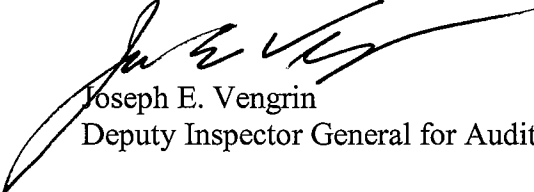




JAN 17 2008

TO: Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services

FROM: 
Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Review of Medicare Payments to iCare Medical Supply for Home Blood-Glucose Test Strip and Lancet Supplies (A-09-05-00063)

Attached is an advance copy of our final report on Medicare payments to iCare Medical Supply, Inc. (iCare), for home blood-glucose test strip and lancet supplies (test strips and lancets). We will issue this report to iCare within 5 business days.

Medicare Part B covers test strips and lancets that physicians prescribe for diabetics. Medicare requires that these supplies be reasonable and necessary for the treatment of a beneficiary's illness. The quantity of supplies that Medicare covers depends on the beneficiary's usual medical needs.

Our objective was to determine whether iCare claimed reimbursement for test strips and lancets in accordance with Medicare requirements. We reviewed \$8,664,874, representing payments of more than \$200 each for 12,492 beneficiaries.

iCare did not claim reimbursement for test strips and lancets in accordance with Medicare requirements. Medical reviewers from Palmetto GBA, the region C durable medical equipment regional carrier, found that none of iCare's claims for the 100 sampled beneficiaries met Medicare requirements and that each service line item on each claim had one or more errors.

These errors occurred because iCare did not have adequate controls to ensure that test strips and lancets billed to Medicare were medically necessary and documented in accordance with Medicare requirements. As a result, iCare received \$73,040 in unallowable Medicare payments for the 100 sampled beneficiaries. Projecting these results to the population, we estimate that at least \$8,233,476 of the \$8,664,874 paid to iCare for test strips and lancets provided in calendar years 2002 and 2003 was unallowable for Medicare reimbursement.

We recommend that iCare refund \$8,233,476 to the Medicare program and work with the Centers for Medicare & Medicaid Services to determine the allowability of test strips and lancets billed after calendar year 2003.

In its comments on our draft report, iCare did not address our recommendations. iCare disagreed with our findings and with certain aspects of the audit criteria and methodology. After reviewing iCare's comments, we disagree with iCare's interpretations of the criteria and continue to support our findings and recommendations.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact George M. Reeb, Assistant Inspector General for the Centers for Medicare & Medicaid Audits, at (410) 786-7104 or through e-mail at George.Reeb@oig.hhs.gov or Lori A. Ahlstrand, Regional Inspector General for Audit Services, Region IX, at (415) 437-8360 or through e-mail at Lori.Ahlstrand@oig.hhs.gov. Please refer to report number A-09-05-00063.

Attachment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

JAN 23 2008

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

Report Number: A-09-05-00063

Mr. Chris Baker
Former President
iCare Medical Supply, Inc.
14255 U.S. Highway 1
Juno Beach, Florida 33418

Dear Mr. Baker:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Medicare Payments to iCare Medical Supply for Home Blood-Glucose Test Strip and Lancet Supplies." 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.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, within 10 business days after the final report is issued, it will be posted on the Internet at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Jerry McGee, Audit Manager, at (323) 261-7218, extension 603, or through e-mail at Jerry.Mcgee@oig.hhs.gov. Please refer to report number A-09-05-00063 in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Lori A. Ahlstrand".

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Mr. Tom Lenz, Consortium Administrator
Consortium for Financial Management & Fee for Service Operations
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 235
Kansas City, Missouri 64106

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF
MEDICARE PAYMENTS TO
ICARE MEDICAL SUPPLY
FOR HOME BLOOD-GLUCOSE
TEST STRIP AND
LANCET SUPPLIES**



Daniel R. Levinson
Inspector General

January 2008
A-09-05-00063

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 and 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:

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The Office of Audit Services (OAS) provides all 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.

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THIS REPORT IS AVAILABLE TO THE PUBLIC
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In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR part 5.)

OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS 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. Medicare requires that these supplies be reasonable and necessary for the treatment of a beneficiary's illness.

The quantity of supplies that Medicare covers depends on the beneficiary's usual medical needs. 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. (Medicare considers 50 test strips as one unit and 100 lancets as one unit.) Medicare will cover a higher quantity of supplies if the reason for the quantity in excess of the utilization guidelines and the actual frequency of testing have been documented in the beneficiary's medical record. For any quantity of supplies, the supplier's records must contain evidence that the beneficiary or the beneficiary's caregiver specifically requested the supplies before shipment. Further, the physician's order for test strips and lancets must include certain elements, such as the quantity of items to be dispensed.

iCare Medical Supply, Inc. (iCare), a durable medical equipment supplier in Jupiter, Florida, received \$8,916,868 in Medicare payments for providing test strips and lancets in calendar years (CY) 2002 and 2003. We limited our review to \$8,664,874, representing payments of more than \$200 each for 12,492 beneficiaries.

The Medicare claims data for the 100 beneficiaries in our statistical sample consisted of 491 claims and 919 service line items. Each service line item had one or more units of test strips or lancets. We contracted with Palmetto GBA, the durable medical equipment regional carrier to which iCare submitted Medicare claims, to evaluate the 919 service line items for compliance with Medicare requirements.

OBJECTIVE

Our objective was to determine whether iCare claimed reimbursement for test strips and lancets in accordance with Medicare requirements.

SUMMARY OF FINDINGS

iCare did not claim reimbursement for test strips and lancets in accordance with Medicare requirements. Medical reviewers from Palmetto GBA found that none of iCare's claims for the 100 sampled beneficiaries met Medicare requirements and that each service line item on each claim had one or more errors. The types of errors that occurred most frequently were:

- medically unnecessary supplies (64 beneficiaries and 428 service line items),
- undocumented testing frequency (84 beneficiaries and 729 service line items),
- unrequested shipment of supplies (82 beneficiaries and 675 service line items), and
- incomplete physician orders (74 beneficiaries and 501 service line items).

These errors occurred because iCare did not have adequate controls to ensure that test strips and lancets billed to Medicare were medically necessary and documented in accordance with Medicare requirements. As a result, iCare received \$73,040 in unallowable Medicare payments for the 100 sampled beneficiaries. Projecting these results to the population, we estimate that at least \$8,233,476 of the \$8,664,874 paid to iCare for test strips and lancets provided in CYs 2002 and 2003 was unallowable for Medicare reimbursement.

RECOMMENDATIONS

We recommend that iCare refund \$8,233,476 to the Medicare program and work with the Centers for Medicare & Medicaid Services to determine the allowability of test strips and lancets billed after CY 2003.

iCARE'S COMMENTS AND OFFICE OF INSPECTOR GENERAL'S RESPONSE

In its comments on our draft report (Appendix D), iCare did not address our recommendations. iCare disagreed with our findings and with certain aspects of the audit criteria and methodology. iCare stated that we appeared to have applied the durable medical equipment regional carriers' current policy guidelines to claims submitted in 2002 and 2003. In addition, iCare stated that we had prevented it from taking part in obtaining documentation to support its Medicare claims.

After reviewing iCare's comments, we disagree with iCare's interpretations of the criteria and continue to support our findings and recommendations. Determinations that claims for test strips and lancets were unallowable were based on reviews of beneficiaries' medical records and criteria effective in 2002 and 2003. In addition, we did not prevent iCare from taking part in obtaining documentation.

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INTRODUCTION

BACKGROUND

The Medicare program, established by Title XVIII of the Social Security Act (the Act) in 1965, provides health insurance coverage to people age 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. CMS contracts with four durable medical equipment regional carriers (DMERC) to process Medicare Part B claims for durable medical equipment (DME), prosthetics, orthotics, and supplies.

Home Blood-Glucose Test Strip and Lancet Supplies

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

DME suppliers provide test strips and lancets to beneficiaries and submit claims for reimbursement to one of the four DMERCs. Medicare requires that these supplies be reasonable and necessary for the treatment of a beneficiary's illness.

The quantity of supplies that Medicare covers depends on the beneficiary's usual medical needs. Each of the four DMERCs has a local medical review policy (LMRP), which 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.¹ Medicare will cover a higher quantity of supplies if the reason for the quantity in excess of the utilization guidelines and the actual frequency of testing have been documented in the beneficiary's medical record. For any quantity of supplies, the supplier's records must contain evidence that the beneficiary or the beneficiary's caregiver specifically requested the supplies before shipment. Further, the physician's order for test strips and lancets must include certain elements, such as the quantity of items to be dispensed.

iCare Medical Supply, Inc.

iCare Medical Supply, Inc. (iCare), a DME supplier, provided test strips and lancets to Medicare beneficiaries nationwide. It submitted Medicare claims to Palmetto GBA, the region C DMERC, which transmitted some of the claims to the three other DMERCs, as appropriate, based on the location of the beneficiary's residence. iCare's main office was located in Jupiter, Florida.

On October 27, 2005, iCare sold its assets (i.e., customer relationships and inventory) to another company, and it no longer provides DME supplies, including test strips and lancets, to Medicare beneficiaries. iCare's attorney informed us that any sales proceeds left after paying secured lenders and wholesale manufacturers would remain in iCare's bank account and be used to

¹Medicare considers 50 test strips as one unit and 100 lancets as one unit.

refund any overpayments that our review identified. On October 29, 2005, iCare voluntarily terminated its Medicare provider number with Palmetto GBA.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether iCare claimed reimbursement for test strips and lancets in accordance with Medicare requirements.

Scope

iCare received \$8,916,868 in Medicare payments for providing test strips and lancets in calendar years (CY) 2002 and 2003. We limited our review to \$8,664,874, representing Medicare payments of more than \$200 each for 12,492 beneficiaries.

During our review, we found that iCare had very limited controls. For example, iCare had no written procedures, and its employees had only a limited understanding of the Medicare requirements for billing test strips and lancets. Based on this information, we did not attempt to perform an internal control review and proceeded to substantive testing to determine allowability of the supplies claimed.

We performed our review from August 2005 through September 2006 and conducted fieldwork at iCare in Jupiter, Florida.

Methodology

From the population of 12,492 beneficiaries, we selected a random sample of 100 beneficiaries. The Medicare claims data for the 100 beneficiaries consisted of 491 claims and 919 service line items. Each service line item had one or more units of test strips or lancets. (See Appendix A for details of our sample methodology and results.) Medicare payments to iCare for the 100 beneficiaries totaled \$73,040 for test strips and lancets provided in CYs 2002 and 2003.

We contracted with Palmetto GBA to perform a medical review of documentation supporting test strips and lancets provided to the 100 sampled beneficiaries. Palmetto GBA evaluated each of the 919 service line items for the sampled beneficiaries to determine whether iCare claimed reimbursement for test strips and lancets in accordance with Medicare requirements. Palmetto GBA reported its results using 17 error codes. We developed these error codes in coordination with Palmetto GBA based on the LMRPs issued by the four DMERCs. (See Appendix B for descriptions of the error codes.)

In addition, we:

- reviewed applicable Federal requirements,
- reviewed and compared LMRPs and supplier manuals from the four DMERCs,

- used CMS National Claims History data to identify the 12,492 Medicare beneficiaries for whom iCare received Medicare payments of more than \$200 each for providing test strips and lancets in CYs 2002 and 2003,
- obtained medical records from iCare and the beneficiaries' physicians for all 100 sampled beneficiaries,
- reviewed iCare's policies and procedures for billing Medicare for test strips and lancets,
- interviewed iCare officials to obtain an understanding of iCare's Medicare billing processes for test strips and lancets, and
- used an unrestricted variable appraisal program to estimate the dollar impact of overpayments in the population.

We conducted our review in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

iCare did not claim reimbursement for test strips and lancets in accordance with Medicare requirements. Medical reviewers from Palmetto GBA found that none of iCare's claims for the 100 sampled beneficiaries met Medicare requirements and that each service line item on each claim had one or more errors. (See Appendix C for the number of errors for each of the 17 error codes used in our review.) The types of errors that occurred most frequently were:

- medically unnecessary supplies (64 beneficiaries and 428 service line items),
- undocumented testing frequency (84 beneficiaries and 729 service line items),
- unrequested shipment of supplies (82 beneficiaries and 675 service line items), and
- incomplete physician orders (74 beneficiaries and 501 service line items).

These errors occurred because iCare did not have adequate controls to ensure that test strips and lancets billed to Medicare were medically necessary and documented in accordance with Medicare requirements. As a result, iCare received \$73,040 in unallowable Medicare payments for the 100 sampled beneficiaries. Projecting these results to the population, we estimate that at least \$8,233,476 of the \$8,664,874 paid to iCare for test strips and lancets was unallowable for Medicare reimbursement.

PAYMENT ERRORS

Medically Unnecessary 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. Chapter 5, section 2, of the "Medicare Program Integrity Manual" (Rev. 3, 11-22-00) states: "neither a physician's order nor a CMN [Certificate

of Medical Necessity] nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician. There must be clinical information in the patient's medical record that supports the medical necessity for the item"

A CMS program memorandum, Transmittal No. B-98-33, states:

Medicare will pay for all test strips and lancets that are reasonable and necessary. The DMERCs will determine and publish usual utilization guidelines and documentation requirements. Documentation must be maintained in the physician and supplier beneficiary medical record justifying the need for prescribed amounts that are billed to Medicare. The DMERCs will conduct medical reviews.

The LMRPs issued by the four DMERCs outline Medicare utilization guidelines for test strips and lancets. The LMRPs state 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. Medicare will cover a higher quantity of supplies if the reason for the quantity in excess of the utilization guidelines has been documented in the beneficiary's medical record. Further, the LMRPs specify that the beneficiary medical records must contain adequate documentation to support the medical necessity of all supplies ordered. The supplier is responsible for obtaining this documentation before billing Medicare.

For 64 of the 100 sampled beneficiaries, representing 428 of the 919 service line items, iCare provided medically unnecessary test strips and lancets.² Specifically, there was no documentation in the medical records supporting medical necessity for the prescribed frequency of testing.

For example, for one beneficiary, iCare submitted a claim for 18 units of test strips and 6 units of lancets, or 900 strips and 600 lancets, for a 3-month period. The physician order indicated a testing frequency of 10 times a day for 3 months, which would require the patient to test approximately 900 times over a 3-month period. The documentation in the medical records substantiated that the beneficiary was an insulin-treated diabetic. However, the documentation did not contain justification for the prescribed testing frequency, which exceeded the Medicare utilization guidelines by 600 test strips and 300 lancets.

Undocumented Testing Frequency

The LMRPs issued by the four DMERCs require that if the quantity of supplies dispensed exceeds Medicare's utilization guidelines, the physician's or supplier's records should document that the beneficiary's actual frequency of testing was consistent with the quantity of supplies dispensed. Examples of acceptable documentation include a specific narrative statement by the physician that adequately documents the beneficiary's actual frequency of testing or a copy of the beneficiary's log that includes the date, approximate time, and result of each test. The beneficiary's actual frequency of testing should corroborate the quantity of supplies dispensed.

²Palmetto GBA used error codes 3, 8, and 9 to denote medically unnecessary supplies.

Chapter 5, section 2.1, of the “Medicare Program Integrity Manual” (Rev. 3, 11-22-00) states that the supplier should obtain as much documentation from the beneficiary’s medical record, including the physician’s office records, as it needs to ensure that the coverage criteria for an item have been met.

iCare provided test strips and lancets to 84 of the 100 sampled beneficiaries, representing 729 of the 919 service line items, without documentation of the actual frequency of testing.³ For example, iCare provided 300 test strips and 300 lancets for a 3-month period to one non-insulin-treated beneficiary, contrary to the physician order for 100 test strips and 100 lancets. The quantity provided corresponded to a testing frequency of three times a day and exceeded both the prescribed amount and Medicare’s utilization guideline of 100 test strips and 100 lancets for a 3-month period. However, the medical records contained no evidence that the beneficiary actually tested three times a day.

Unrequested Shipment of Supplies

According to the LMRPs issued by the four DMERCs, the supplier’s records must contain evidence that the beneficiary or the beneficiary’s caregiver specifically requested the supplies before shipment. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has preauthorized the automatic shipment.

iCare provided test strips and lancets to 82 of the 100 sampled beneficiaries, representing 675 of the 919 service line items, without obtaining specific requests from the beneficiary or the beneficiary’s caregiver.⁴ iCare’s delivery confirmation forms also served as requests for automatic shipping of the next order of test strips and lancets. iCare included a copy of the form in each supply shipment and instructed beneficiaries to sign the form and mail it to iCare when they received the shipment. According to iCare’s patient contact logs, some beneficiaries called iCare to request that supplies not be shipped or to complain that they had many outdated supplies.

Incomplete Physician Orders

The LMRPs issued by the four DMERCs require that the supplier have an original order for test strips and lancets, signed and dated by the physician treating the patient’s diabetes. The order must include all of the following:

- the items to be dispensed,
- the quantity of items to be dispensed,
- the specific frequency of testing, and
- whether the patient has insulin- or non-insulin-treated diabetes.

³Palmetto GBA used error code 11 to denote undocumented testing frequency.

⁴Palmetto GBA used error code 13 to denote unrequested shipment of supplies.

iCare provided test strips and lancets to 74 of the 100 sampled beneficiaries, representing 501 of the 919 service line items, based on incomplete physician orders.⁵ In most instances, the physician orders did not include the specific items to be dispensed or the quantity of those items. Further, the physician orders did not always include the date of the physician's signature, the frequency of testing, or whether the beneficiary was insulin- or non-insulin-treated.

INADEQUATE CONTROLS

iCare did not have adequate controls to ensure that test strips and lancets billed to Medicare were medically necessary and documented in accordance with Medicare requirements. iCare had no written procedures, and its employees had a limited understanding of the Medicare requirements for billing test strips and lancets.

EFFECT OF IMPROPER BILLINGS

For the 100 sampled beneficiaries, iCare received \$73,040 in Medicare payments for test strips and lancets that did not meet Medicare requirements. Projecting these results to the population, we estimate that at least \$8,233,476 of the \$8,664,874 paid to iCare for test strips and lancets provided in CYs 2002 and 2003 was unallowable for Medicare reimbursement.

RECOMMENDATIONS

We recommend that iCare refund \$8,233,476 to the Medicare program and work with CMS to determine the allowability of test strips and lancets billed after CY 2003.

iCARE'S COMMENTS AND OFFICE OF INSPECTOR GENERAL'S RESPONSE

In its comments on our draft report (Appendix D), iCare did not address our recommendations. As discussed below, iCare disagreed with our findings and with certain aspects of the audit criteria and methodology.

Medically Unnecessary Supplies

iCare's Comments

iCare commented that there was no specific requirement in the Spring 2002 "Region C DMEPOS [Durable Medical Equipment, Prosthetics, Orthotics, and Supplies] Supplier Manual" that the supplier obtain any medical record documentation before billing Medicare. In addition, iCare commented that we had contacted only the prescribing physicians, but no other health care providers, to obtain medical records that would support the need for the supplies prescribed.

Office of Inspector General's Response

Determinations that supplies were not medically necessary were not based on whether iCare obtained medical record documentation to support medical necessity before billing Medicare.

⁵Palmetto GBA used error code 14 to denote incomplete physician orders.

These determinations were based on whether the beneficiary medical records contained adequate documentation to support the medical necessity of all supplies ordered in accordance with criteria effective in 2002 and 2003, including section 1862(a)(1)(A) of the Act; Chapter 5, section 2, of the “Medicare Program Integrity Manual” (Rev. 3, 11-22-00); a CMS program memorandum, Transmittal No. B-98-33; and the LMRPs issued by the four DMERCs.

We obtained the medical records of not only the prescribing physicians but also hospitals, nursing homes, home health agencies, and other durable medical suppliers. The prescribing physicians provided this information when available.

Undocumented Testing Frequency

iCare’s Comments

iCare commented that the report appeared to indicate that it is the supplier’s responsibility, not the physician’s, to maintain documentation of the beneficiary’s actual frequency of testing. Further, iCare commented that suppliers are obligated to obtain only those documents that they need to assure themselves that the coverage criteria for an item have been met.

Office of Inspector General’s Response

We did not indicate in our report whether it was the supplier’s or the physician’s responsibility to maintain supporting documentation for testing frequency. We stated that the physician’s or supplier’s records should document that the beneficiary’s actual frequency of testing was consistent with the quantity of supplies dispensed when the quantity dispensed exceeded Medicare’s utilization guidelines. For 84 beneficiaries, neither iCare’s nor the physicians’ medical records contained any supporting documentation for testing frequency.

Unrequested Shipment of Supplies

iCare’s Comments

iCare commented that it had always been its policy to verify the patient’s need before shipping supplies and to dispense supplies only to beneficiaries who specifically requested them before shipment. iCare stated that without additional information about the beneficiaries involved, it could not respond further to this finding.

Office of Inspector General’s Response

The medical records for 82 beneficiaries did not contain any documentation of specific requests from the beneficiary or the beneficiary’s caregiver. Further, at the time of our audit, iCare did not have any written procedures to verify the patient’s need before shipping supplies and to dispense supplies only to beneficiaries who specifically requested them before shipment. iCare’s employees had only a limited understanding of the Medicare requirements for billing test strips and lancets. After we notified iCare of our review, it started working with its attorney to develop a Medicare compliance program and training its employees about Medicare billing requirements.

iCare had sufficient information about the beneficiaries to respond to this finding because iCare provided us with the supplier records that were the basis of our finding.

Incomplete Physician Orders

iCare's Comments

iCare commented that “The policy in place in 2002 did not require that the physician order indicate the specific quantity of the items to be dispensed.” iCare stated that because it did not know the percentage of errors related to the quantity of items to be dispensed, it was unable to adequately respond to this finding.

Office of Inspector General's Response

Effective October 1, 2002, the LMRPs issued by the four DMERCs required the physician order to include the specific quantity of items to be dispensed. The policies in effect during 2002 and 2003 provided the basis for determinations that iCare provided test strips and lancets based on incomplete physician orders. As shown in Appendix C, for error code 14.2, iCare provided test strips and lancets for 364 (approximately 40 percent) of the 919 service line items based on physician orders that did not specify the quantity of items to be dispensed.

Additional Comments

iCare's Comments

iCare stated that our findings were entirely inconsistent with its internal and carrier audit findings for the same period. In addition, iCare stated that we had prevented it from taking part in obtaining documentation to support its Medicare claims.

Office of Inspector General's Response

We requested copies of audit-related documentation from iCare on September 25, 2005. However, iCare did not provide the requested documentation and closed its business October 27, 2005. Therefore, we have no basis to evaluate iCare's comment.

We did not prevent iCare from taking part in obtaining documentation. To expedite our audit, we asked the beneficiaries' physicians to send documentation directly to us. Our standard procedure is to discuss any documentation deficiencies with the auditee and provide the auditee an opportunity to obtain additional documentation for any questionable claims. However, because iCare closed its business about 2 months after we started our fieldwork, it did not have staff available to follow up with physicians.

APPENDIXES

SAMPLE METHODOLOGY AND RESULTS**METHODOLOGY****Objective**

Our objective was to determine whether iCare Medical Supply, Inc. (iCare), claimed reimbursement for home blood-glucose test strip and lancet supplies (test strips and lancets) in accordance with Medicare requirements.

Population

The population consisted of 12,492 Medicare beneficiaries for whom iCare received Medicare payments of more than \$200 each for providing test strips and lancets during calendar years (CY) 2002 and 2003. The payments for these beneficiaries totaled \$8,664,874.

Sample Unit

The sample unit was a Medicare beneficiary for whom iCare received Medicare payments of more than \$200 each for providing test strips and lancets in CYs 2002 and 2003.

Sample Design

We used a simple random sample.

Sample Size

The sample size was 100 Medicare beneficiaries.

Source of Random Numbers

The source of the random numbers was the Office of Inspector General, Office of Audit Services, statistical sampling software dated June 2005. We used the random number generator for our simple random sample.

Method of Selecting Sample Items

We sequentially numbered the population of Medicare beneficiaries from 1 through 12,492. After generating 100 random numbers, we correlated each selected random number to the population number and selected that population number for our sample.

Estimation Methodology

We used the Office of Audit Services RAT-STATS unrestricted variable appraisal program to project the sample results. We used the lower limit of the 90-percent confidence level for our recommended refund.

RESULTS AND PROJECTION

	<u>Population</u>	<u>Sample</u>	<u>Errors</u>
Beneficiaries	12,492	100	100
Payments	\$8,664,874	\$73,040	\$73,040

Projection of Sample Results

Precision at the 90-Percent
Confidence Level

Point estimate	\$9,124,139
Lower limit	\$8,233,476
Upper limit	\$10,014,803
Precision percent	9.76%

ERROR CODES

Error Code	Description Per Local Medical Review Policies
1	The entire medical record for the beneficiary was missing from iCare.
2	The physician order for supplies was missing from iCare.
3	The supplies provided to the Medicare beneficiary were not reasonable and medically necessary.
4	The beneficiary did not have diabetes that was being treated by a physician.
5	The supplies were not ordered by the physician who was treating the beneficiary's diabetes.
6	The beneficiary (or the beneficiary's caregiver) did not complete training or was not scheduled to begin training in the use of the monitor, test strips, and lancing devices.
7	The beneficiary (or the beneficiary's caregiver) was not capable of using the test results to assure the beneficiary's appropriate glycemic control.
8	The treating physician did not maintain records reflecting the care provided, including, but not limited to, evidence of medical necessity for the prescribed frequency of testing.
9	The quantity of supplies was not covered based on the usual medical needs of the diabetic patient.
10	The treating physician did not see the beneficiary and evaluate his or her diabetes control within 6 months prior to ordering quantities of supplies that exceeded the utilization guidelines.
11	There was no documentation in the physician's records or in the supplier's records that the beneficiary was actually testing at a frequency that corroborated the quantity of supplies that had been dispensed.
12	The supplies were not billed with the correct modifier that designated whether the beneficiary was insulin- or non-insulin-treated.
13	The beneficiary or the beneficiary's caregiver did not specifically request each and every refill of supplies before it was dispensed.
14	The order for the supplies did not contain all of the required elements.
14.1	Missing the item(s) dispensed
14.2	Missing the quantity of item(s) to be dispensed
14.3	Missing specific frequency of testing
14.4	Missing whether the patient was insulin-treated or non-insulin-treated diabetic
14.5	Missing the treating physician's signature
14.6	Missing the date of the treating physician's signature
15	The supplier did not have a delivery record for supplies.
16	The supplier billed incorrect units of supplies.
17	All other – Specify any other conditions not covered by one of the codes above and specific circumstances that lead to a determination that the service should be deemed unallowable.

ERROR COUNTS FOR EACH ERROR CODE

Error Code	Beneficiaries With Errors	Service Line Items With Errors
1	0	0
2	1	2
3 ¹	63	422
4	0	0
5	20	175
6	5	35
7	5	29
8	59	382
9	55	349
10	10	65
11	84	729
12	5	16
13	82	675
14	74	501
14.1	25	168
14.2	61	364
14.3	2	5
14.4	27	115
14.5	0	0
14.6	5	28
15	78	570
16	5	21
17	4	6

¹The combination of error codes 3, 8, and 9, which represent medically unnecessary supplies, resulted in errors for 64 beneficiaries and 428 service line items.

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August 6, 2007

Lori A. Ahlstrand
Inspector General for Audit Services
Office of Inspector General
Department of Health and Human Services
Region 990-Seventh Street, Suite 3-650
San Francisco, CA 94103

Via Overnight Delivery

Re: iCare Medical Supply, Inc. ("iCare")
Report No. A-09-05-00063

Dear Ms. Ahlstrand:

We represent iCare. We are writing in response to your letter dated June 25, 2007, regarding the Office of Inspector General's ("OIG") review of Medicare payments to iCare for home blood glucose test strips and lancets. The following is our response to the findings of the OIG as set forth in the report.

As stated in the report, the period in question included calendar years 2002 and 2003. Based on the review, the OIG report indicated that errors were found primarily in the following areas.

Unnecessary Supplies

According to the report, 64 of the 100 sampled beneficiaries were provided with medically unnecessary test strips and lancets. The report states that these errors were based specifically on the fact that there was no documentation in the medical records supporting medical necessity for the prescribed frequency of testing. In addition, the report cites the local medical review policy in place at the time as support for the statement that "the supplier is responsible for obtaining this documentation before billing Medicare." Such documentation would include copies of the beneficiary's medical records, which would contain documentation to support medical necessity.

According to the Region C DMEPOS Supplier Manual from Spring 2002 ("Supplier Manual"), there is no specific requirement that the supplier obtain any medical record documentation prior to billing Medicare. Page 41.4 of the Supplier Manual states:

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“Section 1833(e) of the Social Security Act precludes payment to any provider of services unless “there has been furnished such information as may be necessary in order to determine the amounts due such provider.” (42USC, Section 1395-1(e)). It is expected that the patient’s medical record will reflect the need for the care provided. The patient’s medical records include the physician’s office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.”

The policy in place in 2002 does not contain the requirement that such information be obtained prior to billing Medicare. In addition, at the time the OIG audited iCare and attempted to obtain medical records from prescribing physicians, iCare was specifically instructed that it was to take no part in attempting to collect supporting documentation. It is our understanding that the OIG contacted only the prescribing physician and did not contact any nursing homes, home health agencies, hospitals or other healthcare professionals to obtain medical records that would support the need for the product prescribed and would meet criteria of the local medical review policy in place at the time. Preventing iCare from taking part in obtaining this documentation circumvents the supplier’s ability to provide this information “upon request.” The supplier, in many cases, might have a relationship with the healthcare provider that would allow the supplier to obtain medical records when the OIG fails. For these reasons, we do not believe that the OIG fully understood the local medical review policy in place at the time and prevented iCare from meeting its obligations under the local medical review policy to be involved in obtaining the medical record documentation needed to support its claim.

Undocumented Testing Frequency

According to the report, 84 of the 100 sampled beneficiaries were provided supplies without documentation of the actual frequency of testing. According to the report, the Local Medical Review Policies (“LMRPs”) require that, if the quantity of supplies dispensed exceeds Medicare’s utilization guidelines, the physician’s or supplier’s records should document that the beneficiary’s actual frequency of testing was consistent with quantity of supplies dispensed. In addition, the report appears to indicate that it is the supplier’s responsibility, not the physician’s, to maintain this documentation. The report quotes Chapter 5, Section 2.1 of the Medicare Program Integrity Manual (“Integrity Manual”):

“The supplier should obtain as much documentation from the beneficiary’s medical record, including the physician’s office record, as it needs to ensure coverage criteria for an item has been met.”

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The precise language from Section 2.1 of the Integrity Manual states: "The supplier should also obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criteria for an item has been met."

This provision is less direct than indicated in the report. The Integrity Manual makes no specific reference to the physician's office record and, in fact, limits the supplier's obligation to obtain only those documents that "they determine they need to assure themselves that coverage criteria for an item has been met."

As indicated by the LMRPs, upon request, suppliers should be given the opportunity to obtain documentation from the physician. Without the opportunity to assist the OIG in obtaining adequate documentation, iCare has been prevented from meeting its obligations under the LMRPs and is unable to obtain the documentation needed to address the OIG's concerns.

Unrequested Shipment of Supplies

According to the report, 82 of the 100 sampled beneficiaries were provided test strips and lancets without obtaining a specific request from the beneficiary or the beneficiary's caregiver. It has always been the company's policy to verify the patient's need prior to shipping supplies. Without significant additional information concerning the beneficiaries involved and the individual information in such patient records, iCare is unable to respond to these allegations other than to say that at all times during the period in question, iCare policy was to dispense supplies only to beneficiaries who specifically requested the supplies prior to shipment.

Incomplete Physician Orders

The report states that the LMRPs require the supplier to have an original order for supplies that includes: "(1) the items to be dispensed; (2) the quantity of items to be dispensed; (3) the specific frequency of testing; and (4) whether the patient has insulin or non-insulin treated diabetes." The Supplier Manual describes the information required for patients receiving test strips and lancets:

"The supplier must have an order that is signed and dated by the physician who is treating the patient's diabetes. For supplies, the order must list the items that are to be dispensed and the specific frequency of testing. An order that only states, "as needed" will result in those items being denied as not medically necessary. A narrative diagnosis and/or ICD-9-CM diagnosis code must be present on each order for a glucose monitor or related accessory or supply. The order must also include a statement indicating whether the patient is being treated with insulin injections. The supplier is required to have a new written order from the treating physician every 12 months. This renewal of the order must also contain the information specified above."

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The policy in place in 2002 did not require that the physician order indicate the specific quantity of the items to be dispensed. Subsequent changes to the medical review policies require specific quantities. Without knowing what percentage of the alleged errors contained in the report relate to the quantity of items to be dispensed, iCare is unable to adequately respond to the allegations. However, iCare adamant that, at all times during the period in question and afterwards, iCare policy required a valid physician order prior to shipment.

Review of the OIG Documentation

As stated in the report, iCare sold its assets on October 27, 2005, and is no longer a supplier of DME products. iCare's Medicare supplier number was voluntarily terminated on October 29, 2005. For almost two years, iCare has not been involved in the provision of medical products or services to any patient, or submitted any claims for products or services to Medicare or any other payor. Since it ceased operation in October, 2005, iCare does not have any staff remaining to assist in reviewing the charts obtained by the OIG. At the time the OIG conducted its audit, iCare provided all requested and available documentation to the OIG. In its internal review at the time, iCare identified some errors. However, the percentage determined by iCare varies greatly from the percentage stated in the report.

Based on the findings of the report, iCare wishes to provide the following information concerning its disagreement with the report's conclusion:

1. Without specific additional information concerning the individual allegations of incomplete documentation, iCare cannot adequately dispute the allegations made by the OIG. However, the OIG's findings are entirely inconsistent with iCare's internal audit findings as well as carrier audits reviewing records from the same time period. In addition, iCare implemented changes to its documentation and process as a result of such prior carrier audits.
2. To the extent that the OIG is alleging that iCare had inadequate medical records and documentation to support its claims, iCare believes that it could have provided significant medical record documentation to support its claims if it had been given the opportunity to do so by the OIG. The OIG prevented iCare from contacting healthcare providers in relation to this audit and iCare was prevented from "providing the documentation upon request" as contemplated by the LMRPs.
3. Since iCare ceased operation in late 2005, it does not have the resources or infrastructure to specifically reaudit the charts in question and to address the specific shortcomings contained in the report.

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4. It appears that the OIG is (at least in some cases) applying current LMRP guidelines to claims submitted in 2002 and 2003 to determine whether or not iCare was in compliance with carrier policy.

Conclusion


While iCare disagrees with the OIG's findings, iCare understands that recordkeeping errors may always occur. However, prior carrier audits as well as the company's internal audits reflect a much lower error rate.

In conclusion, iCare wishes to strongly reiterate the following:

1. iCare never shipped any products to any beneficiary without first obtaining a physician order.
2. iCare never submitted a claim to Medicare or any other payor for a product that it did not ship.
3. iCare did not ship products to beneficiaries if the beneficiary did not request product shipment; and
4. If any patient returned products to iCare, iCare promptly provided a full refund of the patient's portion, as well as a complete refund of any amount paid by any insurance company, including Medicare.

For all of these reasons, iCare strongly disagrees with the findings of the OIG.

Sincerely,



Clay Stribling

sk
c: Chris Baker