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

Washington, D.C. 20201

February 10, 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 B (A-09-08-00044)

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 B. We will issue this report to National Government Services, Inc., 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 George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at George.Reeb@oig.hhs.gov or Lori A. Ahlstrand, Regional Inspector General for Audit Services, Region IX, at (415) 437-8360 or through email at Lori.Ahlstrand@oig.hhs.gov. Please refer to report number A-09-08-00044.

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

February 17, 2011

Report Number: A-09-08-00044

Ms. Sandra Miller
President
National Government Services, Inc.
8115 Knue Road
Indianapolis, IN 46250-1936

Dear Ms. Miller:

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 B.* 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-09-08-00044 in all correspondence.

Sincerely,

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

Enclosure

Direct Reply to HHS Action Official:

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

Daniel R. Levinson
Inspector General

February 2011
A-09-08-00044

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. 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.

National Government Services, Inc. (NGS), the DME MAC for Jurisdiction B, allowed for payment $297 million in Medicare Part B claims for test strips and/or lancets for calendar year (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 NGS allowed for payment $92 million for the claims that we identified as high utilization claims.

OBJECTIVE

Our objective was to determine whether high utilization claims for test strips and/or lancets that NGS 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, 17 claims were supported in accordance with Medicare documentation requirements. However, the remaining 83 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 specific reason for the additional supplies, the actual frequency of testing, or the treating physician's evaluation of the patient's diabetic control within 6 months before ordering the supplies (61 claims).

- There was no documentation supporting that refill requirements had been met (36 claims).

- Physician orders were missing or incomplete (24 claims).

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

For CY 2007, based on our sample results, we estimated that NGS inappropriately allowed for payment approximately $56.2 million in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that NGS inappropriately paid approximately $42.2 million to DME suppliers.

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

NGS could have saved Medicare an estimated $42.2 million for CY 2007 if it 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 NGS:

- 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

In its written comments on our draft report, NGS agreed with our recommendations and provided information on actions that it had taken or planned to take to address the recommendations. NGS's comments are included in their entirety as Appendix E.

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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. 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[1] 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.

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 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

[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.

generally outline the conditions under which a service or device is considered covered. MACs are required to follow NCDs.

A Local Coverage Determination (LCD) is a decision by a Medicare contractor, such as a MAC or program safeguard contractor, whether to cover a particular item or service on a contractorwide basis pursuant to 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.[2] 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 MACs 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 MAC 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.[3]

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

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

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

patient's diabetic control within 6 months before ordering the quantity of supplies in excess of the guidelines.

National Government Services, Inc.

National Government Services, Inc. (NGS), a wholly owned subsidiary of WellPoint, Inc., has been the DME MAC for Jurisdiction B since January 1, 2007. CMS awarded a DME MAC contract for Jurisdiction B to AdminaStar Federal, Inc. (AdminaStar), on January 6, 2006. The operations of AdminaStar and a few other companies were combined to form NGS. NGS's main office is located in Indianapolis, Indiana, through which it serves Medicare beneficiaries residing in Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin.[4]

NGS allowed for payment $297 million in Medicare Part B claims for test strips and/or lancets for calendar year (CY) 2007.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

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.[5] We estimated that NGS allowed for payment $92 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 NGS. Rather, we limited our review of internal controls to those that were significant to the objective of our audit.

We performed our review from July 2008 to July 2010 and conducted fieldwork at NGS's office in Indianapolis, Indiana.

[4] AdminaStar temporarily served as the DME MAC for Virginia and West Virginia because of delays in awarding the DME MAC contract for Jurisdiction C. After this contract was awarded and implemented in June 2007, these two States became part of Jurisdiction C.

[5] 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.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed the LCD adopted by NGS;
- reviewed the Statement of Work for NGS prepared by CMS for the administration of DMEPOS;
- reviewed NGS's policies and procedures for processing Medicare claims for test strips and/or lancets;
- interviewed NGS officials to obtain an understanding of its Medicare claim processing procedures for test strips and/or lancets;
- obtained from the CMS National Claims History (NCH) files NGS'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 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 NGS allowed for payment (Appendixes A and B);
- randomly selected a sample of 100 high utilization claims[6] to estimate the amounts that NGS allowed for payment and paid to suppliers for claims that were not supported in accordance with Medicare documentation requirements (Appendixes C and D);
- 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 NGS.

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

[6] Of the 100 claims, 24 claims were within the Medicare utilization guidelines based on our review of the beneficiaries' medical records and additional analysis of the claim information.

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, 17 claims were supported in accordance with Medicare documentation requirements. However, the remaining 83 claims were not supported because each claim had one or more deficiencies. For CY 2007, based on our sample results, we estimated that NGS inappropriately allowed for payment approximately $56.2 million in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that NGS inappropriately paid approximately $42.2 million to DME suppliers.

The table below summarizes the deficiencies noted and the number of claims that contained each type of deficiency.

Summary of Deficiencies in Sampled Claims

Type of Deficiency	No. of Claims With Deficiencies[7]
Lack of Documentation for Quantities in Excess of Utilization Guidelines	61
Lack of Documentation To Support Refills of Supplies	36
Missing or Incomplete Physician Orders	24
Missing Proof-of-Delivery Records	7

NGS made improper payments to DME suppliers because NGS did not have controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements. Specifically, NGS did not have system edits to identify, and review when necessary, high utilization claims. In addition, NGS did not have system edits to identify claims with overlapping service dates for the same beneficiary. This billing pattern caused NGS 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 L11530 requires that the treating physician document in the medical records the specific reason for the additional supplies.

[7] The total exceeds 83 because 50 of the 83 claims contained more than 1 deficiency.

LCD L11530 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 L11530 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 61 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.

No Documentation of Specific Reason for Additional Supplies

For 56 of the 61 claims, the beneficiary's medical records did not indicate a specific reason for the additional supplies. For example, for one claim, a supplier provided a copy of a physician order, which was prepared by the supplier on a preprinted form and signed by the physician, 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 approximately three times a day. The patient's medical records indicated that the patient was treated with insulin but did not indicate a specific reason for the additional supplies.

No Documentation of Actual Testing Frequency

For 30 of the 61 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 DME supplier dispensed 7 units of test strips for an insulin-treated patient, which would be the quantity for a testing frequency of approximately 12 times a day. This testing frequency corresponded to the physician order. However, neither the physician nor the supplier maintained records documenting that the patient was actually testing 12 times a day, such as a specific narrative statement from the physician or a copy of the beneficiary's log.

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

For 2 of the 61 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 dispensed on February 23, 2007, to a non-insulin-treated patient based on a physician order signed April 11, 2006. The physician order indicated a testing frequency of four times a day, which was in excess of the guidelines. However, the patient's medical records showed that the physician was a cardiologist who had performed heart-related procedures for the beneficiary in February 2006 before the order date. The medical records did not indicate that the physician had treated the patient for a diabetic condition or had evaluated the patient's diabetic control.

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 L11530 states that the DME supplier may not dispense test strips and lancets until the beneficiary has nearly exhausted the previously dispensed supplies. In addition, 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.

For 36 of the 100 sampled claims, suppliers did not have documentation that refill requirements had been met.

Previously Dispensed Supplies Not Nearly Exhausted

For 29 of the 36 claims, DME suppliers dispensed test strips and/or lancets when the beneficiaries had not nearly exhausted the previously dispensed supplies. Of the 29 claims, 12 claims had multiple suppliers that had dispensed test strips and/or lancets for the same beneficiary with overlapping service dates. In one instance, two suppliers had billed Medicare for claims with overlapping service dates for the same beneficiary. The beneficiary's physician had ordered a testing frequency of three times a day for an insulin-treated patient. The supplier for the selected sample claim dispensed four units of test strips and submitted a claim to NGS for service dates covering the period February 6 through May 5, 2007. In addition, a supplier dispensed six units of test strips and submitted a claim to NGS for the same beneficiary covering the period January 30 through April 29, 2007. NGS allowed payment for both of these claims.

Refills Not Specifically Requested

For 10 of the 36 claims, the beneficiary or the beneficiary's caregiver had not specifically requested the refill before the supplies were dispensed. For example, for one claim, a DME supplier did not have documentation supporting the specific refill request from the beneficiary or the beneficiary's caregiver before it dispensed two units of test strips on June 8, 2007. When we requested the documentation, the supplier stated that it did not maintain documentation indicating that beneficiaries specifically requested refills.

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 L11530 states: "An order for each item billed must be signed and dated by the physician who is treating the patient's diabetes, kept on file by the supplier, and made available upon request." Further, the LCD requires that the order for test strips and lancets include (1) the specific frequency of testing, (2) the treating physician's signature, and (3) the date of the treating physician's signature.

For 24 of the 100 sampled claims, suppliers submitted claims when physician orders were missing or incomplete.

Missing Physician Orders

For 13 of the 24 claims, the DME suppliers did not have written physician orders. For 11 of the 13 claims, suppliers did not provide copies of the written orders. For example, when we contacted a supplier to obtain a copy of the order for one of the claims, an official stated that the supplier did not maintain copies of written orders after supplies had been dispensed. For the remaining two 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 11 of the 24 claims, the DME suppliers had physician orders without required elements, including the specific frequency of testing, the treating physician's signature, and the date of the physician signature:

- For nine claims, copies of the physician orders did not indicate the specific frequency of testing. Instead, they indicated "as directed" and/or the quantity of supplies (e.g., "50 test strips").

- For three claims, copies of the physician orders did not have the physicians' signatures. For example, for one claim, a supplier provided a copy of the physician order signed by a licensed practical nurse.

- For one claim, the copy of the physician order did not have the date of the physician's signature. The physician's records did not indicate that he had ordered the supplies.

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 7 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 or provided printouts from their computerized dispensing systems containing dispensing information that did not correspond to the sampled claims. For example, for one claim, a supplier did not provide any

documentation. When we requested proof of delivery, the supplier informed us that it could not locate the documentation.

EFFECT OF UNALLOWABLE CLAIMS

For 83 of the items in our sample, claims for test strips and/or lancets that we identified as high utilization claims were not supported in accordance with Medicare documentation requirements. As a result, NGS allowed $7,348 in Medicare Part B payments for unallowable claims. Of this amount, NGS inappropriately paid $5,519 to suppliers.

For CY 2007, based on our sample results, we estimated that NGS inappropriately allowed for payment $56,221,550 in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that NGS inappropriately paid $42,227,372 to suppliers.

LACK OF CONTROLS

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

NGS could have saved Medicare an estimated $42,227,372 for CY 2007 if it 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 NGS:

- 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

In its written comments on our draft report, NGS agreed with our recommendations and provided information on actions that it had taken or planned to take to address the recommendations.

Regarding the first recommendation, NGS stated that it had implemented a service-specific edit after a probe review in May 2008 found a high error rate for glucose monitor supplies. Regarding the second recommendation, NGS stated that it is developing an edit to address the problem of overlapping service dates on claims for individual beneficiaries. Regarding the third recommendation, NGS described multiple efforts to enforce Medicare documentation requirements, including identifying DME suppliers with a high volume of high utilization claims, conducting prepayment reviews for glucose monitor supplies, and referring suppliers to other Medicare contractors for further review. NGS'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 L11530 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 28 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 5 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 test strips included an incorrect unique identification number for the referring (i.e., ordering) physician. The supplier received its medication refill request form from the referring physician's office before dispensing the supplies. However, the supplier incorrectly recorded the unique identification number on the claim, which appeared to be a typographical error.

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/or lancet supplies (test strips and/or lancets) that National Government Services, Inc. (NGS), 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 NGS 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 NGS 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 2,920,352 claims for test strips and/or lancets for 933,082 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 2,920,352 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 933,082 beneficiaries for whom the 2,920,352 test strip and/or lancet claims had been submitted to NGS.

To identify high utilization claims for the frame sample, we analyzed the information submitted by durable medical equipment (DME) suppliers on the claim form. 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 the DME supplier. 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 NGS 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 933,082. 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 NGS 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
933,082	2,920,352	500	1,684	163	412

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 NGS 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
933,082	$295,517,387	500	$169,084	163	$49,486

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	768,860	$92,348,413
Lower limit	644,743	76,922,019
Upper limit	892,977	107,774,807

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 NGS 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 2,920,352. Using the random numbers in the order in which 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 utilization 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, 24 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 NGS for claims that we identified as high utilization claims and were not supported in accordance with Medicare documentation requirements and (2) amount that NGS 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 NGS Allowed for Payment

Sample Size	No. of Claims With Deficiencies	Value of Sample	Value of Unallowable Amount
100	83	$11,655	$7,348

Sample Results for Amount That NGS Paid to DME Suppliers

Sample Size	No. of Claims With Deficiencies	Value of Sample	Value of Unallowable Amount
100	76[1]	$8,730	$5,519

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

	Amount NGS Allowed for Payment	Amount NGS Paid to DME Suppliers
Point estimate	$56,221,550	$42,227,372
Lower limit	43,122,050	31,945,161
Upper limit	69,321,049	52,509,583

[1] Payments for 76 of the 83 claims with deficiencies were made to DME suppliers. The payments for two claims were made to the Medicare beneficiaries. For the remaining five claims, the payments were made to neither suppliers nor the beneficiaries because the beneficiaries were required to pay deductibles.

APPENDIX E: AUDITEE COMMENTS

National Government Services

National Government Services, Inc.
8115 Knue Road
Indianapolis, Indiana 46250-1936
A CMS Contracted Agent

Medicare

Report Number: A-09-08-00044

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

Dear Ms. Ahlstrand:

National Government Services (NGS) appreciates the opportunity to review and comment on the above referenced draft audit report. Responses to the recommendations made by the Office of Inspector General are included below.

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.

   NGS Response:
   We agree with the OIG's recommendation. Glucose monitor supplies, test strips and lancets, have been a focus of the National Government Services (NGS) Jurisdiction B DME MAC medical review (MR) activities since the MR function returned to the DME MAC in March 2008. The data analysis that we perform to establish our Medical Review Strategy gives strong weight to the fact that glucose monitor supplies are high in terms of allowed charges (currently the second highest policy group in Jurisdiction B) and that they have been consistently at or near the top in terms of CERT errors (currently second highest). They have been the highest priority item for our MR department as evidenced by the fact that, over the past two and a half years, they have represented the greatest volume of developed and reviewed claims.

   NGS' initiated a widespread (i.e., service-specific) probe review of glucose monitor supplies in May 2008. The high error rate found on that review resulted in our establishing a service-specific edit for glucose monitor supplies which has continued to the present. We have prioritized our widespread review activities by focusing on those claims that represented the most egregious overutilization.

   Our ability to thoroughly address the problem of overutilization of glucose monitor supplies is limited by the resources that are available to us. Jurisdiction B receives

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approximately 3.6 million claims per year for glucose monitor supplies. Based on our data analysis, approximately 20% of those represent claims for quantities of test strips and/or lancets that exceed the utilization guidelines in the LCD. Based on our funding, the total number of claims on which we are able to perform complex manual MR for all DMEPOS items is a small fraction of the test strip and lancet claims that represent suspected overutilization.

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

NGS Response:
We agree with the OIG's recommendation. Up to this time, our edits have focused on individual claims that exceed the utilization guidelines defined in the Glucose Monitors Local Coverage Determination (LCD). However, we are currently in the process of developing an edit that will address the problem of overlapping dates of services on claims for individual beneficiaries.

In addition to implementation of system edits, our Provider Outreach and Education (POE) department recently sent a letter to Medicare beneficiaries who received their supplies from three or more suppliers. Beneficiaries with multiple suppliers are very likely to have claims with overlapping dates of service.

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.

NGS Response:
We agree with the OIG's recommendations. We have identified high volume suppliers, especially those that represented significant overutilization, as targets for supplier-specific reviews.

Our reviews of claims for glucose monitor supplies, both widespread and supplier-specific, have been conducted on a prepayment basis to maximize efficiency and to keep Medicare from paying for items that are not medically necessary and/or do not meet other documentation requirements.

Jurisdiction B MR also refers to other contractors when appropriate.

- We refer suppliers to the PSC if we identify suspected fraudulent behavior. The PSC determines when it is appropriate to refer a case to the Office of the Inspector General.

- We have referred one large volume national supplier to the National Supplier Clearinghouse for consideration of revocation of its supplier number because it has repeatedly not responded to our requests for documentation.

- We have recommended that the Recovery Audit Contractor (RAC) consider review of high volume problem suppliers. Since the RAC has more ability to expand their medical review resources and thus address a much higher volume of claims, its review would have more of an impact on suppliers and would more likely result in a change in their behavior.

In addition to our MR activities, NGS is addressing the problem of overutilization through a number of other interventions. Our POE Department has conducted webinars and has a web-based self-study course to educate all suppliers. Our POE department provides individualized education to suppliers who have been the subject of supplier-specific reviews. A letter from the Jurisdiction B medical director to prescribing physicians is available on our web site to assist suppliers in educating physicians concerning Medicare policy.

4. **Other Matters – Incorrect Modifier**
LCD L11530 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 29 of the 100 sampled claims, DME suppliers submitted claims with incorrect modifiers.

NGS Response:
We have identified similar errors in the reviews that we have conducted. We have included education on this issue with individual suppliers as a follow-up to supplier-specific reviews. He has included information about the correct use of modifiers in our general education on glucose monitors supplies.

5. **Other Matters – 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 5 of the 100 sampled claims, DME suppliers submitted claims with incorrect unique identification numbers for referring physicians.

NGS Response:
Education concerning the importance of accuracy in reporting the National Provider Identifier (NPI) for referring physicians is a routine part of our general Provider Education and Outreach activities.

In conclusion, the Jurisdiction B DME MAC is working to address all of the recommendations outlined in the OIG report – within the scope of our available resources. We will continue with these efforts and look for additional interventions to help address the problems with overutilization of glucose test strips and lancets.

Sincerely,

David Barnett
Jurisdiction B DME MAC Project Manager