



January 31, 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 D (A-09-08-00046)

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 D. We will issue this report to Noridian Administrative Services, LLC, within 5 business days.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Robert A. Vito, Acting Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at [Robert.Vito@oig.hhs.gov](mailto:Robert.Vito@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](mailto:Lori.Ahlstrand@oig.hhs.gov). Please refer to report number A-09-08-00046.

Attachment



February 4, 2011

Report Number: A-09-08-00046

Ms. Emy Stenerson  
Vice President of DME Operations  
Noridian Administrative Services, LLC  
900 42<sup>nd</sup> Street South  
Fargo, ND 58103

Dear Ms. Stenerson:

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 D*. 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](mailto:Yun.Kim@oig.hhs.gov). Please refer to report number A-09-08-00046 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 12<sup>th</sup> 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 D**



Daniel R. Levinson  
Inspector General

February 2011  
A-09-08-00046

# *Office of Inspector General*

<http://oig.hhs.gov>

---

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health & Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

## *Office of Audit Services*

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

## *Office of Evaluation and Inspections*

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

## *Office of Investigations*

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

## *Office of Counsel to the Inspector General*

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

# *Notices*

---

**THIS REPORT IS AVAILABLE TO THE PUBLIC**  
at <http://oig.hhs.gov>

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.

## **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.

Noridian Administrative Services, LLC (Noridian), the DME MAC for Jurisdiction D, allowed for payment \$219 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 Noridian allowed for payment \$76 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 Noridian 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, 29 claims were supported in accordance with Medicare documentation requirements. However, the remaining 71 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).
- Physician orders were missing or incomplete (20 claims).
- There was no documentation supporting that refill requirements had been met (12 claims).
- Proof-of-delivery records were missing (seven claims).

For CY 2007, based on our sample results, we estimated that Noridian inappropriately allowed for payment approximately \$40.5 million in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that Noridian inappropriately paid approximately \$30.9 million to DME suppliers.

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

Noridian could have saved Medicare an estimated \$30.9 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 Noridian:

- 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, Noridian concurred with our recommendations and provided information on actions that it had taken or planned to take to address the recommendations. Noridian's comments are included in their entirety as Appendix E.

# TABLE OF CONTENTS

	<u>Page</u>
<b>INTRODUCTION</b> .....	1
<b>BACKGROUND</b> .....	1
Medicare Program.....	1
Durable Medical Equipment.....	1
National and Local Coverage Determinations.....	1
Home Blood-Glucose Test Strip and Lancet Supplies .....	2
Noridian Administrative Services, LLC .....	3
<b>OBJECTIVE, SCOPE, AND METHODOLOGY</b> .....	3
Objective.....	3
Scope.....	3
Methodology.....	4
<b>FINDINGS AND RECOMMENDATIONS</b> .....	5
<b>UNSUPPORTED CLAIMS FOR TEST STRIPS AND/OR LANCETS</b> .....	5
Lack of Documentation for Quantities in Excess of Utilization Guidelines .....	5
Missing or Incomplete Physician Orders .....	7
Lack of Documentation To Support Refills of Supplies.....	8
Missing Proof-of-Delivery Records.....	8
<b>EFFECT OF UNALLOWABLE CLAIMS</b> .....	9
<b>LACK OF CONTROLS</b> .....	9
<b>RECOMMENDATIONS</b> .....	9
<b>AUDITEE COMMENTS</b> .....	10
<b>OTHER MATTERS</b> .....	10
<b>INCORRECT MODIFIER</b> .....	10
<b>INCORRECT UNIQUE IDENTIFICATION NUMBER</b> .....	10
<b>APPENDIXES</b>	
A: FRAME SAMPLE DESIGN AND METHODOLOGY	
B: FRAME SAMPLE RESULTS AND ESTIMATES	
C: ERROR SAMPLE DESIGN AND METHODOLOGY	

D: ERROR SAMPLE RESULTS AND ESTIMATES

E: AUDITEE COMMENTS

## 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 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

---

<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 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.<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 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

---

<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.

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

### **Noridian Administrative Services, LLC**

On January 6, 2006, CMS awarded the DME MAC contract for Jurisdiction D to Noridian Administrative Services, LLC (Noridian), a wholly owned subsidiary of Noridian Mutual Insurance Company. As of September 30, 2006, Noridian assumed full responsibility for administering the DME MAC work and began processing DMEPOS claims for Jurisdiction D. Noridian's main office is located in Fargo, North Dakota, through which it serves Medicare beneficiaries residing in Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, the Northern Mariana Islands, Oregon, South Dakota, Utah, Washington, and Wyoming.

Noridian allowed for payment \$219 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 Noridian 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 Noridian allowed for payment \$76 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 Noridian. 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 August 2010 and conducted fieldwork at Noridian's office in Fargo, North Dakota.

---

<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.

## Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed the LCD adopted by Noridian;
- reviewed the Statements of Work for Noridian prepared by CMS for the administration of DMEPOS;
- reviewed Noridian's policies and procedures for processing Medicare claims for test strips and/or lancets;
- interviewed Noridian 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 Noridian'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 Noridian allowed for payment (Appendixes A and B);
- randomly selected a sample of 100 high utilization claims<sup>5</sup> to estimate the amounts that Noridian 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 Noridian.

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

---

<sup>5</sup> Of the 100 claims, 21 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, 29 claims were supported in accordance with Medicare documentation requirements. However, the remaining 71 claims were not supported because each claim had one or more deficiencies. For CY 2007, based on our sample results, we estimated that Noridian inappropriately allowed for payment approximately \$40.5 million in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that Noridian inappropriately paid approximately \$30.9 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**

<b>Type of Deficiency</b>	<b>No. of Claims With Deficiencies<sup>6</sup></b>
Lack of Documentation for Quantities in Excess of Utilization Guidelines	61
Missing or Incomplete Physician Orders	20
Lack of Documentation To Support Refills of Supplies	12
Missing Proof-of-Delivery Records	7

Noridian made improper payments to DME suppliers because Noridian did not have controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements. Specifically, Noridian did not have system edits to identify, and review when necessary, high utilization claims. In addition, Noridian did not have system edits to identify claims with overlapping service dates for the same beneficiary. This billing pattern caused Noridian 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 L196 requires that the treating physician document in the medical records the specific reason for the additional supplies.

---

<sup>6</sup> The total exceeds 71 because 43 of the 71 claims contained more than 1 deficiency.

LCD L196 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 L196 states that the treating physician must have evaluated the patient’s diabetes 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 55 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 indicating a testing frequency of eight 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 To Support Refills*

For 39 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 a refill consisting of six units of test strips for a non-insulin-treated patient, which would be the quantity for a testing frequency of approximately four times a day. This testing frequency corresponded to the physician order, which was signed by the physician. However, neither the physician nor the supplier maintained records documenting that the patient was actually testing four 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 8 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 and lancets provided to an insulin-treated patient based on a physician order signed June 4, 2007. The physician order indicated a testing frequency of four times a day, which was in excess of the guidelines. When we contacted a community clinic where the physician practiced, the clinic provided medical records showing that the physician saw the patient on March 22, 2006, which was almost 14 months before the date of the physician order.

## 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 *Medicare Program Integrity Manual* (the Manual), Pub. No. 100-08, 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 L196 states: “An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request.” Further, the LCD requires that the order for test strips and lancets include (1) the specific frequency of testing, (2) the treating physician’s signature, and (3) the date of the treating physician’s signature.

For 20 of the 100 sampled claims, suppliers submitted claims when physician orders were missing or incomplete.

### *Missing Physician Orders*

For 10 of the 20 claims, the DME suppliers did not have written physician orders. For 9 of the 10 claims, the suppliers had documentation of verbal orders from the treating physicians but did not have written orders or references to them. For the remaining claim, the supplier did not provide a copy of the written order. When we contacted the supplier to obtain a copy of the order, an official stated that the supplier could not locate the order.

### *Incomplete Physician Orders*

For 10 of the 20 claims, the DME suppliers had physician orders without required elements, including the treating physician’s signature, the specific frequency of testing, and the date of the physician signature:

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

## **Lack of Documentation To Support Refills of Supplies**

The Manual, 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 L196 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 12 of the 100 sampled claims, suppliers did not have documentation to support that refill requirements had been met.

### *Previously Dispensed Supplies Not Nearly Exhausted*

For 11 of the 12 claims, DME suppliers dispensed test strips and/or lancets when the beneficiaries had not nearly exhausted the previously dispensed supplies. Of the 11 claims, 6 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 six units of test strips and submitted a claim to Noridian for service dates covering the period September 17 through December 15, 2007. In addition, another supplier dispensed four units of test strips and submitted a claim to Noridian for the same beneficiary covering the period July 31 through October 29, 2007. Noridian allowed payment for both of these claims.

### *Refills Not Specifically Requested*

For 1 of the 12 claims, there was no documentation supporting that the beneficiary or the beneficiary’s caregiver had specifically requested the refill before the supplies were dispensed. When we attempted to contact the DME supplier to obtain documentation, we found that the supplier had filed for bankruptcy on June 12, 2008.

## **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. For example, a supplier submitted a claim for eight units of test strips and four units of lancets for the service

date beginning May 15, 2007. When we requested proof of delivery, the supplier provided only a delivery carrier's tracking number and stated that additional documentation was not available.

### **EFFECT OF UNALLOWABLE CLAIMS**

For 71 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, Noridian allowed \$6,320 in Medicare Part B payments for unallowable claims. Of this amount, Noridian inappropriately paid \$4,821 to suppliers.

For CY 2007, based on our sample results, we estimated that Noridian inappropriately allowed for payment \$40,506,383 in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that Noridian inappropriately paid \$30,898,935 to suppliers.

### **LACK OF CONTROLS**

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

Noridian could have saved Medicare an estimated \$30,898,935 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 Noridian:

- 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, Noridian concurred with our recommendations and provided information on actions that it had taken or planned to take to address the recommendations. Regarding the first recommendation, Noridian stated that it had implemented system edits in April 2008 to suspend claims with the highest utilization of test strips and/or lancets. Noridian also stated that it manually reviews these claims for compliance with Medicare documentation requirements. Regarding the second recommendation, Noridian stated that it had significantly reduced the volume of claims that had overlapping service dates for the same beneficiary by implementing system edits that monitor the utilization of test strips and lancets. Regarding the third recommendation, Noridian stated that it had implemented system edits to identify high utilization claims for prepayment review. In addition, Noridian stated that the DME medical directors had worked with CMS to revise the LCD, which, when finalized, will enable the DME MACs to curb the overutilization of test strips and lancets.

Noridian'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 L196 requires that a Medicare claim for test strips and/or lancets include the KX modifier for insulin-treated patients and the KS modifier for non-insulin-treated patients.

For 24 of the 100 sampled claims, DME suppliers submitted claims with incorrect modifiers. For example, a claim from one supplier for test strips included the KX modifier rather than the KS modifier when the physician order did not indicate that the beneficiary was being treated with insulin. The documentation in the treating physician's medical records also supported that the beneficiary was not 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 10 of the 100 sampled claims, DME suppliers submitted claims with incorrect unique identification numbers for referring physicians. For example, a claim from one supplier for lancets included an incorrect unique identification number for the referring (i.e., ordering) physician. The supplier received a verbal order 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 Noridian Administrative Services, LLC (Noridian), 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 Noridian 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 Noridian 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 2,086,642 claims for test strips and/or lancets for 634,578 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 2,086,642 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 634,578 beneficiaries for whom the 2,086,642 test strip and/or lancet claims had been submitted to Noridian.

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

claim based solely on the claim information submitted by DME suppliers. Further, we did not perform additional analysis of all claims. As a result, the sampling frame of high utilization claims contained claims in which the quantity of test strips and/or lancets was within the Medicare 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 Noridian 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 634,578. 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 Noridian 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>
634,578	2,086,642	500	1,651	180	504

**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 Noridian 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>
634,578	\$207,547,411	500	\$162,170	180	\$60,173

**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	639,655	\$76,368,556
Lower limit	544,580	63,745,257
Upper limit	734,729	88,991,855

## **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 Noridian 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 2,086,642. 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.<sup>1</sup>

---

<sup>1</sup> Of the 100 claims, 21 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 Noridian for claims that we identified as high utilization claims and were not supported in accordance with Medicare documentation requirements and (2) amount that Noridian 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 Noridian Allowed for Payment**

<b>Sample Size</b>	<b>No. of Claims With Deficiencies</b>	<b>Value of Sample</b>	<b>Value of Unallowable Amount</b>
100	71	\$12,324	\$6,320

**Sample Results for Amount That Noridian Paid to DME Suppliers**

<b>Sample Size</b>	<b>No. of Claims With Deficiencies</b>	<b>Value of Sample</b>	<b>Value of Unallowable Amount</b>
100	67 <sup>1</sup>	\$9,386	\$4,821

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

	<b>Amount Noridian Allowed for Payment</b>	<b>Amount Noridian Paid to DME Suppliers</b>
Point estimate	\$40,506,383	\$30,898,935
Lower limit	30,684,250	23,102,391
Upper limit	50,328,516	38,695,480

---

<sup>1</sup> Of the 71 claims with deficiencies, payments for 67 claims were made to DME suppliers. The payment for one claim was made to the Medicare beneficiary. For the remaining three claims, the payments were made to neither suppliers nor the beneficiaries because the beneficiaries were required to pay deductibles.

## APPENDIX E: AUDITEE COMMENTS



900 42nd Street South  
Fargo, ND 58103

Medicare

October 25, 2010

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

Dear Ms. Ahlstrand,

RE: Report Number A-09-08-00046

NAS has reviewed the September 21, 2010 draft report A-09-08-00046 entitled *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets - Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D*. We agree there is a widespread problem among DME suppliers on exceeding the utilization of blood glucose supplies.

We concur with the following recommendations as outlined in the report. The OIG's recommendations are listed below, followed by NAS' response on the corrective action taken or planned.

- 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

**Corrective Action taken or planned:** System edits, called AFNs, were implemented by NAS in April 2008 to pend (suspend) claims that contain the highest utilization of test strips and/or lancets. These claims are manually reviewed on a pre-payment basis. If documentation is not on file in our office to support the higher utilization, it is requested. NAS will review the documentation for compliance with Medicare documentation requirements. The services are denied if the documentation does not meet documentation requirements. Documentation requirements include physician order, proof of delivery, testing logs, 6 month evaluation by physician, etc.

As mentioned in the draft OIG report, NAS did not assume the medical review (MR) activities for Jurisdiction D until March 2008. NAS posted [Glucose Monitors and Related Accessories and Supplies](#) to our website on March 12, 2008, reminding suppliers of the LCD and Policy Article requirements. Between March 2008 and October 2010, we have published 12 additional articles and provided 13 workshops specifically on the topic of blood glucose test strips and/or lancet requirements. We identified diabetic supplies as a high CERT error and initiated probe reviews in May 2008 for the top diabetic suppliers. Since that time, diabetic supplies continue to be a focus of MR reviews. NAS conducted 46 probe reviews and 16 complex targeted reviews on 36 suppliers billing for diabetic supplies since assuming the MR activities. Additionally, NAS initiated a widespread service-specific review for diabetic strips in 2010 which is still in process.

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

**Corrective Action taken or planned:** Although there are VMS system limitations to eliminating the overpayment of services for the same beneficiary with overlapping dates, NAS has significantly reduced the volume of claims reimbursed for overlapping dates. This was accomplished by implementing system edits (AFNs) that monitor the utilization of test strips and/or lancets. Those services that exceed our defined thresholds are pended (suspended) for review. During this pre-payment review, we compare the dates of service on the current claim against the patient's history of claims processed. If the dates of service on the current claim overlap with a claim that has already been processed, the current claim is denied or reduced accordingly.

Overpayments incurred by the four DME MACs due to overlapping dates were a topic of discussion at the *Fall 2010 DME Coordination* meeting. The Pricing Data Analysis Contractor (PDAC) provided statistical data to demonstrate the impact of these claims are getting through to payment. A resolution to this system limitation was a recommendation for reducing improper payments for diabetic supplies.

- 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 pre-payment review of those DME suppliers, and (3) referring them to the OIG or CMS for further review or investigation when necessary

**Corrective Action taken or planned:** As of April, 2008, NAS has implemented system edits (AFNs) that identify claims with a high utilization of test strips and/or lancets. For these claims a pre-payment review is conducted. If the documentation to support the higher utilization is not on file in our office, it is requested. We review the documentation for compliance with Medicare documentation requirements and rationale from treating physician for the additional supplies. Services that are not substantiated through proper documentation are denied.

A change to the LCD L196 is currently in process that will, upon finalization, greatly improve the DME MAC's ability to enforce well-defined limits for the utilization of test strips and/or lancets. The DME medical directors (DMDs) have worked diligently with CMS to firm up the

LCD and once the revision is implemented, it will enable the DME MACs to effectively and efficiently curb the over-utilization of these services.

NAS is pleased with the significant changes we have made to mitigate the improper payments on test strips and/or lancets. We will continue to pursue additional cost effective avenues to further achieve savings for the Medicare program.

Please contact me by phone at 701-282-1356 or by email at [emy.stenerson@noridian.com](mailto:emy.stenerson@noridian.com) with any questions regarding NAS' response.

Sincerely,

\Emy Stenerson\

Emy Stenerson  
NAS Vice President  
Jurisdiction D Project Manager