



August 25, 2010

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

**FROM:** /George M. Reeb/  
Acting Deputy Inspector General for Audit Services

**SUBJECT:** Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—  
Durable Medical Equipment Medicare Administrative Contractor for  
Jurisdiction A (A-09-08-00043)

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 A. We will issue this report to NHIC, Corp., 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) 786-4558 or through email at [Robert.Vito@oig.hhs.gov](mailto: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](mailto:Lori.Ahlstrand@oig.hhs.gov). Please refer to report number A-09-08-00043.

Attachment



August 30, 2010

Report Number: A-09-08-00043

Ms. Anne Bockhoff Dalton  
Vice President  
NHIC, Corp.  
75 Sgt. William B. Terry Drive  
Hingham, MA 02043

Dear Ms. Dalton:

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 A*. 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 James Kenny, Audit Manager, at (415) 437-8370 or through email at [James.Kenny@oig.hhs.gov](mailto:James.Kenny@oig.hhs.gov). Please refer to report number A-09-08-00043 in all correspondence.

Sincerely,

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

Enclosure

cc:

Ms. Jennifer Otten  
American Society of Quality Certified Manager of Quality/  
Organizational Excellence Quality Manager  
NHIC, Corp.

**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 12<sup>th</sup> Street, Room 235  
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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 A**



Daniel R. Levinson  
Inspector General

August 2010  
A-09-08-00043

# *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 DME 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 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 DME 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 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 treating 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.

NHIC, Corp. (NHIC), the DME MAC for Jurisdiction A, allowed for payment \$225 million in Medicare Part B claims for test strips and 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 Medicare claim forms. We did not verify the accuracy of the claim information. We estimated that NHIC allowed for payment \$95 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 NHIC 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, 30 were supported in accordance with Medicare documentation requirements. However, the remaining 70 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 (55 claims).
- There was no documentation supporting that refill requirements had been met (27 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 NHIC inappropriately allowed for payment approximately \$49.2 million in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that NHIC inappropriately paid approximately \$39.2 million to DME suppliers.

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

NHIC could have saved Medicare an estimated \$39.2 million for CY 2007 if it 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 NHIC:

- 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; 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 DME 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, NHIC provided information on actions that it had taken to address our recommendations. NHIC'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<sup>1</sup> on these claims to determine whether they are 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 DME 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

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<sup>1</sup> 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 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 it 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.<sup>2</sup> 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.<sup>3</sup>

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 DME 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 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 treating physician must have seen the patient and

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<sup>2</sup> *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, chapter 1, section 40.2, effective June 19, 2006.

<sup>3</sup> Medicare considers 50 test strips as 1 unit and 100 lancets as 1 unit.

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

## **NHIC, Corp.**

NHIC, Corp. (NHIC), a wholly owned subsidiary of EDS Corporation, has been the DME MAC for Jurisdiction A since July 1, 2006. NHIC's main office is located in Hingham, Massachusetts, through which it serves Medicare beneficiaries residing in Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

NHIC allowed for payment \$225 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 NHIC 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.<sup>4</sup> We estimated that NHIC allowed for payment \$95 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 NHIC. Rather, we limited our review of internal controls to those controls that were significant to the objective of our audit.

We performed our review from August 2008 to February 2010 and conducted fieldwork at NHIC's offices in Hingham, Massachusetts, and Los Angeles, California.

### **Methodology**

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed the LCD adopted by NHIC;

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<sup>4</sup> 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.

- reviewed the Statement of Work prepared by CMS for the administration of DMEPOS;
- reviewed NHIC’s policies and procedures for processing Medicare claims for test strips and lancets;
- interviewed NHIC officials to obtain an understanding of its Medicare claim processing procedures for test strips and lancets;
- obtained from the CMS National Claims History (NCH) files NHIC’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 NHIC allowed for payment (Appendixes A and B);
- randomly selected a sample of 100 high utilization claims<sup>5</sup> to estimate the amounts that NHIC allowed for payment and paid to DME suppliers for claims that were not supported in accordance with Medicare documentation requirements (Appendixes C and D);
- obtained medical records and other documentation from DME 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 NHIC.

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.

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<sup>5</sup> Of the 100 claims, 17 claims were within the Medicare utilization guidelines based on our review of the beneficiaries’ medical records and additional analysis of the claim information.

## FINDINGS AND RECOMMENDATIONS

Of the 100 sampled claims for test strips and/or lancets, 30 claims were supported in accordance with Medicare documentation requirements. However, the remaining 70 claims were not supported because each claim had one or more deficiencies. For CY 2007, based on our sample results, we estimated that NHIC inappropriately allowed for payment approximately \$49.2 million in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that NHIC inappropriately paid approximately \$39.2 million to DME suppliers.

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

**Table 1: Summary of Deficiencies in Sampled Claims**

Type of Deficiency	No. of Claims With Deficiencies <sup>6</sup>
Lack of Documentation for Quantities in Excess of Utilization Guidelines	55
Lack of Documentation To Support Refills of Supplies	27
Missing or Incomplete Physician Orders	24
Missing Proof-of-Delivery Records	7

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

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

<sup>6</sup> The total exceeds 70 because 44 of the 70 claims contained more than 1 deficiency.

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 utilization guidelines.

For 55 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 utilization guidelines.

#### *No Documentation of Specific Reason for Additional Supplies*

For 46 of the 55 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 four times a day for a non-insulin-treated patient. The utilization guidelines for a non-insulin-treated patient specify a quantity of supplies indicating a testing frequency of approximately once a day. However, the patient's medical records did not indicate a specific reason for the additional supplies.

#### *No Documentation of Actual Testing Frequency*

For 39 of the 55 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 11 units of test strips and 6 units of lancets for an insulin-treated patient, which would be the quantity for a testing frequency of approximately six times a day. This testing frequency corresponded to the physician order, which was prepared by the DME supplier on a preprinted form and signed by the physician. However, neither the physician nor the DME supplier maintained records documenting that the patient was actually testing six 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 6 of the 55 claims, the beneficiary's medical records did not indicate that the treating 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 November 8, 2006. The physician order indicated a testing frequency of twice a day, which was in excess of the utilization guidelines. When we contacted the physician's office, we were told that the physician did not see the patient on November 8, 2006, and that the last time the physician saw the patient was November 28, 2005, which was almost 1 year before 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 DME 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/or lancets before the DME supplier dispenses supplies to the beneficiary.

For 27 of the 100 sampled claims, DME suppliers did not have documentation to support that refill requirements had been met.

### *Previously Dispensed Supplies Not Nearly Exhausted*

For 18 of the 27 claims, DME suppliers dispensed test strips and/or lancets when the beneficiaries had not nearly exhausted the previously dispensed supplies. Of the 18 claims, 13 claims had multiple DME suppliers that had dispensed test strips and/or lancets for the same beneficiary with overlapping service dates. In one instance, five DME suppliers had billed Medicare for claims with overlapping service dates for the same beneficiary. The beneficiary’s physician had ordered a testing frequency of once a day, which required two units of test strips for a 3-month period. As illustrated in Table 2, the DME supplier for the selected sample claim dispensed two units of test strips and submitted a claim to NHIC for service dates covering the period September 11 through December 11, 2007. In addition, four other DME suppliers submitted claims to NHIC for the same beneficiary covering service periods from June 25 through December 26, 2007. NHIC allowed payment for all of these claims.

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

<b>DME Supplier</b>	<b>Service Dates</b>		<b>Units of Test Strips</b>
1	06/25/2007	09/24/2007	6
2	09/10/2007	12/09/2007	2
3 (Sample Claim)	09/11/2007	12/11/2007	2
4	09/24/2007	12/23/2007	2
5	09/27/2007	12/26/2007	6

### *Refills Not Specifically Requested*

For 9 of the 27 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 four units of test strips and two units of lancets on

July 19, 2007. When we requested the documentation, the DME supplier submitted a refill request form, which was signed by the beneficiary on July 27, 2008.<sup>7</sup>

### **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 Medicare 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 DME 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, DME suppliers submitted claims when physician orders were missing or incomplete.

#### *Missing Physician Orders*

For 18 of the 24 claims, the DME suppliers did not have written physician orders. For 14 of these claims, the DME suppliers did not provide copies of the written orders. For example, when we contacted a DME supplier to obtain a copy of the order for one of the claims, an official responded: “The billing was incorrect and reimbursement must be made. The billing person involved is no longer employed by our company.” For the remaining four claims, the DME suppliers had documentation of verbal orders from the treating 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 6 of the 24 claims, the DME suppliers had physician orders without required elements, including the specific frequency of testing, the physician signature, and the date of the physician signature.

- For four 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”).

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<sup>7</sup> The Medicare claims data showed that the DME supplier dispensed to the beneficiary four units of test strips and two units of lancets on January 19, April 19, and July 19, 2007.

- For one claim, the copy of the physician order did not have the physician's signature. When we contacted the physician, he stated that he had never seen the beneficiary.
- 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, DME suppliers did not maintain proof of delivery. When we requested delivery records, the DME 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 two of the claims, a DME supplier provided computer printouts for prior claims. When we requested printouts for these claims, the DME supplier informed us that it had already provided everything in response to our request for documentation.

### **EFFECT OF UNALLOWABLE CLAIMS**

For 70 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, NHIC allowed \$6,889 in Medicare Part B payments for unallowable claims. Of this amount, NHIC inappropriately paid \$5,488 to DME suppliers.

For CY 2007, based on our sample results, we estimated that NHIC inappropriately allowed for payment \$49,214,902 in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that NHIC inappropriately paid \$39,206,181 to DME suppliers.

### **LACK OF CONTROLS**

NHIC made improper payments to DME suppliers because NHIC did not have controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements. Specifically, NHIC did not have system edits to identify, and review when necessary, high utilization claims. The only edit that NHIC had for claims for test strips and/or lancets was a "medically unlikely" edit, which rejected claims that had service dates covering a range of more than 99 days. In addition, NHIC did not have system edits to identify DME suppliers' claims with overlapping service dates for the same beneficiary. This billing pattern caused NHIC to allow payment for claims when beneficiaries had not nearly exhausted previously dispensed test strips and/or lancets.

NHIC could have saved Medicare an estimated \$39,206,181 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 NHIC:

- 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; 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 DME 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, NHIC provided information on actions that it had taken to address our recommendations. Regarding the first two recommendations, NHIC stated that it had implemented system edits in April 2010 to identify high utilization claims and claims that have overlapping service dates. Further, NHIC stated that it is currently performing several supplier-specific prepayment reviews for test strip and/or lancet claims. Regarding the third recommendation, NHIC stated that it has multiple ongoing efforts to enforce Medicare documentation requirements, including working with the program safeguard contractor and educating suppliers about the requirements. NHIC'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 11 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.

### **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 9 of the 100 sampled claims, DME suppliers submitted claims with incorrect unique identification numbers for referring physicians. For example, a claim from one DME 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 DME supplier claimed the lancets using the unique identification number of the beneficiary's 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 NHIC, Corp. (NHIC), 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 test strip and/or lancet claims that NHIC allowed for payment. However, because high utilization claims were not easily identifiable, we could not determine the total number of high utilization test strip and/or lancet claims without significant time and effort. Therefore, the objective of this sample was to estimate the number of high utilization test strip and/or lancet claims that NHIC 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 2,212,691 claims for test strips and/or lancets for 667,662 Medicare 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 2,212,691 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 for the frame sample consisted of the 667,662 Medicare beneficiaries for whom the 2,212,691 test strip and/or lancet claims had been submitted to NHIC.

To identify high utilization claims for the frame sample, we analyzed the information submitted by durable medical equipment (DME) suppliers on the Medicare claim form. We did not verify the accuracy of the claim information. However, during our audit, we determined that some claims we had identified as high utilization claims were in fact within the Medicare utilization guideline limits 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 Medicare utilization guideline limits.

## **SAMPLE DESIGN**

We used a simple random sample.

## **SAMPLE UNIT**

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

## **SAMPLE SIZE**

The sample size was 500 Medicare 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 667,662. 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 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 claims that we identified as high utilization claims that NHIC 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**

<b>No. of Beneficiaries With Test Strip/Lancet Claims in Sampling Frame</b>	<b>No. of Claims for Beneficiaries in Sampling Frame</b>	<b>No. of Beneficiaries in Sample</b>	<b>No. of Claims for Sampled Beneficiaries</b>	<b>No. of Sampled Beneficiaries That Had High Utilization Claims</b>	<b>No. of High Utilization Claims for Sampled Beneficiaries</b>
667,662	2,212,691	500	1,681	186	535

**Sample Results for Estimate of Amount Allowed for Payment**

<b>No. of Beneficiaries With Test Strip/Lancet Claims in Sampling Frame</b>	<b>Amount Allowed for Payment by NHIC in Sampling Frame</b>	<b>No. of Beneficiaries in Sample</b>	<b>Amount Allowed for Payment in Sample</b>	<b>No. of Sampled Beneficiaries That Had High Utilization Claims</b>	<b>Amount Allowed for High Utilization Claims for Sampled Beneficiaries</b>
667,662	\$224,538,931	500	\$179,527	186	\$70,833

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

	<b>Estimated Total No. of Claims</b>	<b>Estimated Amount Allowed for Payment</b>
Point estimate	714,398	\$94,585,045
Lower limit	604,778	75,463,143
Upper limit	824,019	113,706,947

## **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 NHIC 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 2,212,691. 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 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.<sup>1</sup>

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<sup>1</sup> Of the 100 claims, 17 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 NHIC for claims that we identified as high utilization claims and were not supported in accordance with Medicare documentation requirements and (2) amount that NHIC 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 NHIC Allowed for Payment

Sample Size	No. of Claims With Deficiencies	Value of Sample	Value of Unallowable Amount
100	70	\$11,993	\$6,889

### Sample Results for Amount That NHIC Paid to Suppliers

Sample Size	No. of Claims With Deficiencies	Value of Sample	Value of Unallowable Amount
100	69 <sup>1</sup>	\$9,420	\$5,488

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

	Amount NHIC Allowed for Payment	Amount NHIC Paid to Suppliers
Point estimate	\$49,214,902	\$39,206,181
Lower limit	37,333,868	29,693,533
Upper limit	61,095,935	48,718,828

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<sup>1</sup> Of the 70 claims with deficiencies, payments for 69 claims were made to DME suppliers. The payment for the remaining claim was made to the Medicare beneficiary.

## APPENDIX E: AUDITEE COMMENTS



Durable Medical Equipment  
Medicare Administrative Contractor  
Phone: (781) 741-3029

July 2, 2010

Department of Health & Human Services  
Office of Inspector General  
Office of Audit Services, Region IX  
90 7<sup>th</sup> Street, Suite 3-650  
San Francisco, CA 94103

Attention: Lori A Ahlstrand  
Regional Inspector General for Audit Services

**Subject:** OIG Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets - Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction A. (Report Number A-09-08-00043)

Dear Ms. Ahlstrand:

NHIC appreciates the opportunity to work with the Office of Inspector General on this important issue facing DME contractors. Please find below our response to the recommendations in the draft audit report cited above.

**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;

**NHIC Response**

NHIC agrees that this category represents a problem area in Medicare payments. Glucose testing supplies are a high priority item in NHIC's Medical Review (MR) Strategy. NHIC implemented frequency editing by way of Accumulation File Number (AFN) parameters in April 2010.

Additionally, NHIC currently has several supplier-specific prepay complex reviews ongoing for glucose testing supplies.

**2. Recommendation**

Implement system edits to identify claims for test strips and/or lancets that have overlapping service dates;

**NHIC, Corp.**

75 Sgt. William B. Terry Drive  
Hingham, MA 02043  
A CMS CONTRACTOR

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Document Name: NHIC DME MAC CMS Letterhead  
Release Date: 04/21/2009

Document No: TMP-ADM-0007  
Version: 6.0

OIG Audit A-09-08-00043 Response (page 2 of 4)**NHIC Response**

The AFN editing detailed in the first recommendation response would also encompass claims for test strips and/or lancets that have overlapping service dates.

**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.

**NHIC Response**

NHIC has multiple ongoing efforts to enforce documentation requirements for these items:

- The AFN editing detailed in the first recommendation response contributes to the enforcement of high utilization billings of these items, since services in excess of the AFN parameters are denied.
- During the course of conducting MR activities, the MR team may identify potential fraudulent or abusive activities. NHIC has established internal processes and referral procedures to alert the PSC to a potential fraudulent or abusive situation. NHIC MR provides the following information to ensure that the PSC has complete background for the referral: supplier-specific data, referral date, referring NHIC analyst, description of identified problems, case development activities performed, dollars paid, and leadership approval. These procedures are incorporated into our Joint Operating Agreement (JOA) with the PSC to ensure a joint understanding of responsibilities.
- To further support the CERT error-rate reduction initiative, of which glucose testing supplies is a major contributor, NHIC developed the RAC Work Plan. The RAC Work Plan recommended Jurisdiction A CERT error categories to be addressed through post-pay complex reviews: The NHIC RAC Work Plan promotes the fiscal integrity of Medicare Fee For Service (FFS) benefit administration through the timely and comprehensive sharing of CERT error information with the RAC so that incorrect payments can be recovered. The RAC in Jurisdiction A accepted our recommendations and will incorporate them into their complex review plans.
- NHIC has established internal procedures in place to refer cases to the National Supplier Clearinghouse (NSC) Supplier Audit and Compliance Unit (SACU) department for issues of possible violation of supplier standards.
- NHIC has also implemented the following educational interventions that reinforce the Medicare documentation requirements for claims for test strips and/or lancets:
  - NHIC has developed and posted on our website, very detailed letters that suppliers can provide to the prescribing physician that describe in detail the documentation requirements for common claims payment error DMEPOS categories. "Dear Physician" letters have been published for multiple claims payment error categories, including Glucose monitors and supplies. NHIC developed these letters as a result of the many CERT and MR claim errors caused by the lack of physician medical record documentation. The "Dear Physician" letter clearly and completely explains that the patient's medical record must contain sufficient information about the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The

OIG Audit A-09-08-00043 Response (page 3 of 4)

“Dear Physician” letters can be viewed on our website at [http://www.medicarenhic.com/dme/dmerc\\_cert\\_rec.shtml](http://www.medicarenhic.com/dme/dmerc_cert_rec.shtml).

- NHIC continued our innovative approaches to claims error rate reduction with the launching of a monthly publication of the common CERT errors. The March, April, and May 2010 CERT Errors List serve Articles discussed errors on glucose testing supply claims.

**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 11 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.

**NHIC Response**

A claim submitted with a valid HCPCS code and modifier combination (such as KS or KX) proceeds through the claim adjudication process, if there is no prepay MR edit in place. The issue of the incorrect modifier to identify whether the patient was insulin or noninsulin dependent would be detected through complex medical review activity. Absent performing a complex medical review of every claim submitted with a KX modifier, there is no electronic edit (or any other automated tool) that can determine if the supplier appended the incorrect modifier to denote insulin dependent or non-insulin dependent. The validation of the proper modifier would be performed as part of the prepay complex medical review process.

NHIC will reinforce the importance of using the correct KX or KS modifier through our outreach and education activities.

NHIC will issue a list serv article to suppliers reminding them of the importance of using the correct KX or KS modifier when billing for diabetic testing 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 9 of the 100 sampled claims, DME suppliers submitted claims with incorrect unique identification numbers for referring physicians. For example, a claim from one DME 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 DME supplier claimed the lancets using the unique identification number of the beneficiary’s former physician contained in its billing system.

**NHIC Response**

A claim submitted with a valid unique identification number for the referring physician proceeds through the claims adjudication process unless there is a prepay MR edit in place. Absent performing a complex medical review of every claim submitted, there is no electronic edit (or any other automated tool) that can determine if the supplier indicated the correct referring physician.

OIG Audit A-09-08-00043 Response (page 4 of 4)

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The validation of the referring physician would be performed in the prepay complex medical review process described in the previous response.

NHIC will reinforce the importance of using the correct referring physician information through our outreach and education activities. NHIC will issue a list serv article to suppliers reminding them of the importance of using the correct referring physician information.

If you have any questions about NHIC response, please contact Jennifer Otten, Manager of Audit & Controls, in Chico, California at 530-332-1169 (or at [jennifer.otten@hp.com](mailto:jennifer.otten@hp.com)).

Sincerely,

s/Andrew Conn  
NHIC DME MAC Program Director

cc: Jennifer Otten, NHIC, Corp.  
Karen Grasso, NHIC, Corp.  
Amy A. Capece, NHIC, Corp.  
Paul Hughes, MD, NHIC, Corp.  
Travis Moore, NHIC, Corp.  
Debbie Bach, NHIC, Corp.  
Martin Furman, CMS