DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

June 13, 2012

TO: Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: /Daniel R. Levinson/
Inspector General

SUBJECT: Medicare Contractors Lacked Controls To Prevent Millions in Improper Payments for High Utilization Claims for Home Blood-Glucose Test Strips and Lancets (A-09-11-02027)

The attached final report provides the results of our reviews of Medicare claims for home blood-glucose test strips and lancets at four durable medical equipment Medicare administrative contractors.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (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 your staff may contact Brian P. Ritchie, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through email at Brian.Ritchie@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-09-11-02027 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE CONTRACTORS LACKED CONTROLS TO PREVENT MILLIONS IN IMPROPER PAYMENTS FOR HIGH UTILIZATION CLAIMS FOR HOME BLOOD-GLUCOSE TEST STRIPS AND LANCETS

Daniel R. Levinson
Inspector General

June 2012
A-09-11-02027

Office of Inspector General

http://oig.hhs.gov

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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 (contractor) 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 durable medical equipment supplier (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 (i.e., the quantity for a testing frequency of approximately 3 times per day) for insulin-treated diabetics. The guidelines also allow up to 100 test strips and 100 lancets every 3 months (i.e., the quantity for a testing frequency of approximately 1 time per day) for non-insulin-treated diabetics. To be reimbursed for a claim for any quantity of test strips and/or lancets, the 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 (approximately 5 days before exhaustion) 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 exceed 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.

This report summarizes the results of our individual reviews of the 4 contractors that processed claims for test strips and/or lancets for Jurisdictions A through D, which included all 50 States, 5 territories, and the District of Columbia. Those reviews determined whether high utilization claims for test strips and/or lancets that the contractors allowed for payment were supported in accordance with Medicare documentation requirements. This report also provides the results of our analyses of (1) testing frequencies ordered by physicians for unsupported high utilization claims (by treatment type, i.e., non-insulin-treated and insulin-treated beneficiaries) and (2) unsupported claims with overlapping service dates for the same beneficiary.

The contractors allowed for payment $1.2 billion in Medicare Part B claims for test strips and/or lancets for calendar year (CY) 2007. We focused our reviews on high utilization claims. To identify these claims, we analyzed the information submitted by suppliers on the claim forms. We did not verify the accuracy of the claims information. We estimated that the contractors allowed for payment a total of $484.3 million for the claims that we identified as high utilization claims.

OBJECTIVE

Our objective was to summarize the results of our individual reviews of the four contractors that processed claims for test strips and/or lancets for Jurisdictions A through D.

SUMMARY OF FINDINGS

Of the 400 sampled claims for test strips and/or lancets that we reviewed at the 4 contractors, 97 claims were supported in accordance with Medicare documentation requirements. However, each of the remaining 303 claims (76 percent) had 1 or more deficiencies:

- The quantity of supplies that exceeded utilization guidelines was not supported with documentation that specified the reason for the additional supplies, the actual frequencies of testing, or the treating physicians' evaluations of the patients' diabetic control within 6 months before ordering the supplies (222 of 400 claims, or 56 percent).

- There was no supporting documentation that indicated refill requirements had been met (117 of 400 claims, or 29 percent).

- Physician orders were missing or incomplete (90 of 400 claims, or 23 percent).

- Proof-of-delivery records were missing (33 of 400 claims, or 8 percent).

For CY 2007, based on our analyses of our individual samples of the four contractors, we estimated that the contractors improperly allowed for payment a total of approximately $271 million in claims that we identified as high utilization claims. Of this amount, we estimated that the contractors improperly paid a total of approximately $209 million to suppliers.

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

The contractors could have saved Medicare an estimated $209 million for CY 2007 if they had had controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements. Adequate controls are important to program integrity because they help to prevent improper payments to suppliers for test strips and lancets. Unless the contractors implement system edits to identify for further review high utilization claims and claims that have overlapping service dates for the same beneficiary, they are likely to continue to make improper payments to suppliers.

RECOMMENDATIONS

We recommend that CMS:

- ensure that contractors implement system edits recommended in our individual reports to:
    - identify high utilization claims for test strips and/or lancets and develop cost-effective ways of determining which claims should be further reviewed for compliance with Medicare documentation requirements and
    - identify claims for test strips and/or lancets that have overlapping service dates for the same beneficiary;
- ensure that contractors are enforcing Medicare documentation requirements for claims for test strips and/or lancets by monitoring the contractors' (1) identification of suppliers with a high volume of high utilization claims, (2) performance of prepayment reviews of those suppliers, and (3) referrals of suppliers to the Office of Inspector General or CMS for further review or investigation when necessary; and
- consider the results of our reviews when developing and evaluating coverage and reimbursement policies related to test strips and lancets.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In its written comments on our draft report, CMS concurred with all of our recommendations. CMS's comments are included in their entirety as Appendix B.

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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, Prosthetics, Orthotics, and Supplies

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 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 (contractor) to process and pay Medicare Part B claims for DMEPOS. According to the Statement of Work, the contractors' responsibilities included, but were not limited to, (1) receiving Medicare Part B claims from durable medical equipment suppliers (supplier) and beneficiaries within their jurisdictions,[1] (2) performing edits[2] 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 suppliers on Medicare requirements and billing procedures.

The Statement of Work was modified to require the contractors 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 supplier. Medicare pays the beneficiary or the supplier the amount allowed for payment, less the beneficiary share (i.e., deductibles and coinsurance).

[1] Each contractor is responsible for processing claims for specific States and territories. Suppliers must submit claims to the contractor that serves the State or territory in which the Medicare beneficiary permanently resides.

[2] 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.

National and Local Coverage Determinations

National Coverage Determinations (NCD) describe the circumstances for Medicare coverage nationwide for specific medical service procedures or devices, including DMEPOS, and generally outline the conditions under which a service or device is considered covered. Contractors are required to follow NCDs.

A Local Coverage Determination (LCD) is a decision that a contractor might make to cover a particular item or service on a contractorwide basis pursuant to section 1862(a)(1)(A) of the Act. 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, and 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.

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 contacting their attending physicians for advice and treatment.[3] However, the NCD does not specify utilization guidelines and documentation requirements for test strips and lancets.

To establish utilization guidelines and documentation requirements for test strips and lancets, contractors either established or adopted LCDs,[4] which state that the quantity of test strips and lancets that Medicare covers depends on the beneficiary's usual medical needs. The LCDs for the contractors further state that Medicare covers up to 100 test strips and 100 lancets every month (i.e., the quantity for a testing frequency of approximately 3 times per day) for insulin-treated diabetics. The LCDs also state that Medicare covers up to 100 test strips and 100 lancets every 3 months (i.e., the quantity for a testing frequency of approximately 1 time per day) for non-insulin-treated diabetics.[5]

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

[4] Jurisdictions A and B adopted LCD L11530, Jurisdiction C adopted LCD L11520, and Jurisdiction D adopted LCD L196. Each LCD contains the same documentation requirements.

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

Medicare Documentation Requirements for Test Strips and Lancets

To be reimbursed for a claim for any quantity of test strips and/or lancets, the 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, which is approximately 5 days before the end of usage for the current product. In addition, the supplier may refill an order only when the beneficiary specifically requests that the supplies be dispensed.

There are additional requirements for reimbursement of a claim for a quantity of test strips and/or lancets that exceeds 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. (See Appendix A.)

Office of Inspector General Audits of Test Strips and Lancets

This report summarizes the results of our individual reviews of the 4 contractors that processed claims for test strips and/or lancets for Jurisdictions A through D, which included all 50 States, 5 territories, and the District of Columbia. Those reviews determined whether high utilization claims for test strips and/or lancets that the contractors allowed for payment were supported in accordance with Medicare documentation requirements. The contractors were NHIC, Corp. (NHIC), for Jurisdiction A; National Government Services, Inc. (NGS), for Jurisdiction B; CIGNA Government Services, LLC (CGS), for Jurisdiction C;[6] and Noridian Administrative Services, LLC (Noridian), for Jurisdiction D. The contractors allowed for payment $1.2 billion in Medicare Part B claims for test strips and/or lancets for CY 2007.

We issued individual reports to each of the four contractors. Table 1 provides information on these reports.

Table 1: Reports Issued to Contractors

Jurisdiction	Report Number	Report Issuance Date
A	A-09-08-00043	August 30, 2010
B	A-09-08-00044	February 17, 2011
C	A-09-08-00045	January 21, 2011
D	A-09-08-00046	February 4, 2011

[6] Jurisdiction C's claims for test strips and/or lancets for calendar year (CY) 2007 were processed by Palmetto GBA, LLC, before CGS began processing these claims on June 1, 2007.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to summarize the results of our individual reviews of the four contractors that processed claims for test strips and/or lancets for Jurisdictions A through D.

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 suppliers on the Medicare claim forms. We did not verify the accuracy of the claims information. We estimated that the four contractors allowed for payment a total of $484.3 million for the claims that we identified as high utilization claims.

We did not review the overall internal control structure of the contractors. We focused on those internal controls that were significant to the objective of our audit.

We completed our individual reviews in August 2010. We conducted fieldwork at the contractors' offices in Hingham, Massachusetts, and Los Angeles, California, for Jurisdiction A; Indianapolis, Indiana, for Jurisdiction B; Nashville, Tennessee, for Jurisdiction C; and Fargo, North Dakota, for Jurisdiction D.

Methodology

To accomplish our objective at each of the four contractors, we reviewed applicable Federal laws, regulations, and guidance and the LCD adopted by each contractor. We also reviewed the contractors' policies and procedures for processing Medicare claims for test strips and/or lancets and interviewed contractor officials to obtain an understanding of those procedures.

We randomly selected and reviewed a sample of 100 high utilization claims[7] (error sample) for each of the 4 contractors to determine whether Medicare documentation requirements had been met and to estimate the effect of noncompliance. To determine whether each of the sampled claims was supported in accordance with Medicare documentation requirements, we obtained and reviewed medical records and other documentation.

To estimate the total number and amount of high utilization claims that were allowed for payment, we randomly selected a sample of 500 Medicare beneficiaries (frame sample) for each of the 4 contractors. For each sampled beneficiary, we obtained all the beneficiary's claims for test strips and/or lancets and analyzed the claim information submitted by suppliers to determine the number of high utilization claims. Based on our analyses of our error and frame samples, we estimated the amounts that each contractor allowed for payment and paid to suppliers for claims that were not supported in accordance with Medicare documentation requirements. (See the

[7] 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 claims information. We did not remove these claims from the sample.

individual reports issued to the four contractors for descriptions of our sample design and methodology.)

For this report, we summarized the results of the individual reports. Further, we analyzed testing frequencies ordered by physicians for unsupported high utilization claims (by treatment type, i.e., non-insulin-treated and insulin-treated beneficiaries) and unsupported claims with overlapping service dates for the same beneficiary.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDINGS AND RECOMMENDATIONS

Of the 400 sampled claims for test strips and/or lancets that we reviewed at the 4 contractors, 97 claims were supported in accordance with Medicare documentation requirements. However, each of the remaining 303 claims (76 percent) had 1 or more deficiencies. For CY 2007, based on our analyses of our individual samples of the four contractors, we estimated that the contractors improperly allowed for payment a total of approximately $271 million in claims that we identified as high utilization claims. Of this amount, we estimated that the contractors improperly paid a total of approximately $209 million to suppliers.

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

UNSUPPORTED CLAIMS BY DEFICIENCY TYPE

Table 2 summarizes the deficiencies in the 400 sampled claims for test strips and/or lancets and the number of claims that contained each type of deficiency. Appendix A provides details on Medicare's documentation requirements.

Table 2: Summary of Deficiencies in Sampled Claims

Type of Deficiency	No. of Claims With Deficiencies[8]
Lack of Documentation for Quantities in Excess of Utilization Guidelines	222
Lack of Documentation To Support Refills of Supplies	117
Missing or Incomplete Physician Orders	90
Missing Proof-of-Delivery Records	33

Lack of Documentation for Quantities in Excess of Utilization Guidelines

For a quantity of test strips and lancets that exceed utilization guidelines, Medicare requires supporting documentation that indicates the specific reason for the additional supplies, the actual frequency of testing, and the treating physician's evaluation of the patient's diabetic control within 6 months before ordering the supplies.

Of the 400 sampled claims, 222 claims (56 percent) lacked the documentation required to support a quantity of supplies in excess of utilization guidelines:[9]

- For 187 of the 222 claims, the beneficiaries' medical records did not specify a reason for the additional supplies.

- For 143 of the 222 claims, neither the physicians' nor the suppliers' records documented that the beneficiaries were testing at frequencies that corroborated the quantity of supplies dispensed.

- For 20 of the 222 claims, the beneficiaries' medical records did not indicate that the treating physicians evaluated the patients' diabetic control within 6 months before ordering the quantity of supplies in excess of utilization guidelines.

[8] The total exceeds 303 because 182 of the 303 claims contained more than 1 deficiency.

[9] Our analysis of the claims for test strips and/or lancets that lacked the required documentation to support a quantity of supplies in excess of utilization guidelines is in the section entitled "Testing Frequencies Ordered by Physicians for Unsupported High Utilization Claims (by Treatment Type)."

Lack of Documentation To Support Refills of Supplies

For refills of test strips and lancets, a supplier may refill an order only when the beneficiary has nearly exhausted the previously dispensed supplies. In addition, the 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 117 of the 400 sampled claims (29 percent), suppliers did not have documentation to support that refill requirements had been met:

- For 91 of the 117 claims, suppliers dispensed test strips and/or lancets when the beneficiaries had not nearly exhausted the previously dispensed supplies.[10]

- For 36 of the 117 claims, the beneficiaries or the beneficiaries' caregivers had not specifically requested the refills before the supplies were dispensed.

Missing or Incomplete Physician Orders

A supplier must have an order from the treating physician before dispensing test strips and lancets to a beneficiary. When a supplier dispenses items based on a verbal order, the supplier must have a written order in its records before submitting a claim to the contractor.

For 90 of the 400 sampled claims (23 percent), suppliers submitted claims when physician orders were missing or incomplete:

- For 58 of the 90 claims, suppliers did not have written physician orders. Specifically, suppliers either did not provide copies of the written orders or had documentation of verbal orders from the treating physicians but no written orders.

- For 32 of the 90 claims, suppliers had physician orders without required elements, including testing frequencies (the most prevalent deficiency), treating physicians' signatures, dates of signatures, and items to be dispensed.[11]

Missing Proof-of-Delivery Records

Suppliers are required to maintain in their files for 7 years proof-of-delivery documentation of supplies provided to Medicare beneficiaries.

For 33 of the 400 sampled claims (8 percent), suppliers did not maintain proof of delivery. When we requested delivery records for the 33 claims, the suppliers did not provide proof of

[10] Our analysis of the claims for test strips and/or lancets dispensed when the beneficiaries had not nearly exhausted the previously dispensed supplies is in the section entitled "Unsupported Claims With Overlapping Service Dates for the Same Beneficiary."

[11] Of the 32 claims, 4 claims had more than 1 deficiency related to incomplete physician orders.

delivery or provided printouts from their computerized dispensing systems containing dispensing information that did not correspond to the sampled claims.

UNSUPPORTED CLAIMS BY JURISDICTION

Table 3 summarizes by jurisdiction the numbers of deficiencies by type.

Table 3: Summary of Deficiencies in Sampled Claims

Jurisdiction	No. of Sampled Claims	Lack of Documentation for Quantities in Excess of Utilization Guidelines	Lack of Documentation To Support Refills of Supplies	Missing or Incomplete Physician Orders	Missing Proof-of-Delivery Records	Total No. of Claims With Deficiencies
A	100	55	27	24	7	70
B	100	61	36	24	7	83
C	100	45	42	22	12	79
D	100	61	12	20	7	71
Total	**400**	**222**	**117**	**90**	**33**	**303**

In the 4 jurisdictions, the number of claims with deficiencies ranged from 70 to 83. The primary deficiency was lack of documentation for quantities in excess of utilization guidelines.

TESTING FREQUENCIES ORDERED BY PHYSICIANS FOR UNSUPPORTED HIGH UTILIZATION CLAIMS (BY TREATMENT TYPE)

We have also analyzed the testing frequencies ordered by physicians for the 222 claims that lacked documentation for quantities in excess of utilization guidelines.[12] We have organized the frequencies by treatment type (i.e., non-insulin-treated and insulin-treated beneficiaries). We provide this information for decisionmakers, who may want to use it when revising policies on test strips and lancets.

[12] Medicare requires supporting documentation that specifies the reason for the additional supplies, the actual frequency of testing, and the treating physician's evaluation of the patient's diabetic control within 6 months before ordering the supplies.

Of the 400 sampled claims, 319 claims were for test strips and/or lancets for non-insulin-treated beneficiaries, and 81 claims were for insulin-treated beneficiaries.[13]

- Of the 319 sampled claims for non-insulin-treated beneficiaries, 186 claims (58 percent) lacked the documentation required to support quantities in excess of utilization guidelines.

- Of the 81 sampled claims for insulin-treated beneficiaries, 36 claims (44 percent) lacked the documentation required to support quantities in excess of utilization guidelines.

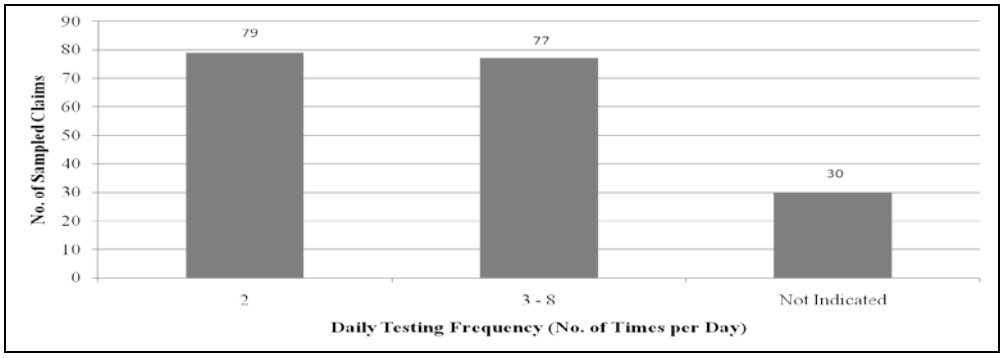
Graph 1 illustrates the range of daily testing frequencies ordered by physicians for non-insulin-treated beneficiaries for the 186 claims that lacked documentation for quantities in excess of utilization guidelines. For non-insulin-treated beneficiaries, Medicare's documentation requirements for quantities in excess of utilization guidelines apply when the ordered frequency of testing is more than once per day.

For a large number of the 186 claims—77—the physicians ordered testing from 3 to 8 times per day. However, we found that for these 77 claims, the physicians ordered testing frequencies that substantially exceeded utilization guidelines without documenting the reasons for ordering the high frequencies.

For 79 of the claims, the physicians ordered testing twice per day, but the claims lacked the documentation required to support testing more than once per day. Based on our analysis of the claims information, we determined that these claims were for quantities of test strips and/or lancets in excess of utilization guidelines.

For a smaller number of claims—30—there were no physician orders or the orders did not indicate testing frequencies. Based on our analysis of the claims information, we determined that these claims were for quantities of test strips and/or lancets in excess of utilization guidelines.

Graph 1: Range of Daily Testing Frequencies Ordered by Physicians for Non-Insulin-Treated Beneficiaries



[13] We identified non-insulin-treated and insulin-treated beneficiaries based on the claims information.

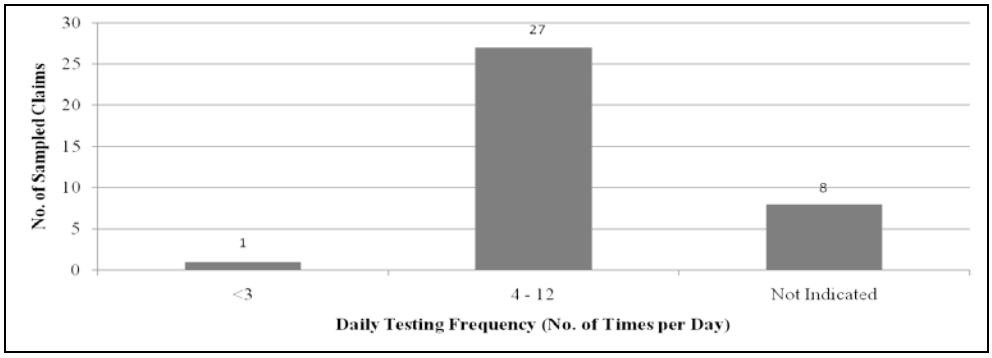
Graph 2 illustrates the range of daily testing frequencies that physicians ordered for insulin-treated beneficiaries for the 36 claims that lacked the documentation required for quantities of test strips in excess of utilization guidelines. For insulin-treated beneficiaries, those requirements apply when the ordered testing frequencies are more than three times per day.

Of the 36 claims, a majority—27—had physician orders for testing 4 to 12 times per day. However, we found that for these 27 claims, the physicians ordered testing frequencies that substantially exceeded utilization guidelines without documenting the reason for ordering the high frequencies.

For one of the claims, there was a physician order for testing twice per day, which is within the guidelines for an insulin-treated patient. The claims information indicated that the beneficiary was insulin-treated. However, based on the claims information, we determined that the claim was for a quantity of test strips for testing many times more than three times per day, which exceeds utilization guidelines.

Eight of the thirty-six claims did not have physician orders or did not indicate testing frequencies on the orders. Based on our analysis of the claims information, we determined that these claims were for a quantity of test strips and/or lancets for testing many times more than three times per day, which exceeds utilization guidelines.

Graph 2: Range of Daily Testing Frequencies Ordered by Physicians for Insulin-Treated Beneficiaries



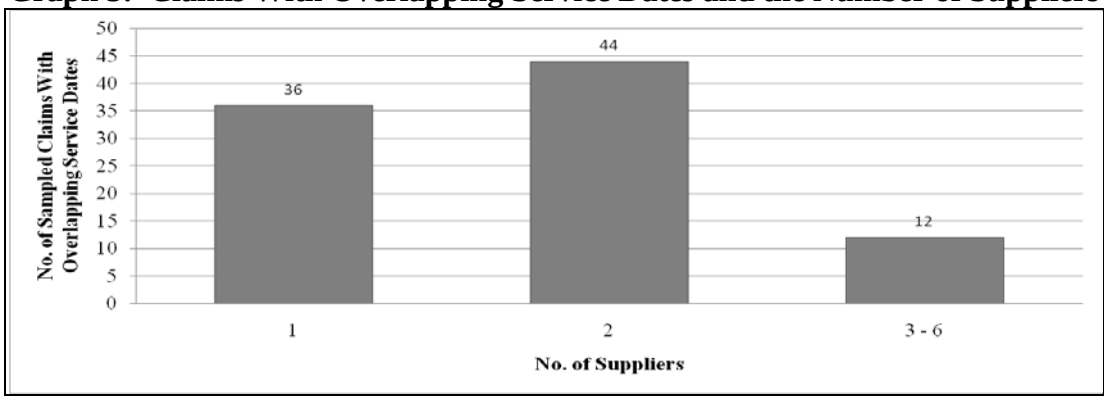
UNSUPPORTED CLAIMS WITH OVERLAPPING SERVICE DATES FOR THE SAME BENEFICIARY

We have also analyzed the number of suppliers for each of the 91 unsupported high utilization claims with overlapping service dates for the same beneficiary. We provide this information for decisionmakers, who may want to use it when revising policies on test strips and lancets.

For 91 of the 400 sampled claims (23 percent), suppliers dispensed test strips and/or lancets when the beneficiaries had not nearly exhausted the previously dispensed supplies.

Graph 3 illustrates the number of sampled claims with overlapping service dates[14] for which a single supplier or multiple suppliers dispensed test strips and/or lancets to the same beneficiary.[15] Specifically, as many as six suppliers submitted claims with overlapping service dates for the same beneficiary; as a result, claims were allowed for payment before the beneficiary had nearly exhausted the previously dispensed supplies.

Graph 3: Claims With Overlapping Service Dates and the Number of Suppliers



Multiple Suppliers

For 56 of the 91 claims with overlapping service dates, multiple suppliers dispensed test strips and/or lancets to the same beneficiary.[16] In one instance, two suppliers billed Medicare for claims with overlapping service dates for the same beneficiary. The physician ordered a testing frequency of three times per day for an insulin-treated patient. The supplier for the selected sampled claim dispensed six units of test strips and submitted a claim to a contractor for service dates September 24 through December 23, 2007.[17] Another supplier dispensed five units of test strips and submitted a claim to the contractor for the same beneficiary for service dates September 17 through December 8, 2007. The contractor allowed payment for both claims.

Single Supplier

For 36 of the 91 claims with overlapping service dates, single suppliers dispensed test strips and/or lancets to the same beneficiary. In one instance, a physician ordered a testing frequency of four times per day for an insulin-treated patient. The supplier for the selected sampled claim dispensed one unit of test strips on May 24, 2007. The same supplier had previously dispensed

[14] The sum of the claims in graph 3 for multiple and single suppliers does not equal 91 because 1 claim had overlapping service dates for both a single supplier and multiple suppliers that dispensed test strips and/or lancets for the same beneficiary.

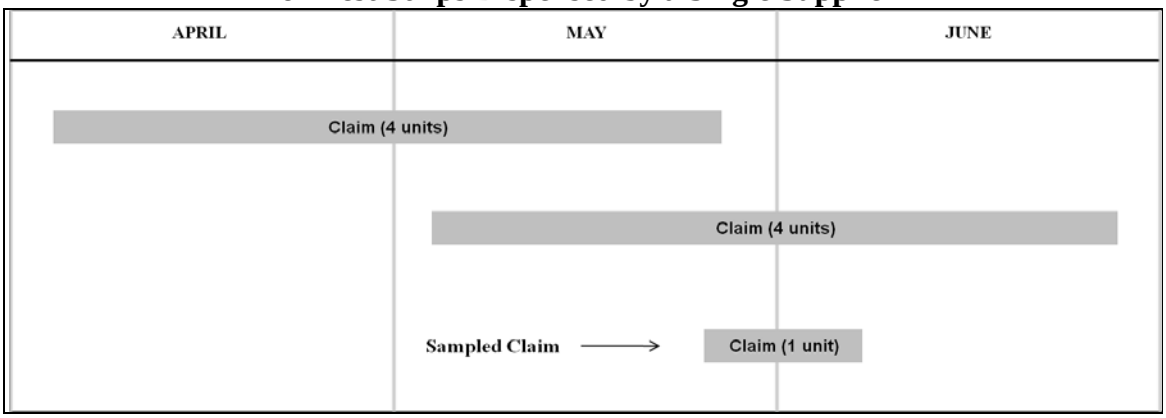
[15] All claims with overlapping service dates for a single beneficiary were submitted to the contractor responsible for the jurisdiction in which the beneficiary resided.

[16] We determined the overlapping service dates based on our review of the beneficiaries' medical records and additional analysis of the claims information.

[17] We obtained service dates from the claims information.

four units of test strips on May 6, 2007, which, based on a testing frequency of four times per day, would have been exhausted around June 25, 2007. The supplier dispensed the test strips for the sampled claim more than 30 days before the beneficiary would have exhausted the previously dispensed supplies. Additionally, the same supplier had also dispensed four units of test strips on April 5, 2007, which, based on a testing frequency of four times per day, would have been exhausted around May 25, 2007 (1 day after the supplies for the sampled claim were dispensed). Graph 4 illustrates the number of units of test strips that the beneficiary received from the single supplier.

Graph 4: Claims With Overlapping Service Dates for Test Strips Dispensed by a Single Supplier



EFFECT OF UNALLOWABLE CLAIMS

Of the 400 sampled claims for test strips and/or lancets that we reviewed, 303 claims were not supported in accordance with Medicare documentation requirements. As a result, the four contractors allowed $29,039 in Medicare Part B payments for unallowable claims. Of this amount, the contractors improperly paid $22,385 to suppliers.

For CY 2007, based on our analysis of each sample, we estimated that the contractors improperly allowed for payment a total of $270,961,017 in claims for test strips and/or lancets that we identified as high utilization claims. Of this amount, we estimated that the contractors improperly paid a total of $208,966,252 to suppliers.

Table 4 summarizes by jurisdiction the estimates of the amounts allowed for payment and paid to suppliers for high utilization claims that were not supported in accordance with Medicare documentation requirements.

Table 4: Estimates of Unallowable Amounts

Jurisdiction	Amount Allowed for Payment	Amount Paid to Suppliers
A	$49,214,902	$39,206,181
B	56,221,550	42,227,372
C	125,018,182	96,633,764
D	40,506,383	30,898,935
Total	**$270,961,017**	**$208,966,252**

LACK OF CONTROLS

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

INTERNAL CONTROL AND POLICY CHANGES RESULTING FROM AUDIT REPORTS TO CONTRACTORS

Internal Control Changes

We issued individual reports to each of the four contractors with recommendations for corrective actions. In response, the contractors stated that they had taken or planned to take corrective actions, including:

- implementation of system edits to identify high utilization claims for test strips and/or lancets,

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

- performance of prepayment reviews of suppliers with high utilization claims for test strips and/or lancets.

NHIC stated that it had established internal processes and referral procedures to alert the program safeguard contractor (PSC) of a potentially abusive situation.[18] NGS stated that it referred suppliers to the PSC if fraudulent behavior was suspected. CGS stated that it had a process in place for referring suppliers of diabetic testing supplies to the zone program integrity contractors (ZPIC).[19]

The four contractors stated that they had improved education of suppliers, prescribing physicians, and/or beneficiaries by reinforcing the Medicare documentation requirements for claims for test strips and/or lancets. These efforts included issuing letters to prescribing physicians to educate them concerning Medicare policy. In addition, NGS indicated that it sent letters to beneficiaries who received test strips and lancets from three or more suppliers because beneficiaries with multiple suppliers were very likely to have claims with overlapping dates of service. The letter informed those beneficiaries that they should be receiving test strips and lancets from one supplier.

Policy Changes

CGS stated that medical directors examined the LCDs to determine whether additional safeguards could be implemented to prevent improper payments and accommodate additional automated editing of claims for diabetic testing supplies. Noridian stated that a change to its LCD was in process and, upon finalization, would improve the contractor's ability to enforce well-defined limits for the utilization of test strips and lancets. The revised LCDs for all four contractors, effective August 2, 2011, made changes to the refill requirements for test strips and lancets. One new requirement is that the supplier must document the remaining quantity of each item that the beneficiary has on hand before delivering the supplies.

CONCLUSION

The contractors could have saved Medicare an estimated $208,966,252 for CY 2007 if they had had controls to ensure that claims for test strips and/or lancets complied with certain Medicare documentation requirements. Adequate controls are important to program integrity because they help to prevent improper payments to suppliers for test strips and lancets. Unless the contractors implement system edits to identify for further review high utilization claims and claims that have overlapping service dates for the same beneficiary, they are likely to continue to make improper payments to suppliers.

We plan to perform additional reviews to determine the effectiveness of the contractors' system edits for identifying claims for test strips and/or lancets that have overlapping service dates for the same beneficiary.

[18] The primary goal of PSCs is to identify cases of suspected fraud, develop them thoroughly and in a timely manner, and take immediate action to prevent improper Medicare payments and recover any overpayments.

[19] ZPICs have the same primary goal as PSCs. PSCs are currently transitioning to ZPICs.

RECOMMENDATIONS

We recommend that CMS:

- ensure that contractors implement system edits recommended in our individual reports to:

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

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

- ensure that contractors are enforcing Medicare documentation requirements for claims for test strips and/or lancets by monitoring the contractors' (1) identification of suppliers with a high volume of high utilization claims, (2) performance of prepayment reviews of those suppliers, and (3) referrals of suppliers to the Office of Inspector General or CMS for further review or investigation when necessary; and

- consider the results of our reviews when developing and evaluating coverage and reimbursement policies related to test strips and lancets.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In its written comments on our draft report, CMS concurred with all of our recommendations:

- In response to our first recommendation, CMS stated that the four contractors have taken actions to implement system edits and that CMS management will track those actions.

- In response to our second recommendation, CMS stated that the contractors have initiated reviews of glucose testing supplies and continue to work with CMS to develop a cost-effective way of addressing the high utilization of those supplies.

- In response to our third recommendation, CMS stated that it will consider the results of our reviews when developing and evaluating coverage and reimbursement policies related to test strips and lancets. CMS noted, however, that certain statutory definitions in Title XVIII of the Act may impact its ability to develop policies that perfectly balance competing interests.

CMS's comments are included in their entirety as Appendix B.

APPENDIXES

APPENDIX A: MEDICARE DOCUMENTATION REQUIREMENTS

Documentation for Quantities in Excess of Utilization Guidelines

For a quantity of home blood-glucose test strip and lancet supplies (test strips and lancets) in excess of utilization guidelines, the Local Coverage Determinations[1] (LCD) require that the treating physician document in the medical records the specific reason for the additional supplies.

The LCDs also require that when a durable medical equipment supplier (supplier) refills a physician's order for a quantity of test strips and lancets in excess of utilization guidelines, "there 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, the LCDs state that the treating physician must have evaluated the patient's diabetic control within 6 months before ordering the quantity of test strips and lancets in excess of the guidelines.

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 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 [durable medical equipment] product no sooner than approximately 5 days prior to the end of usage for the current product."

The LCDs state that the supplier may not dispense test strips and lancets until the beneficiary has nearly exhausted the previously dispensed supplies. In addition, the beneficiary or the beneficiary's caregiver must request the refill of test strips and lancets before the supplier dispenses supplies to the beneficiary.

Physician Orders

Section 1833(e) of the Social Security Act requires that providers furnish contractors with necessary information to receive payment for services provided to Medicare beneficiaries. The Manual, chapter 5, section 5.2.1, requires that the 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 supplier dispenses items based on a verbal order, the supplier must have a written order in its records before submitting a claim to the contractor.

[1] Jurisdictions A and B adopted LCD L11530, Jurisdiction C adopted LCD L11520, and Jurisdiction D adopted LCD L196. Each LCD contains the same documentation requirements.

The LCDs state: "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 LCDs require 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.

Proof-of-Delivery Records

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

APPENDIX B: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR 0 2 2012

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General Draft Report: "Medicare Contractors Lacked Controls to Prevent Millions in Improper Payments for High Utilization Claims for Home Blood-Glucose Test Strips and Lancets" (A-09-11-02027)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) Draft Report titled "Medicare Contractors Lacked Controls to Prevent Millions in Improper Payments for High Utilization Claims for Home Blood-Glucose Test Strips and Lancets" (A-09-11-02027). The Centers for Medicare & Medicaid Services (CMS) appreciates the time and resources the OIG has utilized in reviewing this issue. The OIG's audit focused on paid claims with 2007 dates of service for home blood-glucose strips and lancets processed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for each of the four DME MAC Jurisdictions. The objective was to summarize the results of the individual reviews of the four DME MACs that process Medicare claims for test strips and lancets for Jurisdictions A, B, C, and D.

CMS understands the major deficiency noted during the review was that documentation was often insufficient to validate the quantity of supplies that exceeded utilization guidelines. The finding that only 97 of the 400 sampled claims were supported in accordance with Medicare documentation requirements confirms CMS' own annual error rate analysis.

The OIG estimates the contractors allowed for payment of $1.2 billion in Medicare Part B claims for test strips and/or lancets for calendar year 2007. Further, the OIG estimates contractors allowed for a total payment of $484.3 million for high-utilization claims.

OIG Recommendation
Ensure that contractors implement system edits recommended in our individual reports to:

- Identify high utilization claims for test strips and/or lancets and develop cost-effective ways of determining which claims should be further reviewed for compliance with Medicare documentation requirements and;

- Identify claims for test strips and/or lancets that have overlapping service dates for the same beneficiary.

CMS Response
CMS concurs with this recommendation. In response to the individual reports disseminated to the four DME MACs, actions have been taken and will be tracked by CMS management. Each of the DME MACs has a plan for dealing with this widespread problem which does include implementing systems edits.

CMS will share this summary report with the DME MACs and continue to encourage them to implement corrective actions related to this issue.

OIG Recommendation
Ensure that contractors are enforcing Medicare documentation requirements for claims for test strips and/or lancets by monitoring the contractors':

- Identification of suppliers with a high volume of high utilization claims;

- Performance of prepayment reviews of those suppliers; and

- Referrals of suppliers to the Office of Inspector General or CMS for further review or investigation when necessary.

CMS Response
CMS concurs with this recommendation. The DME MACs have initiated reviews on glucose testing supplies and continue to work with CMS to develop a cost-effective way of addressing the high utilization of glucose test strips and supplies. They also implemented several educational interventions to reinforce the Medicare policy including posting to their Web site the *Dear Physician Letters* that outline the documentation requirements for physicians. The DME MACs have also conducted extensive provider and supplier education regarding proper coding, coverage, and documentation requirements for home blood-glucose monitors and supplies.

OIG Recommendation
Consider the results of our reviews when developing and evaluating coverage and reimbursement policies related to test strips and lancets.

CMS Response
CMS concurs with the recommendation. CMS will consider the results of OIG's reviews when developing and evaluating coverage and reimbursement policies related to test strips and lancets. However, we would like to note that certain statutory definitions in Title XVIII of the Social

Security Act may impact our ability to develop policies that perfectly balance these competing interests.

We appreciate the effort that went into this report and look forward to continuing to work with the OIG on safeguarding the Medicare program.