January 13, 2011

TO: Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C (A-09-08-00045)

Attached, for your information, is an advance copy of our final report on Medicare claims for home blood-glucose test strips and lancets for the durable medical equipment Medicare administrative contractor for Jurisdiction C. We will issue this report to CIGNA Government Services, LLC, within 5 business days.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Robert A. Vito, Acting Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Robert.Vito@oig.hhs.gov or Lori A. Ahlstrand, Regional Inspector for Audit Services, Region IX, at (415) 437-8360 or through email at Lori.Ahlstrand@oig.hhs.gov. Please refer to report number A-09-08-00045.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

January 21, 2011

Report Number: A-09-08-00045

Ms. Jean Rush
President
CIGNA Government Services, LLC
Two Vantage Way
Nashville, TN 37228

Dear Ms. Rush:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C*. 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, or contact Jessica Kim, Audit Manager, at (323) 261-7218, extension 702, or through email at Yun.Kim@oig.hhs.gov. Please refer to report number A-09-08-00045 in all correspondence.

Sincerely,

/Lori A. Ahlstrand/
Regional Inspector General
for Audit Services

Enclosure

cc:
Ms. Jennifer Ullig
Compliance Manager
CIGNA Government Services, LLC

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, MO 64106

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE CLAIMS FOR HOME BLOOD-GLUCOSE TEST STRIPS AND LANCETS

DURABLE MEDICAL EQUIPMENT MEDICARE ADMINISTRATIVE CONTRACTOR FOR JURISDICTION C

Daniel R. Levinson
Inspector General

January 2011
A-09-08-00045

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), 1861(s)(6), and 1861(n) of the Social Security Act, Medicare Part B covers home blood-glucose test strip and lancet supplies (test strips and lancets) that physicians prescribe for diabetics. The Centers for Medicare & Medicaid Services (CMS) contracts with four durable medical equipment Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims for test strips and/or lancets. These DME MACs replaced the Durable Medical Equipment Regional Carriers (DMERC). The amount allowed for payment is equal to the lesser of the Medicare fee schedule amount or the amount charged by a DME supplier. Medicare pays the beneficiary or the supplier the amount allowed for payment, less the beneficiary share (i.e., deductibles and coinsurance).

The quantity of test strips and lancets that Medicare covers depends on the beneficiary's usual medical needs. Medicare utilization guidelines allow up to 100 test strips and 100 lancets every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics. To be reimbursed for a claim for any quantity of test strips and/or lancets, the DME supplier is required to maintain (1) a physician order containing the items to be dispensed, the specific frequency of testing, and the physician's signature with the date and (2) proof of delivery. The supplier may refill an order only when the beneficiary has nearly exhausted the previous supply and specifically requests the supplies to be dispensed.

Additional requirements apply for reimbursement of a claim for a quantity of test strips and/or lancets that exceeds the utilization guidelines (high utilization claim). Specifically, there must be documentation in the beneficiary's medical records supporting the specific reason for the additional supplies and documentation in the physician's or supplier's records supporting the actual frequency of testing. Further, the physician must have seen the patient and evaluated the patient's diabetic control within 6 months before ordering the quantity of supplies in excess of the guidelines.

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 claims of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) for Jurisdiction C as of June 1, 2007. Palmetto Government Benefits Administrators, LLC (Palmetto GBA), was the Region C DMERC and processed the DMEPOS claims through May 31, 2007. During calendar year (CY) 2007, the program safeguard contractor for Jurisdiction C was responsible for the medical review function, which was transferred to CGS effective March 1, 2008.

CGS and Palmetto GBA allowed for payment $499 million in Medicare Part B claims for test strips and/or lancets for CY 2007. We focused our review on high utilization claims. To identify these claims, we analyzed the information submitted by DME suppliers on the claim forms. We did not verify the accuracy of the claim information. We estimated that CGS and Palmetto GBA allowed for payment $221 million for the claims that we identified as high

utilization claims. We reviewed a sample of 100 high utilization claims allowed for payment by CGS and Palmetto GBA.

OBJECTIVE

Our objective was to determine whether high utilization claims for test strips and/or lancets that CGS and Palmetto GBA allowed for payment were supported in accordance with Medicare documentation requirements.

SUMMARY OF FINDINGS

Of the 100 sampled claims for test strips and/or lancets, 21 claims were supported in accordance with Medicare documentation requirements. However, the remaining 79 claims were not supported because each claim had one or more deficiencies:

- The quantity of supplies that exceeded utilization guidelines was not supported with documentation indicating the actual frequency of testing, the specific reason for the additional supplies, or the treating physician's evaluation of the patient's diabetic control within 6 months before ordering the supplies (45 claims).

- There was no documentation supporting that refill requirements had been met (42 claims).

- Physician orders were missing or incomplete (22 claims).

- Proof-of-delivery records were missing (12 claims).

For CY 2007, based on our sample results, we estimated that CGS and Palmetto GBA inappropriately allowed for payment approximately $125 million in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that CGS and Palmetto GBA inappropriately paid approximately $96.6 million to DME suppliers.

CGS and Palmetto GBA made improper payments to DME suppliers because CGS and Palmetto GBA did not have controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements. Specifically, they did not have system edits to identify, and review when necessary, high utilization claims. In addition, they did not have system edits to identify claims with overlapping service dates for the same beneficiary. This billing pattern caused CGS and Palmetto GBA to allow payment for claims when beneficiaries had not nearly exhausted previously dispensed test strips and/or lancets.

CGS and Palmetto GBA could have saved Medicare an estimated $96.6 million for CY 2007 if they had had controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements.

RECOMMENDATIONS

To help achieve potential savings for the Medicare program in future years, we recommend that CGS, as the current DME MAC:

- implement system edits to identify high utilization claims for test strips and/or lancets and work with CMS to develop cost-effective ways of determining which claims should be further reviewed for compliance with Medicare documentation requirements;

- implement system edits to identify claims for test strips and/or lancets that have overlapping service dates for the same beneficiary; and

- enforce Medicare documentation requirements for claims for test strips and/or lancets by (1) identifying DME suppliers with a high volume of high utilization claims, (2) performing prepayment reviews of those suppliers, and (3) referring them to the Office of Inspector General or CMS for further review or investigation when necessary.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its written comments on our draft report, CGS concurred with our recommendations and provided information on actions that it had taken or planned to take to address the recommendations. However, CGS requested that we revise the report to indicate that the PSC for Jurisdiction C was responsible for the medical review function during CY 2007. We revised the report as CGS requested. CGS's comments are included in their entirety as Appendix E.

TABLE OF CONTENTS

INTRODUCTION

BACKGROUND

Medicare Program

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.

Durable Medical Equipment

Pursuant to sections 1832(a)(1), 1861(s)(6), and 1861(n) of the Act, Medicare Part B covers durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). DMEPOS includes items such as wheelchairs, hospital beds, oxygen tents, and medical supplies. Section 1862(a)(1)(A) of the Act requires that, to be paid by Medicare, a service or an item be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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). CMS's *DME MAC Workload Implementation Handbook*, dated March 1, 2007, required the DMERCs to transfer their workloads, including Medicare data, records, and operational activities, to the DME MACs. Further, this handbook required the DME MACs to attempt to retain, to the extent practicable, the DMERCs' existing edits[1] in the claims processing system (system edits).

Pursuant to the Statement of Work, the DME MACs' responsibilities included, but were not limited to, (1) receiving Medicare Part B claims from DME suppliers and beneficiaries within their jurisdictions, (2) performing edits on these claims to determine whether they were complete and reimbursable, (3) calculating Medicare payment amounts and remitting payments to the appropriate parties, and (4) educating DME suppliers on Medicare requirements and billing procedures.[2]

The Statement of Work was modified to require the DME MACs to perform medical reviews as of March 1, 2008. Medical reviews include the collection of information and review of medical records to ensure that Medicare pays only for services that meet all Medicare coverage, coding, and medical necessity requirements. The amount allowed for payment is equal to the lesser of the Medicare fee schedule amount or the amount charged by a DME supplier. Medicare pays the

[1] An edit is programming within the standard claims processing system that selects certain claims; evaluates or compares information on the selected claims or other accessible sources; and, depending on the evaluation, takes action on the claims, such as paying them in full, paying them in part, or suspending them for manual review.

[2] Pursuant to the Statement of Work for DMERCs, their responsibilities were similar to the DME MACs' responsibilities.

beneficiary or the supplier the amount allowed for payment, less the beneficiary share (i.e., deductibles and coinsurance).

National and Local Coverage Determinations

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. Medicare contractors, such as carriers, MACs, or program safeguard contractors (PSC), are required to follow NCDs.

A Local Coverage Determination (LCD) is a decision by a Medicare contractor whether to cover a particular item or service on a contractorwide basis in accordance with section 1862(a)(1)(A) of the Act. Medicare contractors may establish or adopt LCDs when there is no NCD or when they need to further define an NCD. LCDs must be consistent with all statutes; rulings; regulations; and national coverage, payment, and coding policies.

Home Blood-Glucose Test Strip and Lancet Supplies

Pursuant to sections 1832(a)(1), 1861(s)(6), and 1861(n) of the Act, Medicare Part B covers home blood-glucose test strip and lancet supplies (test strips and lancets) that physicians prescribe for diabetics, whether they are insulin-treated or non-insulin-treated. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a test strip, and inserts the strip into a home blood-glucose monitor to obtain a reading of the blood-sugar level. DME suppliers provide test strips and lancets to beneficiaries.

The NCD for home blood-glucose monitors specifies coverage of test strips and lancets for patients who meet certain conditions and use home blood-glucose monitors to better control their glucose levels by frequently checking those levels and appropriately contacting their attending physicians for advice and treatment.[3] However, the NCD does not specify utilization guidelines and documentation requirements for test strips and lancets.

To establish utilization guidelines and documentation requirements for test strips and lancets, DME Medicare contractors either established or adopted LCDs, which state that the quantity of test strips and lancets that Medicare covers depends on the beneficiary's usual medical needs. The LCD for each DME Medicare contractor further states that Medicare covers up to 100 test strips and 100 lancets every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics.[4]

To be reimbursed for a claim for any quantity of test strips and/or lancets, the DME supplier is required to maintain (1) a physician order containing the items to be dispensed, the specific frequency of testing, and the physician's signature with the date and (2) proof of delivery. The

[3] *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, chapter 1, section 40.2, effective June 19, 2006.

[4] Medicare considers 50 test strips as 1 unit and 100 lancets as 1 unit.

supplier may refill an order only when the beneficiary has nearly exhausted the previous supply and specifically requests the supplies to be dispensed.

Additional requirements apply for reimbursement of a claim for a quantity of test strips and/or lancets that exceeds the utilization guidelines (high utilization claim). Specifically, there must be documentation in the beneficiary's medical records supporting the specific reason for the additional supplies and documentation in the physician's or supplier's records supporting the actual frequency of testing. Further, the physician must have seen the patient and evaluated the patient's diabetic control within 6 months before ordering the quantity of supplies in excess of the guidelines.

Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C

CMS awarded the DME MAC contract for Jurisdiction C to CIGNA Government Services, LLC (CGS), a wholly owned subsidiary of Connecticut General Life Insurance Company, which is a parent corporation for a family of companies known as CIGNA HealthCare. 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 Government Benefits Administrators, LLC (Palmetto GBA), was the Region C DMERC and processed DMEPOS claims through May 31, 2007.[5] Palmetto GBA transferred its DMEPOS files to CGS after CMS awarded CGS the DME MAC contract for Jurisdiction C. During calendar year (CY) 2007, the PSC for Jurisdiction C was responsible for the medical review function, which was transferred to CGS effective March 1, 2008.

CGS and Palmetto GBA allowed for payment $499 million in Medicare Part B claims for test strips and/or lancets for CY 2007.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether high utilization claims for test strips and/or lancets that CGS and Palmetto GBA allowed for payment were supported in accordance with Medicare documentation requirements.

[5] CMS 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.

Scope

We focused our review on high utilization claims for test strips and/or lancets for CY 2007. To identify these claims, we analyzed the information submitted by DME suppliers on the Medicare claim forms. We did not verify the accuracy of the claim information.[6] We estimated that CGS and Palmetto GBA allowed for payment $221 million for the claims that we identified as high utilization claims. (See Appendixes A and B.)

We did not review the overall internal control structure of CGS. Rather, we limited our review of internal controls to those that were significant to the objective of our audit. At the time of our review, Palmetto GBA was no longer operating as a DMERC for Region C. Therefore, we limited our review of Palmetto GBA's internal controls to gaining an understanding of Palmetto GBA's system edits in 2007 for test strip and/or lancet claims.

We performed our review from July 2008 to June 2010 and conducted fieldwork at CGS's office in Nashville, Tennessee.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed the LCD adopted by CGS and Palmetto GBA;
- reviewed the Statements of Work for CGS and Palmetto GBA prepared by CMS for the administration of DMEPOS;
- reviewed CGS's policies and procedures for processing Medicare claims for test strips and/or lancets;
- interviewed CGS officials and former Palmetto GBA officials[7] to obtain an understanding of CGS's and Palmetto GBA's Medicare claim processing procedures for test strips and/or lancets;
- obtained from the CMS National Claims History (NCH) files CGS's and Palmetto GBA's Medicare Part B claims for test strips and/or lancets with service dates ending in CY 2007 and removed any service line in which the amount allowed for

[6] During our audit, we determined that some claims we had identified as high utilization claims were in fact within the Medicare utilization guidelines based on our review of the beneficiaries' medical records and additional analysis of the claim information.

[7] We were unable to substantiate information that the former Palmetto GBA officials provided during the interview because documentation of Palmetto GBA's claim processing procedures for test strip and/or lancet claims for 2007 was not available.

payment was less than the lowest nationwide Medicare Part B fee schedule amount in CY 2007 ($32.74 for test strips and $10.83 for lancets);

- created a sampling frame from the NCH data and randomly selected a sample of 500 Medicare beneficiaries to estimate the number of high utilization claims that CGS and Palmetto GBA allowed for payment (Appendixes A and B);

- randomly selected a sample of 100 high utilization claims[8] to estimate the amounts that CGS and Palmetto GBA allowed for payment and paid to suppliers for claims that were not supported in accordance with Medicare documentation requirements (Appendixes C and D);[9]

- obtained medical records and other documentation from suppliers and physicians for the 100 sampled claims;

- reviewed medical records and other documentation to determine whether each of the 100 sampled claims was supported in accordance with Medicare documentation requirements; and

- shared the results of our review with CGS.

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

Of the 100 sampled claims for test strips and/or lancets, 21 claims were supported in accordance with Medicare documentation requirements. However, the remaining 79 claims were not supported because each claim had one or more deficiencies. For CY 2007, based on our sample results, we estimated that CGS and Palmetto GBA inappropriately allowed for payment approximately $125 million in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that CGS and Palmetto GBA inappropriately paid approximately $96.6 million to DME suppliers.

Table 1 summarizes the deficiencies noted and the number of claims that contained each type of deficiency.

[8] Of the 100 claims, 31 claims were within the Medicare utilization guidelines based on our review of the beneficiaries' medical records and additional analysis of the claim information.

[9] Palmetto GBA and CGS processed and allowed for payment 44 and 56 sampled claims, respectively.

Table 1: Summary of Deficiencies in Sampled Claims

Type of Deficiency	No. of Claims With Deficiencies[10]
Lack of Documentation for Quantities in Excess of Utilization Guidelines	45
Lack of Documentation To Support Refills of Supplies	42
Missing or Incomplete Physician Orders	22
Missing Proof-of-Delivery Records	12

CGS and Palmetto GBA made improper payments to DME suppliers because CGS and Palmetto GBA did not have controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements. Specifically, they did not have system edits to identify, and review when necessary, high utilization claims. In addition, they did not have system edits to identify claims with overlapping service dates for the same beneficiary. This billing pattern caused CGS and Palmetto GBA to allow payment for claims when beneficiaries had not nearly exhausted previously dispensed test strips and/or lancets.

UNSUPPORTED CLAIMS FOR TEST STRIPS AND/OR LANCETS

Lack of Documentation for Quantities in Excess of Utilization Guidelines

For a quantity of test strips and lancets in excess of the utilization guidelines, LCD L11520 requires that the treating physician document in the medical records the specific reason for the additional supplies.

LCD L11520 also requires that when a DME supplier refills a physician order for a quantity of test strips and lancets in excess of the utilization guidelines, "[T]here must be documentation in the physician's records (e.g., a specific narrative statement that adequately documents the frequency at which the patient is actually testing or a copy of the beneficiary's log) or in the supplier's records (e.g., a copy of the beneficiary's log) that the patient is actually testing at a frequency that corroborates the quantity of supplies that have been dispensed."

Finally, LCD L11520 states that the treating physician must have evaluated the patient's diabetic control within 6 months before ordering the quantity of test strips and lancets in excess of the guidelines.

For 45 of the 100 sampled claims, the beneficiary's medical records did not have the required documentation to support a quantity of supplies in excess of the guidelines.

[10] The total exceeds 79 because 45 of the 79 claims contained more than 1 deficiency.

No Documentation of Actual Testing Frequency To Support Refills

For 35 of the 45 claims, neither the physician's nor the supplier's records contained documentation supporting that the beneficiary was actually testing at a "frequency that corroborates the quantity of supplies that have been dispensed." For example, for one claim, a supplier dispensed a refill consisting of six units of test strips and three units of lancets for a non-insulin-treated patient, which would be the quantity for a testing frequency of about three times a day. This frequency corresponded to the physician order, which was signed by the physician. However, neither the physician nor the supplier maintained records documenting that the patient was actually testing three times a day, such as a specific narrative statement from the physician or a copy of the beneficiary's log.

No Documentation of Specific Reason for Additional Supplies

For 30 of the 45 claims, the beneficiary's medical records did not indicate a specific reason for the additional supplies. For example, for one claim, a DME supplier provided a copy of a physician order indicating a testing frequency of six times a day for an insulin-treated patient. The utilization guidelines for an insulin-treated patient specify a quantity of supplies indicating a testing frequency of three times a day. However, the patient's medical records did not indicate a specific reason for the additional supplies.

No Documentation of Treating Physician's Evaluation of Patient's Diabetic Control

For 4 of the 45 claims, the beneficiary's medical records did not indicate that the physician evaluated the patient's diabetic control within 6 months before ordering the quantity of supplies in excess of the utilization guidelines. For example, a DME supplier submitted a claim for test strips provided to a non-insulin-treated patient based on a physician order signed December 20, 2006. The physician order indicated a testing frequency of two times a day, which was in excess of the guidelines. When we contacted the physician, he provided medical records showing that he saw the patient on March 28, 2006, which was almost 9 months before the date of the physician order. The physician did not see the patient again until March 12, 2007, which was after the date of the physician order.

Lack of Documentation To Support Refills of Supplies

The *Medicare Program Integrity Manual* (the Manual), Pub. No. 100-08, chapter 4, section 4.26.1, states that, when a DME supplier refills an original order, the supplier must contact the beneficiary before dispensing the refill. Further, the Manual states: "For subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product."

LCD L11520 states that the DME supplier may not dispense test strips and lancets until the beneficiary has nearly exhausted the previously dispensed supplies. A beneficiary or the beneficiary's caregiver must specifically request the refill of test strips and lancets before the supplier dispenses supplies to the beneficiary. In addition, the LCD states: "The supplier must

not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has 'authorized' this in advance."

For 42 of the 100 sampled claims, suppliers did not have documentation that refill requirements had been met.

Previously Dispensed Supplies Not Nearly Exhausted

For 33 of the 42 claims, DME suppliers dispensed test strips and/or lancets when the beneficiaries had not nearly exhausted the previously dispensed supplies. Of the 33 claims, 25 claims had multiple suppliers that had dispensed test strips and/or lancets for the same beneficiary with overlapping service dates. In one instance, five suppliers had billed Medicare for claims with overlapping services dates for the same beneficiary. The beneficiary's physician had ordered a testing frequency of four times a day, which required eight units of test strips and four units of lancets for a 3-month period. As illustrated in Table 2, the supplier for the selected sample claim dispensed six units of test strips and three units of lancets and submitted a claim to CGS for service dates covering the period July 12 through September 19, 2007 (approximately a 2-month period). In addition, four other suppliers submitted claims to CGS or Palmetto GBA for the same beneficiary covering service periods from April 30 through October 29, 2007. CGS and Palmetto GBA allowed payment for all of these claims.

Table 2: Multiple DME Suppliers' Billing of a Beneficiary's Test Strips

DME Supplier	Service Dates		Units of Test Strips	Units of Lancets
1	04/30/2007	07/29/2007	8	4
2	06/24/2007	09/23/2007	6	3
3	06/27/2007	09/26/2007	4	2
4 (Sample Claim)	07/12/2007	09/19/2007	6	3
5	07/19/2007	10/16/2007	2	1
1	07/30/2007	10/29/2007	8	4

Refills Not Specifically Requested

For 16 of the 42 claims, the beneficiary or the beneficiary's caregiver had not specifically requested the refill before the supplies were dispensed. For example, for one claim, when we requested documentation supporting the specific refill request, a DME supplier provided a preprinted form with the statement "Unless otherwise arranged, I request automatic delivery of my diabetic supplies and will notify you when I have too many supplies on hand." The beneficiary's caregiver signed this form on March 17, 2006, which was more than a year before five units of test strips and three units of lancets were dispensed on September 14, 2007.

Missing or Incomplete Physician Orders

Section 1833(e) of the Act requires that providers furnish DME MACs with necessary information to receive payment for services provided to Medicare beneficiaries.

The Manual, chapter 5, section 5.2.1, requires that the DME supplier obtain an order from the treating physician before dispensing supplies to a beneficiary. The Manual, chapter 5, sections 5.2.2 and 5.2.3, provide that, when a DME supplier dispenses items based on a verbal order, the supplier must have a written order in its records before submitting a claim to the DME MAC.

LCD L11520 states: "An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request." Further, the LCD requires that the order for test strips and lancets include the specific frequency of testing and the items to be dispensed.

For 22 of the 100 sampled claims, suppliers submitted claims when physician orders were missing or incomplete.

Missing Physician Orders

For 17 of the 22 claims, the DME suppliers did not have written physician orders. For 14 of these claims, the suppliers did not provide copies of the written orders. For example, a supplier provided a physician order that appeared to be signed by a physician on February 9, 2007. When we contacted the physician, he told us that he had not signed the order. For the three remaining claims, the suppliers had documentation of verbal orders from the physicians but did not have written orders. The physician records did not contain copies of written orders or references to them.

Incomplete Physician Orders

For 5 of the 22 claims, the DME suppliers had physician orders without required elements, including the specific frequency of testing and the items to be dispensed:

- For three claims, copies of the physician orders did not indicate the specific frequency of testing. Instead, they indicated either "as directed" or the quantity of supplies (e.g., "100 test strips").

- For two claims, copies of the physician orders did not indicate the items to be dispensed.

Missing Proof-of-Delivery Records

Pursuant to 42 CFR § 424.57(c)(12), DME suppliers are required to maintain proof of delivery of DME supplies provided to Medicare beneficiaries. The Manual, chapter 4, section 4.26, requires that DME suppliers maintain proof-of-delivery documentation in their files for 7 years.

For 12 of the 100 sampled claims, suppliers did not maintain proof of delivery. When we requested delivery records, the suppliers did not provide proof of delivery. For example, a supplier submitted a claim for six units of test strips and three units of lancets for the service date

beginning December 23, 2006. When we requested proof of delivery, the supplier provided a patient contact log with a note that the beneficiary refused to accept the supplies.[11]

EFFECT OF UNALLOWABLE CLAIMS

For 79 of the items in our sample, DME suppliers' high utilization claims for test strips and/or lancets were not supported in accordance with Medicare documentation requirements. As a result, CGS and Palmetto GBA allowed $8,483 in Medicare Part B payments for unallowable claims. Of this amount, CGS and Palmetto GBA inappropriately paid $6,557 to suppliers.

For CY 2007, based on our sample results, we estimated that CGS and Palmetto GBA inappropriately allowed for payment $125,018,182 in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that CGS and Palmetto GBA inappropriately paid $96,633,764 to suppliers.

LACK OF CONTROLS

CGS and Palmetto GBA made improper payments to DME suppliers because CGS and Palmetto GBA did not have controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements. Specifically, they did not have system edits to identify, and review when necessary, high utilization claims. (CGS did have edits for test strips and/or lancets that rejected claims submitted without the required modifier and an appropriate diagnosis code.) In addition, CGS and Palmetto GBA did not have system edits to identify suppliers' claims with overlapping service dates for the same beneficiary. This billing pattern caused them to allow payment for claims when beneficiaries had not nearly exhausted previously dispensed test strips and/or lancets.

CGS and Palmetto GBA could have saved Medicare an estimated $96,633,764 for CY 2007 if they had had controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements.

RECOMMENDATIONS

To help achieve potential savings for the Medicare program in future years, we recommend that CGS, as the current DME MAC:

- implement system edits to identify high utilization claims for test strips and/or lancets and work with CMS to develop cost-effective ways of determining which claims should be further reviewed for compliance with Medicare documentation requirements;

- implement system edits to identify claims for test strips and/or lancets that have overlapping service dates for the same beneficiary; and

[11] The DME supplier stated that it had initiated the process of refunding the overpayment for the claim to CGS in December 2008, which was after we requested documentation from the supplier.

- enforce Medicare documentation requirements for claims for test strips and/or lancets by (1) identifying DME suppliers with a high volume of high utilization claims, (2) performing prepayment reviews of those suppliers, and (3) referring them to the Office of Inspector General or CMS for further review or investigation when necessary.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its written comments on our draft report, CGS concurred with our recommendations and provided information on actions that it had taken or planned to take to address the recommendations. However, CGS requested that we revise the report to indicate that the PSC for Jurisdiction C was responsible for the medical review function during CY 2007. We revised the report as CGS requested.

Regarding the first two recommendations, CGS stated that it had implemented edits since March 2008 to identify high utilization claims and claims that have overlapping dates of service for the same beneficiary. Regarding the third recommendation, CGS described multiple ongoing efforts to enforce Medicare documentation requirements, including examining the LCD to determine whether additional safeguards can be implemented and conducting prepayment reviews of suppliers with high utilization claims. CGS's comments are included in their entirety as Appendix E.

OTHER MATTERS

We identified issues with DME suppliers' use of modifiers and unique physician identification numbers for test strip and/or lancet claims.

INCORRECT MODIFIER

LCD L11520 requires that a Medicare claim for test strips and/or lancets include the KX modifier for insulin-treated patients and the KS modifier for non-insulin-treated patients.

For 24 of the 100 sampled claims, DME suppliers submitted claims with incorrect modifiers. For example, a claim from one supplier for test strips included the KS modifier rather than the KX modifier when the physician order indicated that the beneficiary was being treated with insulin. The physician's medical records also supported that the beneficiary was being treated with insulin.

INCORRECT UNIQUE IDENTIFICATION NUMBER

Section 1833(q)(1) of the Act requires that a Medicare claim include the unique identification number for the referring physician.

For 13 of the 100 sampled claims, DME suppliers submitted claims with incorrect unique identification numbers for referring physicians. For example, a claim from one supplier for lancets included an incorrect unique identification number for the referring (i.e., ordering) physician. The beneficiary obtained an order for lancets from a new physician and submitted the

order to the DME supplier. However, the supplier claimed the lancets using the unique identification number of the former physician contained in its billing system.

APPENDIXES

APPENDIX A: FRAME SAMPLE DESIGN AND METHODOLOGY

OBJECTIVE

To accomplish our audit objective, we reviewed a sample of claims (error sample) to determine whether Medicare documentation requirements had been met and to estimate the effect of noncompliance. The error sample included Medicare Part B claims for home blood-glucose test strip and lancet supplies (test strips and lancets) that CIGNA Government Services, LLC (CGS), and Palmetto Government Benefits Administrator, LLC (Palmetto GBA), allowed for payment with quantities that exceeded Medicare utilization guidelines based on our analysis of claims (high utilization claims). To estimate the effect of noncompliance, it was necessary to determine the total number of high utilization claims that CGS and Palmetto GBA allowed for payment. However, because high utilization claims were not easily identifiable, we could not determine the total number of high utilization claims without significant time and effort. Therefore, the objective of reviewing this sample was to estimate the number of high utilization claims that CGS and Palmetto GBA allowed for payment (frame sample).

POPULATION

The population consisted of high utilization claims. The population was limited to the Part B claims included in the Centers for Medicare & Medicaid Services (CMS) National Claims History file for calendar year (CY) 2007, updated as of December 2007.

SAMPLING FRAME

We extracted Medicare Part B claims for test strips and/or lancets (Healthcare Common Procedure Coding System codes A4253 and A4259, respectively) with service dates ending in CY 2007. We removed from the claims any service line in which the amount allowed for payment was less than the lowest nationwide CY 2007 Medicare fee schedule amount ($32.74 for test strips and $10.83 for lancets). The result was a data file containing 4,361,179 claims for test strips and/or lancets for 1,488,636 beneficiaries. This data file included claims with all quantities of test strips and/or lancets.

To identify high utilization claims for test strips and/or lancets, we determined that an in-depth analysis of each of the 4,361,179 claims in the data file was needed. However, because it was not practical to analyze all of these claims, we used a random sample to estimate the total number of and the amount allowed for payment for high utilization claims. The sampling frame contained the 1,488,636 beneficiaries for whom the 4,361,179 test strip and/or lancet claims had been submitted to CGS and Palmetto GBA.

To identify high utilization claims for the frame sample, we analyzed the information submitted by durable medical equipment (DME) suppliers on the claim forms. We did not verify the accuracy of the information. However, during our audit, we determined that some claims we had identified as high utilization claims were in fact within the Medicare utilization guidelines based on our review of the beneficiaries' medical records and additional analysis of the claim information. Because it was not practical to obtain and review the medical records for all

beneficiaries with test strip and/or lancet claims, we considered a claim to be a high utilization claim based solely on the claim information submitted by DME suppliers. Further, we did not perform additional analysis of all claims. As a result, the sampling frame of high utilization claims contained claims in which the quantity of test strips and/or lancets was within the utilization guidelines.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE UNIT

The sample unit was a beneficiary with one or more claims for test strips and/or lancets that CGS and Palmetto GBA allowed for payment.

SAMPLE SIZE

The sample size was 500 beneficiaries.

SOURCE OF RANDOM NUMBERS

We used the Office of Inspector General, Office of Audit Services (OAS), statistical software to generate a set of random numbers.

METHOD OF SELECTING SAMPLE UNITS

To select the sample units, we consecutively numbered the sample units in the frame from 1 to 1,488,636. After generating 500 random numbers, we selected the corresponding frame items. No frame sample unit was replaced.

CHARACTERISTICS TO BE MEASURED

For each sample unit, we obtained all the beneficiary's claims for test strips and/or lancets and analyzed the claim information submitted by DME suppliers to determine the number of high utilization claims.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the total number of high utilization claims that CGS and Palmetto GBA allowed for payment, as well as the amount allowed for payment.

APPENDIX B: FRAME SAMPLE RESULTS AND ESTIMATES

Sample Results for Estimate of Total Number of Claims

No. of Beneficiaries With Test Strip/Lancet Claims in Sampling Frame	No. of Claims for Beneficiaries in Sampling Frame	No. of Beneficiaries in Sample	No. of Claims for Sampled Beneficiaries	No. of Sampled Beneficiaries That Had High Utilization Claims	No. of High Utilization Claims for Sampled Beneficiaries
1,488,636	4,361,179	500	1,488	188	493

Sample Results for Estimate of Amount Allowed for Payment

No. of Beneficiaries With Test Strip/Lancet Claims in Sampling Frame	Amount Allowed for Payment by CGS and Palmetto GBA in Sampling Frame	No. of Beneficiaries in Sample	Amount Allowed for Payment in Sample	No. of Sampled Beneficiaries That Had High Utilization Claims	Amount Allowed for High Utilization Claims for Sampled Beneficiaries
1,488,636	$497,281,558	500	$181,316	188	$74,237

Estimates for High Utilization Claims
(Limits Calculated for a 90-Percent Confidence Interval)

	Estimated Total No. of Claims	Estimated Amount Allowed for Payment
Point estimate	1,467,795	$221,024,069
Lower limit	1,275,919	189,751,195
Upper limit	1,659,671	252,296,943

APPENDIX C: ERROR SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of Medicare Part B high utilization claims for test strips and/or lancets that CGS and Palmetto GBA allowed for payment. The population was limited to the Part B claims included in CMS's National Claims History file for CY 2007, updated as of December 2007.

SAMPLING FRAME

The number of sample units in the sampling frame was unknown and was estimated by the sample described in Appendixes A and B.

SAMPLE DESIGN

We used a simple random sample.

SAMPLE UNIT

The sample unit was a high utilization claim for test strips and/or lancets.

SAMPLE SIZE

The sample size was 100 high utilization claims for test strips and/or lancets.

SOURCE OF RANDOM NUMBERS

We used the OAS statistical software to generate the random numbers.

METHOD OF SELECTING SAMPLE UNITS

To select the sample units, we consecutively numbered the test strip and/or lancet claims in the data file from 1 to 4,361,179. Using the random numbers in the order they were generated, we matched each random number to the corresponding test strip and/or lancet claim. We analyzed the claim corresponding to the first randomly generated number to determine whether the claim was within the Medicare utilization guidelines. If the claim exceeded the guidelines, we included it in the sample as a high utilization claim. If the claim did not exceed the guidelines, we replaced it with the claim corresponding to the next randomly generated number and analyzed the newly selected claim. We continued this process until we had identified 100 high utilization claims.[1]

[1] Of the 100 claims, 31 claims were within the utilization guidelines based on our review of the beneficiaries' medical records and additional analysis of the claim information.

ESTIMATION METHODOLOGY

Based on the results of this sample and the sample described in Appendixes A and B, we used the OAS statistical software to estimate the (1) amount allowed for payment by CGS and Palmetto GBA for claims that we identified as high utilization claims and were not supported in accordance with Medicare documentation requirements and (2) amount that CGS and Palmetto GBA paid to DME suppliers for claims that we identified as high utilization claims and were not supported in accordance with Medicare documentation requirements.

APPENDIX D: ERROR SAMPLE RESULTS AND ESTIMATES

Sample Results for Amount That CGS and Palmetto GBA Allowed for Payment

Sample Size	No. of Claims With Deficiencies	Value of Sample	Value of Unallowable Amount
100	79	$12,535	$8,483

Sample Results for Amount That CGS and Palmetto GBA Paid to DME Suppliers

Sample Size	No. of Claims With Deficiencies	Value of Sample	Value of Unallowable Amount
100	76[1]	$9,769	$6,557

Estimates of Unallowable Amounts
(Limits Calculated for a 90-Percent Confidence Interval)

	Amount CGS and Palmetto GBA Allowed for Payment	Amount CGS and Palmetto GBA Paid to DME Suppliers
Point estimate	$125,018,182	$96,633,764
Lower limit	98,337,687	75,849,567
Upper limit	151,698,677	117,417,961

[1] Payments for 76 of the 79 claims with deficiencies were made to DME suppliers. The payment for one claim was made to the Medicare beneficiary. For the remaining two claims, the payments were made to neither suppliers nor the beneficiaries because the beneficiaries were required to pay deductibles.

APPENDIX E: AUDITEE COMMENTS

Jean Rush
President

CIGNA Government Services

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September 16, 2010

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand,

On August 20, 2010, CIGNA Government Services (CGS) received Draft Report A-09-08-00045: "Review of Medicare Claims For Home Blood Glucose Test Strips and Lancets." CGS has reviewed the report and acknowledges the facts presented in the report. CGS' response to the recommendations noted in the report is included as requested. However, it should be noted that the report is missing relevant information which is critical to an understanding of the recommendations.

CGS requests that the OIG consider revising the report to account for the following relevant information. The draft report does not include the fact that the Program Safeguard Contractor (PSC) was responsible for medical review activities during the scope of the review (CY2007). Although CGS did assume responsibility for claims processing in Jurisdiction C on June 1, 2007 as noted in the report, CGS was not responsible for medical review activities until March 2008. This distinction is critical to note in the report since a large percentage of errors attributed to CGS and/or Palmetto GBA were documentation errors that would be determined only through complex medical review (which was handled by the PSC).

In addition to the item noted above, CGS submits the following comments in relation to the items noted in the "Other Matters" section of the report:

1. Other Matters – Incorrect Modifier

LCD L11520 requires that a Medicare claim for test strips and/or lancets include the KX modifier for insulin-treated patients and the KS modifier for non-insulin-treated patients. For 24 of the 100 sampled claims, DME suppliers submitted claims with incorrect modifiers. For example, a claim from one DME supplier for test strips included the KS modifier rather than the KX modifier when the physician order indicated that the beneficiary was being treated with insulin. The documentation in the treating physician's medical records also supported that the beneficiary was being treated with insulin.

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CGS Response
During CY2007, CGS did not have complex medical review. Therefore, the only editing CGS could have implemented to detect these types of billing errors, was automated claim denials. Current LCD language does not allow for automated editing. According to Internet-Only Manual 100-8, Chapter 3, Sections 3.4.1.1 and 3.5.1, automated review must have clear policy that serves as the basis for denial. In addition, Chapter 13, Section 13.5.3 instructs contractors, when developing LCDs, to avoid the use of absolute terms and instead *"use phrases such as 'rarely medically necessary' or 'not usually medically necessary' in proposed LCDs to describe situations where a service is considered to be, in almost all instances, not reasonable and necessary."*

The current LCD attempts to balance limits on utilization while still allowing for clinical circumstances when additional supplies are necessary. This is accomplished through coverage criteria stating that additional supplies may be provided if the treating physician documents that the supplies are reasonable and necessary. The lack of absolute language stating a service is "never medically necessary" or will "always be denied" prevents editing to automatically deny claims. Consequently, claims with amounts of testing supplies exceeding the guidelines in the LCD must be manually reviewed. As previously stated, CGS did not have the authority to perform complex medical review during the timeframe included in the scope of this review. The PSC was responsible for the medical review function in CY2007. CGS did not assume responsibility for Medical Review until March 2008.

CGS does concur with the recommendations in the report. CGS has or will take the following actions in response to the recommendations:

1. Recommendation: Implement system edits to identify high utilization claims for test strips and/or lancets and work with CMS to develop cost-effective ways of determining which claims should be further reviewed for compliance with Medicare documentation requirements.

CGS Response
CGS assumed responsibility for the Medical Review (MR) function in March 2008. Since then, manual edits have been implemented to identify over-utilization claims which require further development and complex medical review. Glucose testing supplies are a high priority item in CGS's Medical Review strategy as well as other operational areas (i.e., Claims, Provider Outreach and Education). The DME MAC Medical Directors are examining the Local Coverage Determination (LCD) for blood glucose monitors and supplies to determine if additional safeguards, such as incorporation of absolute language can be implemented. This will help prevent inappropriate payments and accommodate additional automated editing of claims for testing supplies (see response number three below for related information).

2. Recommendation: Implement system edits to identify claims for test strips and/or lancets that have overlapping service dates for the same beneficiary

CGS Response
Additional edits have been implemented to identify and deny claims from multiple suppliers with overlapping dates of service for the same beneficiary.

3. Recommendation: Enforce Medicare documentation requirements for claims for test strips and/or lancets by:

1. identifying DME suppliers with a high volume of high utilization claims
2. performing prepayment reviews of those DME suppliers, and
3. referring them to the Office of Inspector General or CMS for further review or investigation when necessary.

CGS Response

1. As noted in CGS' response to Recommendation 1, CGS has implemented system edits for over-utilization. The DME MAC Medical Directors are examining the LCD to determine if additional safeguards can be implemented to prevent inappropriate payments.
2. CGS Medical Review (MR), through data analysis, has conducted (and continues to conduct) prepayment review of suppliers with high utilization of diabetic testing supplies.
3. CGS MR has a process in place for referring suppliers of diabetic testing supplies to the Recovery Audit Contractors (RAC) and Zoned Program Integrity Contractors (ZPIC). This is consistent with guidance outlined in the Internet Only Manual (IOM), which places the responsibility for making referrals to the OIG on the PSCs and ZPICs, not the DME MAC Contractor. Per the IOM, publication 100-08, chapter 4, section 4.2.2:

   "The PSC and the ZPIC BI unit is responsible for preventing, detecting, and deterring Medicare fraud. The PSC and the ZPIC BI unit: Refers cases to the Office of the Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions."

In addition, CGS has made the following efforts to encourage policy compliance within the provider community:

- In August 2008, CGS MR issued a "Dear Physician" letter to the top 1,500 ordering physicians of diabetic testing supplies in Jurisdiction C. In this letter, Dr. Robert Hoover, Jurisdiction C Medical Director, outlined Medicare requirements for blood glucose testing as well as required physician documentation requirements.

- CGS released a "Documentation Checklist" on the Jurisdiction C website for the Glucose Monitors and Supplies policy in June 2008. This checklist can be used as a tool for suppliers to ensure they are following requirements related to the diabetic supplies policy.
- CGS's Provider Outreach and Education department (POE) has conducted extensive provider and supplier education with regard to proper coding, coverage, and documentation requirements for home blood glucose monitors and supplies. These efforts include multiple bulletin articles, workshops, state and trade association meetings, webinars, documentation checklists and a segment in CGS' online video education series, Medicare Minute. CGS POE has also developed a KX Modifier Chart that provides specific education and instruction on how the KX modifier should be appended based on the type of item or service being provided and billed in reference to diabetic supplies.

If you have any questions or additional requests related to this review, please contact Elizabeth Noelting, Compliance Specialist at 615-782-4541.

Sincerely,

Jean Rush
President
CIGNA Government Services