claims in the Comprehensive Error Rate Testing Program

CMS’s CERT contractor is AdvanceMed, a PSC. As part of the Medicare error rate process, the CERT contractor conducts medical record reviews of a random sample of paid claims. CMS’s contract requires that the CERT contractor make medical review decisions in accordance with the Integrity Manual; section 7 of the PSC Umbrella Statement of Work; and applicable guidance, such as NCDs, LCDs, and CMS coding manuals.

On August 22, 2008, we issued a report on the medical review of DME claims for the fiscal year (FY) 2006 CERT program. That report highlighted differences between the CERT contractor’s medical review methodology and the methodology that an independent medical review contractor used to make medical necessity determinations. The most significant difference in the methodology that the two contractors used to make their medical necessity determinations was that the CERT contractor applied clinical inference to the limited medical records available from suppliers, whereas the independent medical review contractor reviewed the full medical records available from physicians and did not rely on clinical inference.

CMS generally agreed with the recommendations in our report, which included requiring the CERT contractor to review all available supplier documentation and all medical records necessary to determine compliance with applicable medical necessity requirements. In its response, CMS stated that beginning with the FY 2007 improper payment report period, the CERT contractor had asked both physicians and suppliers for supporting information on DME claims.

Independent Medical Review Contractor

In September 2008, CMS contracted with Palmetto GBA (Palmetto) to perform an independent review of a subsample of DME claims that the CERT contractor had reviewed as part of the FY 2008 DME error rate process. The purpose of Palmetto’s review, as stated in the “CMS Financial Report, Fiscal Year 2008,” was to “strengthen our confidence in the CERT review findings and assure the accuracy of the reported error rate.” CMS’s contract required Palmetto to follow guidance in NCDs; LCDs; and CMS manuals, including the Integrity Manual, and to use the same documentation that the CERT contractor had used to assess whether payments for DME items met Medicare medical necessity and documentation requirements. With the exception of the requirement that Palmetto use the same documentation that the CERT contractor used, these review requirements are consistent with the definition of a complex medical review in the Integrity Manual.

---

2“Medical Review of Claims for the Fiscal Year 2006 Comprehensive Error Rate Testing Program” (A-01-07-00508).

3Palmetto has been a Medicare Part A and Part B contractor since the Medicare program began. Palmetto conducted prepayment and postpayment medical reviews of DME claims from January 1993 to March 2006, when the responsibility for all medical review activities transitioned to PSCs.
Congressionally Requested Review

We conducted this review at the request of the Senate Committee on Finance.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine whether (1) Palmetto complied with the CMS contract in performing medical reviews of a subsample of claims from the FY 2008 CERT DME sample and (2) Palmetto’s results provided assurance that the FY 2008 DME error rate was accurate.

Scope

Our review covered Palmetto’s evaluation of a subsample of 250 paid claims from the sample of 14,221 DME claims that the CERT contractor had reviewed in determining the FY 2008 DME error rate.

We limited our review of internal controls to obtaining an understanding of CMS’s written policies regarding medical reviews and of Palmetto’s adherence to those policies.

We performed our fieldwork at AdvanceMed in Richmond, Virginia, and at Palmetto in Columbia, South Carolina, during October and November 2008.

Methodology

To accomplish our objectives, we:

- reviewed Medicare requirements and CMS’s policies regarding medical reviews, including the requirements detailed in the Integrity Manual and the PSC Umbrella Statement of Work;
- reviewed CMS’s contracts with both the CERT contractor and Palmetto;
- interviewed Palmetto officials to obtain an understanding of their medical review procedures;
- monitored all correspondence between CMS and Palmetto to ensure that Palmetto performed independent medical reviews;
- reviewed the medical records and associated documents that the CERT contractor had provided to Palmetto for medical reviews;
- compared Palmetto’s results with the CERT contractor’s results;
• participated in a meeting with Palmetto and the CERT contractor to discuss differences in medical review determinations;

• discussed with officials of the four DME Medicare administrative contractors the methods they used for postpayment medical reviews; and

• discussed the results of our review with CMS officials.

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 objectives.

FINDINGS AND RECOMMENDATIONS

Palmetto complied with its CMS contract in performing medical reviews of a subsample of claims from the FY 2008 CERT DME sample. Using the same documentation that the CERT contractor had used, Palmetto followed the protocols in the applicable NCDs, LCDs, and CMS manuals to determine whether the DME items in the subsample were medically necessary and adequately documented.

Palmetto’s results did not provide assurance that the FY 2008 DME error rate was accurate. Palmetto found that 175 of the 250 sampled claims were in error, significantly exceeding the 23 errors found by the CERT contractor. After further review, the CERT contractor agreed with 17 of Palmetto’s additional error determinations (for a total of 40 error determinations) but disagreed with the remaining 135 error determinations. Most of Palmetto’s error determinations were based on insufficient documentation to establish medical necessity.

Palmetto’s review determinations differed from those of the CERT contractor because of (1) incorrect medical necessity determinations by the CERT contractor and (2) differences in review standards and methodology. Specifically, the CERT contractor agreed that it had made incorrect determinations on 17 claims after it reviewed Palmetto’s determinations. The differences in review standards and methodology were due to the CERT contractor’s use of clinical inference to make medical necessity determinations based on its review of supplier documents, beneficiary claim histories, and limited medical records. In contrast, officials of Palmetto—as well as other DME medical review contractors—stated that they required beneficiary medical records to perform medical reviews and make medical necessity determinations.

The CERT contractor’s acknowledgment of the additional 17 errors and its use of limited medical records to infer medical necessity, which was inconsistent with the methodology used by Palmetto and other DME medical review contractors, cast doubt on the accuracy of the FY 2008 DME error rate.
PROGRAM REQUIREMENTS

Medicare Payment Requirements

Section 1833(e) of the Social Security Act (the Act) precludes payment to any provider of services or other person without information necessary to determine the amount due the provider.

Section 1862(a)(1)(A) of the Act states that no Medicare payment may be made for items or services that are not reasonable and necessary for diagnosing or treating illness or injury or for improving the functioning of a malformed body member.

Medical Reviews of Durable Medical Equipment Claims

The Integrity Manual, chapter 5, section 5.7, states: “For any DME item to be covered by Medicare, the patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable).”

COMPLIANCE WITH CONTRACT

Palmetto complied with the CMS contract in performing medical reviews of a subsample of claims from the FY 2008 CERT DME sample. Using the same documentation that the CERT contractor had used, Palmetto followed the protocols in the applicable NCDs, LCDs, and CMS manuals to determine whether the DME items in the subsample were medically necessary and adequately documented.

ASSURANCE OF ERROR RATE ACCURACY

Palmetto’s results did not provide assurance that the FY 2008 DME error rate was accurate. Palmetto found that 175 of the 250 sampled claims were in error, more than seven times the 23 erroneous claims that the CERT contractor had found. Palmetto agreed with the CERT contractor that the 23 claims were in error.

Palmetto’s Error Determinations

The table on the next page shows the types of documentation that Palmetto received from the CERT contractor and Palmetto’s determinations based on that documentation. Specifically, Palmetto determined that 160 of the 175 erroneous claims had insufficient documentation to establish medical necessity and that the remaining 15 claims had sufficient documentation to establish that the DME items were not medically necessary.
### Table: Documentation Reviewed and Palmetto’s Error Determinations

<table>
<thead>
<tr>
<th>Documentation Reviewed</th>
<th>No. of Erroneous Claims</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier documents⁴ only</td>
<td>16</td>
<td>Insufficient documentation</td>
</tr>
<tr>
<td>Supplier documents and physician orders or prescriptions</td>
<td>107</td>
<td>Insufficient documentation</td>
</tr>
<tr>
<td>Supplier documents and limited medical records</td>
<td>37</td>
<td>Insufficient documentation</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>160</td>
<td></td>
</tr>
<tr>
<td>Supplier documents and adequate medical records</td>
<td>15⁵</td>
<td>Sufficient documentation to determine that DME was not medically necessary</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>175</td>
<td></td>
</tr>
</tbody>
</table>

### Response to Palmetto’s Additional Error Determinations

Because of the significant number of differences between Palmetto’s determinations and the CERT contractor’s determinations, we participated in a dispute resolution process with medical review staff from Palmetto, the CERT contractor, and CMS. During that process, the CERT contractor agreed with 17 of Palmetto’s 152 additional error determinations but disagreed with 135.

#### Agreement on 17 Claims

The CERT contractor agreed with Palmetto that 17 claims were in error:

- For 10 claims, the documentation was insufficient to support the medical necessity and/or utilization requirements specified by the applicable LCDs.
- For seven claims, the medical records were sufficient to determine that the items were not medically necessary.

---

⁴Supplier documents include certificates of medical necessity (CMN), supplier notes, and proof of delivery documents.

⁵For 2 of the 15 claims, both the CERT contractor and Palmetto agreed that the claims were in error. For 7 of the 15 claims, the CERT contractor agreed with Palmetto’s error determinations after further review. For 6 of the 15 claims, the CERT contractor disagreed with Palmetto’s error determinations.
Clinical Inference of Medical Necessity Disputed on 135 Claims

The CERT contractor disagreed with Palmetto that 135 claims were in error on the grounds that the supplier documents, limited medical records, and beneficiary claim histories were sufficient to reasonably infer that the DME items were medically necessary. CMS asked Palmetto to review the CERT contractor’s written response to Palmetto’s determinations. Palmetto maintained that all 135 claims had been paid in error. Specifically, Palmetto concluded:

- For 129 claims, the documentation was insufficient to demonstrate medical necessity based on applicable NCD, LCD, and Integrity Manual requirements.
- For six claims, the documentation was sufficient to support its determinations that the items were not medically necessary.

DIFFERENCES IN REVIEW DETERMINATIONS

Palmetto’s review determinations differed from those of the CERT contractor because of (1) the CERT contractor’s incorrect medical necessity determinations and (2) differences in review standards and methodology. After its initial review, the CERT contractor believed that only 23 claims were in error. However, at the end of the claim dispute resolution process, both contractors agreed that 40 claims were in error. The CERT contractor acknowledged that it had made incorrect determinations on 17 claims.

For the 135 claims in dispute, Palmetto’s review determinations differed from those of the CERT contractor because of fundamental differences between the documentation standards and medical review methodology that the two contractors used to determine the medical necessity of DME items. Specifically, whereas Palmetto required sufficient medical records to support medical necessity determinations, the CERT contractor stated that it could infer medical necessity and compliance with applicable NCD and LCD requirements using supplier documents, beneficiary claim histories (e.g., hospital and physician claims), and limited medical records. Thus, the CERT contractor’s medical reviews did not generally include obtaining sufficient medical records.

In contrast, in its prior role as a DME medical review contractor, Palmetto obtained and relied extensively on beneficiary medical records to make medical review determinations. During the dispute resolution process, Palmetto officials told us that when they reviewed a claim to determine medical necessity, they required beneficiary medical records to support the information on the CMN and/or physician’s order. These officials stated that they could not make a decision regarding medical necessity without medical records. Accordingly, Palmetto based 160 of its 175 error determinations on insufficient documentation to determine medical necessity. If the CERT contractor had obtained sufficient medical records to determine medical necessity, Palmetto would likely have had fewer error determinations.

To determine whether the standards and methodology that Palmetto used were consistent with those that CMS’s other DME medical review contractors use, we interviewed medical review officials from the four DME Medicare administrative contractors. These officials stated that they
do not rely solely on the CMN and/or the physician’s order to make postpayment medical review determinations. Instead, they said that they perform medical reviews that rely extensively on beneficiary medical records.

CONCLUSION

Palmetto’s results did not provide assurance that the FY 2008 DME error rate was accurate. The CERT contractor’s failure to identify 17 errors and its use of limited medical records to infer medical necessity, which was inconsistent with the methodology used by Palmetto and other DME medical review contractors, cast doubt on the accuracy of the FY 2008 DME error rate.

For most of the 250 claims in our subsample, both the CERT contractor and Palmetto based their medical necessity determinations on their review of supplier documents and limited medical records. Our prior report noted that the FY 2006 DME error rate likely would have been significantly higher if the CERT contractor had reviewed additional records from physicians and other health care providers and information obtained from beneficiary interviews. Conversely, Palmetto would likely have found fewer errors in the subsample of FY 2008 CERT DME claims if the CERT contractor had obtained sufficient medical records to determine medical necessity.

RECOMMENDATIONS

We recommend that CMS require the CERT contractor to:

- develop a corrective action plan to reduce its number of incorrect determinations and
- perform a complex medical review by obtaining and reviewing all medical records from all relevant providers to support the medical necessity of DME items.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In comments on our draft report, CMS concurred with our findings and recommendations and outlined the steps it has taken to begin implementing our recommendations. In a technical comment, CMS requested a clarification of the number of sampled claims reviewed. We met with CMS officials and resolved their technical comment. The subsample contained 250 claims.

CMS’s comments are included in their entirety as the Appendix.
DATE: MAR 31, 2009

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera
Acting Administrator


Thank you for the opportunity to review and comment on the OIG’s draft report, “Independent Contractor’s Review of Durable Medical Equipment Claims From the Fiscal Year 2008 Comprehensive Error Rate Testing Program.” The Centers for Medicare & Medicaid Services (CMS) appreciates the time and resources the OIG has invested to determine the validity of the Comprehensive Error Rate Testing (CERT) durable medical equipment (DME) error rate reviews for fiscal year (FY) 2008.

As you know, CMS established the CERT program to comply with the Improper Payments Information Act of 2002. The CERT program calculates the Medicare fee-for-service (FFS) error rate and estimate of improper claim payments using a methodology approved by the OIG. The CERT methodology includes randomly selecting a sample of approximately 120,000 submitted claims, requesting medical records from providers who submitted the claims, and reviewing the claims and medical records for compliance with Medicare coverage, coding, and billing rules.

The CMS is committed to continually reviewing and refining its processes to improve the Medicare FFS error rate. This report, in addition to OIG’s earlier report on the FY 2006 CERT DME error rate (A-01-07-00508), has helped identify several areas for improvement, particularly regarding CMS guidance to contractors in its manuals. After the OIG’s earlier report on the FY 2006 CERT DME error rate, we instructed the CERT contractor to change the way they request documentation for DME claims. Now, the CERT contractor requests ordering physician medical records from the supplier. If the supplier fails to submit these records, the CERT contractor requests the records directly from the ordering physician.

In addition, CMS initiated its own internal review through an independent contractor of the FY 2008 DME error rate. We also reviewed our manual instructions to the contractors. Based on our own analysis and the OIG’s findings, CMS has determined that further direction needs to be
given to CMS contractors on our manual instructions. Contractors have interpreted manuals differently, especially regarding the use of clinical judgment. Our internal review found that there are two distinct interpretations that could be made and would allow a reviewer to arrive at different payment determinations.

All contractors request the same types of medical record documentation. However, CMS’ Program Integrity Manual (PIM) is vague regarding how much clinical judgment contractors can use when reviewing this documentation. As a result, the CERT contractor relied more heavily on clinical judgment than other contractors when making payment determinations in accordance with one section of our manuals. (PIM, Chapter 3, §3.4.5, Section C ¶4) For complex postpayment medical review, the DME Medicare Administrative Contractors (DME MACs), strictly applied another section of our manuals and therefore required more extensive medical records to be present in order to determine medical necessity. (PIM, Chapter 5, §5.7) Both interpretations are reasonable since our manuals allow reviewers to make a determination if they believe the submitted documentation and other available information provides sufficient information to determine medical necessity. As indicated in the OIG draft report, it is likely that additional documentation would have supported the payment decision made by the CERT contractor based on clinical judgment in many cases.

The CMS will revise its manuals to clarify requirements for reviewing documentation to promote uniform interpretation of our policies across all medical reviews performed by Medicare contractors and to reconcile any apparent conflicts between different sections of the manuals.

Additionally, CMS has provided direction to the CERT contractor regarding the use of clinical judgment. This direction clarified that clinical judgment cannot supersede documentation requirements in CMS statute, regulations, policies, or manuals. CMS plans to incorporate this clarification into the PIM.

The CMS goal is to pay the right amount to a legitimate provider, for correctly coded, medically necessary services, provided to an eligible beneficiary in an appropriate setting. In particular, CMS has set the goal of reducing the claims payment error rate to 3.7 percent by 2009. To achieve those error rate goals, we have realigned our resources by combining three divisions – Medical Review, Recovery Audit Operations, and Error Rate Measurement – into a new group within the Office of Financial Management named the Provider Compliance Group. This realignment will ensure that those entities that have primary responsibility for complex medical review activities are applying Medicare rules consistently and accurately.

Using the findings from this and the prior report, CMS is also planning to conduct an overall evaluation and assessment of the CERT DME process to determine whether changes should be made. For example, one of our current projects for the FY 2009 error rate is to conduct beneficiary and provider interviews for claims for DME items, such as oxygen or power mobility devices, that have been identified as highly vulnerable to fraud to verify the legitimacy of those claims. Given the current DME sample size, it would be very resource-intensive for us to do this type of review on all DME claims. Based on findings from this project, CMS will investigate the feasibility and value of incorporating these enhanced reviews into the CERT process. Any
changes that are deemed necessary should be made to ensure adherence with the CMS manuals in order to assure consistency and accuracy.

Our detailed comments on the report recommendations follow. In addition, we have included one technical comment regarding the number of claims reviewed by Palmetto.

**OIG Recommendation**

Require the CERT contractor to develop a corrective action plan to reduce its number of incorrect determinations.

**CMS Response**

The CMS concurs and is working with the CMS contracting office to formally request the CERT contractor to develop a corrective action plan. CMS will monitor the contractor’s corrective actions and their progress toward reducing incorrect determinations.

The CMS has already taken steps to improve the CERT contractor’s medical review quality control process. We are in the process of revising the CERT contractor’s statement of work to increase the number of quality assurance reviews conducted for DME claims. Additionally, the CERT contractor has, on its own initiative, implemented an internal quality review of DME claims included in the 2009 improper payment report period.

**OIG Recommendation**

Require the CERT contractor to perform a complex medical review by obtaining and reviewing all medical records from all relevant providers to support the medical necessity of DME items.

**CMS Response**

The CMS agrees with the OIG that it is important that the Medicare contractors obtain and review all required medical records when making payment determinations. As discussed above, CMS has directed the CERT contractor that clinical judgment cannot be used to supersede specific documentation requirements in statute, regulations, policies, or manuals. CMS will ensure that all claims in the FY 2009 improper payment measurement are reviewed in accordance with this policy.

**Technical Comment**

The OIG states the sample of claims reviewed by Palmetto was 250 claims. According to our records, the number of claims reviewed by Palmetto was actually 299. CMS respectfully requests a clarification of the number of sampled claims reviewed for the study.