

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICAL EQUIPMENT
SUPPLIERS:
COMPLIANCE WITH MEDICARE
ENROLLMENT REQUIREMENTS**



Daniel R. Levinson
Inspector General

March 2007
OEI-04-05-00380

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:

Office of Audit Services

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.

Office of Evaluation and Inspections

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

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.



E X E C U T I V E S U M M A R Y

OBJECTIVE

To determine if selected Medicare durable medical equipment, prosthetics, orthotics, and supply (DMEPOS) suppliers physically existed at their listed addresses and were open to conduct business.

BACKGROUND

According to the Centers for Medicare & Medicaid Services (CMS), Medicare expenditures for DMEPOS were approximately \$10 billion in calendar year (CY) 2005. DMEPOS includes devices such as power wheelchairs, oxygen equipment, diabetic equipment, canes, braces, and artificial limbs.

DMEPOS suppliers provide equipment to Medicare beneficiaries and submit claims to the Federal Government for reimbursement. At the time of our review, DMEPOS suppliers were required to meet 21 Medicare standards in order to obtain a supplier number for these billing privileges, pursuant to 42 CFR § 424.57(c). Suppliers must obtain a different supplier number for each location at which they will furnish equipment. The National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefit Administrators (GBA), reviews DMEPOS suppliers through site visits at enrollment, and 3 years later for reenrollment, to determine if they meet the Medicare standards. Generally, no site visits occur outside of the 3-year cycle. However, NSC may conduct out-of-cycle site visits if it receives notification that a supplier may be in violation of one or more Medicare standards. Out-of-cycle site visits have detected suppliers not meeting the standards. For example, in April and May of 2005, Palmetto GBA's Supplier Audit and Compliance Unit conducted out-of-cycle site visits of 40 DMEPOS suppliers in Miami, resulting in the revocation of 27 supplier numbers, 68 percent of the suppliers visited.

There are planned changes for DMEPOS supplier enrollment in the Medicare program. Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Medicare program to develop and implement quality standards for DMEPOS suppliers. In August 2006, CMS issued a final rule requiring DMEPOS suppliers to go through an accreditation process. This process will utilize approved quality standards that DMEPOS suppliers must meet to participate in and bill the Medicare program. Until these changes are fully implemented, NSC will continue with its enrollment

responsibilities, which include conducting site visits and reenrolling DMEPOS suppliers.

In a 2001 report, the Office of Inspector General (OIG) recommended that CMS conduct random site visits of DMEPOS suppliers. In response to our recommendations, CMS stated that it would increase site visits to suppliers who did not pass inspection. However, CMS did not directly address whether it would conduct random site visits of the larger DMEPOS supplier population. In a September 2005 report, the Government Accountability Office recommended that CMS establish an annual minimum of out-of-cycle site visits of DMEPOS suppliers. CMS has agreed to conduct these site visits as resources permit.

For our evaluation, we conducted out-of-cycle site visits of 169 DMEPOS suppliers from October 24 to November 4, 2005, to determine if they met the Medicare requirements of maintaining a physical facility and were open to conduct business. We chose these requirements because they directly impact the ease of beneficiary access to DMEPOS services. We determined compliance with these Medicare requirements through physical site observations and attempts to gain access to the facilities.

FINDINGS

Of 169 DMEPOS suppliers, 10 did not exist at their business address, yet they billed Medicare almost \$393,000 in the 2 months after we had determined that they were absent. Pursuant to 42 CFR § 424.57(c)(7), DMEPOS suppliers that bill Medicare must maintain a physical facility. At the time of our site visits, 10 suppliers did not exist at the business address listed on their enrollment application. We confirmed with NSC that we had conducted our site visits at the correct business addresses. In one instance, there was a law office at the DMEPOS business address. One of the attorneys informed us that he had been there for about 1 year, and that he was unaware of a DMEPOS supplier at that location. The 10 absent suppliers should have been located in 6 of the 27 counties where we conducted our site visits, and represented 13 percent (1 of 8) to 40 percent (2 of 5) of the total number of suppliers that we visited in each of those counties. Because these suppliers were not randomly selected, our results are not representative of the entire six counties where the absent suppliers should have been located.

The 10 absent DMEPOS suppliers collectively billed Medicare \$392,720 for services rendered from the day of our site visits through the end of

CY 2005. Of the \$392,720 in submitted claims, the suppliers had received a total of \$196,842 in reimbursements as of December 31, 2005.

From our site visits, we cannot determine whether the absent suppliers were submitting claims that should not have been paid by Medicare, or were submitting legitimate claims from another location. However, suppliers are required to have a different billing number for each of their locations, and the 10 suppliers were not at the locations associated with the Medicare billing numbers used to receive reimbursement in the 2 months after our site visits.

Of 169 DMEPOS suppliers, 6 were closed during posted business hours at the time of our site visits.

Pursuant to 42 CFR § 424.57(c)(8), DMEPOS suppliers that bill Medicare must be accessible to beneficiaries and to CMS. Six DMEPOS suppliers existed at the business address on their enrollment application, but were closed during their posted hours of operation at the time of our single site visit. For example, the proprietor of a business adjacent to one DMEPOS establishment informed us that the DMEPOS staff were absent for months at a time. One of the six closed suppliers was in one of the same counties where we could not locate the suppliers previously described. The six closed suppliers collectively submitted \$101,833 in Medicare claims, and had been reimbursed \$51,948 of this amount as of December 31, 2005. These claims were for services rendered from the day of our site visits through the end of CY 2005.

CONCLUSION

We conducted primarily observational, out-of-cycle site visits of DMEPOS suppliers to determine if they were in compliance with selected Medicare requirements. We found that as many as 40 percent (2 of 5) of the establishments visited in one county did not physically exist at their business address, yet they continued to receive Medicare reimbursements. These results are not representative of the entire county because the suppliers that we visited were not randomly selected.

While this study did not uncover supplier noncompliance with Medicare requirements in all areas visited, our findings suggest that out-of-cycle site visits of targeted DMEPOS suppliers may be warranted in other areas of the country. By helping to ensure the legitimacy of DMEPOS suppliers, out-of-cycle site visits may help to prevent fraud, waste, and abuse in the Medicare program. CMS may want to consider the

findings of our study as they determine how and to what extent out-of-cycle site visits of DMEPOS suppliers will occur.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with the basic findings of this report. CMS agreed that out-of-cycle site visits can identify suppliers who are no longer in business or do not meet basic supplier standards. CMS also noted that there can be added value from using an abbreviated protocol. However, CMS is concerned that using an abbreviated site visit protocol would not be adequate to appropriately revoke supplier numbers and ensure revocation decisions are upheld upon appeal. CMS also stated that it is in the process of taking several aggressive actions, such as requiring DMEPOS suppliers to go through an accreditation process.

OIG is encouraged that CMS is in the process of taking additional steps to ensure that suppliers meet the required Medicare standards. Regarding CMS's concern that abbreviated site visits could hamper the process to appropriately revoke supplier numbers, this study was designed to determine if suppliers were meeting selected enrollment standards. We continue to believe that the findings of this review provide an accurate picture of how DMEPOS suppliers were doing business on the days we visited them. CMS may want to consider our findings as they determine how and to what extent out-of-cycle site visits of DMEPOS suppliers will occur.

▶ T A B L E O F C O N T E N T S

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS 5

 Ten DMEPOS businesses were not physically present 5

 Six DMEPOS businesses were closed during posted hours 6

CONCLUSION 7

 Agency Comments and Office of Inspector General Response 7

ENDNOTES 9

APPENDIX 11

 A: Medicare Standards 11

 B: Agency Comments 15

ACKNOWLEDGMENTS 17

OBJECTIVE

To determine if selected Medicare durable medical equipment, prosthetics, orthotics, and supply (DMEPOS) suppliers physically existed at their listed addresses and were open to conduct business.

BACKGROUND

Durable Medical Equipment, Prosthetics, and Orthotics Supplies

According to the Centers for Medicare & Medicaid Services (CMS), Medicare expenditures for DMEPOS were approximately \$10 billion in calendar year (CY) 2005.¹ DMEPOS includes devices such as power wheelchairs, oxygen equipment, diabetic equipment, canes, braces, and artificial limbs.²

DMEPOS Supplier Enrollment

DMEPOS suppliers provide equipment to Medicare beneficiaries and submit claims to the Federal Government for reimbursement. To obtain these billing privileges, suppliers must enroll in the Medicare program and apply for a supplier number from CMS. At the time our review was conducted, Medicare DMEPOS suppliers were required to meet 21 standards in order to obtain a supplier number, pursuant to 42 CFR § 424.57(c). (See Appendix A for the Medicare standards.)³ Suppliers must obtain a different number for each location where they will furnish equipment.

To verify that Medicare DMEPOS applicants meet the required standards, CMS contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefit Administrators (GBA), to review applications and to conduct site visits for supplier enrollment.

Every 3 years, DMEPOS suppliers must reenroll with NSC to maintain their Medicare billing privileges. During the reenrollment process, NSC conducts and oversees site visits of DMEPOS suppliers to confirm their continued compliance with the Medicare standards. Generally, no site visits occur outside of the 3-year cycle. However, NSC may initiate out-of-cycle site visits if it receives notification from sources such as beneficiaries or Palmetto GBA's Benefit Integrity Unit that a supplier may be in violation of one or more Medicare standards. NSC may also conduct out-of-cycle site visits when notified by Palmetto GBA's Supplier Audit and Compliance Unit (SACU) about unusual supplier billing activity. Out-of-cycle site visits have detected suppliers not

meeting the Medicare standards. For example, in April and May 2005 Palmetto GBA's SACU conducted unannounced, out-of-cycle site visits of 40 DMEPOS suppliers in Miami. These site visits resulted in the revocation of 27 supplier numbers, 68 percent of the suppliers visited.⁴

CMS Activities Relating to Medicare DMEPOS Supplier Standards

There are planned changes for DMEPOS supplier enrollment in the Medicare program. Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Medicare program to develop and implement quality standards for DMEPOS suppliers.⁵ Pursuant to a final rule published by CMS, all suppliers are required to meet quality standards included as part of the accreditation process to participate in and bill the Medicare program.⁶ According to the final rule, CMS will phase in the accreditation process of DMEPOS suppliers.⁷ Until these changes are fully implemented, NSC will continue with its enrollment responsibilities, which include conducting site visits and reenrolling DME providers.

Related Work

The Office of Inspector General (OIG) has issued two reports on DMEPOS supplier compliance with Medicare standards. First, a 1997 report included recommendations for CMS to conduct site visits at the physical locations of DMEPOS supplier applicants.⁸ Subsequently, site visits became part of the DMEPOS supplier enrollment process. Second, a 2001 report recommended that CMS and NSC institute random, unannounced site visits of DMEPOS businesses at times other than initial enrollment and reenrollment.⁹ In response to our recommendations, CMS stated that it would increase site visits to suppliers who did not pass inspection. However, CMS did not directly address whether it would conduct random, unannounced site visits of the larger DMEPOS supplier population.

In a September 2005 study, the Government Accountability Office (GAO) determined that CMS should improve the DMEPOS supplier enrollment process and its oversight of NSC in verifying DMEPOS supplier compliance with the Medicare standards.¹⁰ In addition, GAO recommended that CMS establish an annual minimum of out-of-cycle site visits of DMEPOS suppliers. CMS has agreed to conduct these site visits as resources permit.

METHODOLOGY

The Medicare standards set forth in 42 CFR § 424.57(c) often contain multiple requirements within each standard. For our evaluation, we selected two requirements from two Medicare standards.¹¹ We conducted out-of-cycle site visits of a purposive sample of DMEPOS suppliers to determine if they met these two requirements. We first determined if suppliers physically existed at the business address on their enrollment application. We next determined if they were open to conduct business. We conducted our site visits from October 24 to November 4, 2005, using DMEPOS business addresses on file with NSC. We confirmed that these addresses were current as of the date of our site visits. We visited DMEPOS suppliers only once, unless we arrived outside of their posted hours of operation. We did not return to sites that were closed during posted business hours. We determined if the DMEPOS suppliers were in compliance with the selected Medicare requirements by observing the external appearance of, and attempts to gain access to, the facilities.

Site Selection

To select DMEPOS suppliers for our site visits, we started from a list of 116,740 suppliers eligible to receive Medicare reimbursement on file with NSC as of August 2006. From this list, we excluded suppliers associated with large chains (25 stores or more, such as Rite-Aid or CVS), self-reported physicians' and dentists' offices, hospitals, pharmacies, nursing homes, and skilled nursing facilities. We further excluded suppliers under OIG investigation at the time we conducted our study. From the remaining suppliers, we chose sites that had undergone an NSC site visit 16 to 20 months prior to August 15, 2005. This timeframe was selected so that our site visits would be out of cycle with the 3-year NSC schedule. This process left us with 7,747 suppliers.

Next, we used the data mining software Clementine® to further analyze the 7,747 suppliers remaining from our initial exclusions. We chose sites associated with supplier numbers used to bill Medicare at least once in CY 2004, and performed cluster analysis on the suppliers based upon CY 2004 county-level supplier billing and enrollment data. In addition, we also used CY 2004 supplier-level billing and enrollment data. The suppliers were selected based on high billing amounts and, in some cases, unusual billing patterns (e.g., billing in only one quarter). Clementine® also identified suppliers with an unusually rapid increase in the number of beneficiaries served. This process identified

I N T R O D U C T I O N

2,312 suppliers in 80 counties. Based on CMS data, all of the suppliers in these areas had claims activity in the month of September 2005. We checked our selected suppliers against OIG's exclusion list to confirm that none had been excluded from the Medicare program.

From the listing of 2,312 suppliers, we chose some of the leading suppliers based on high billing amounts and unusual billing patterns. We were unable to select suppliers at the top of this list because they were located in Florida and the area was recovering from a hurricane at the time we conducted this study. Our final selection consisted of 169 DMEPOS suppliers in 27 counties in 10 States. Because these 169 suppliers were not randomly selected, the results of our site visits are not representative of all DMEPOS suppliers, or of the 27 counties that we visited.

DMEPOS Claims Data

To determine the extent to which DMEPOS suppliers that did not meet the Medicare requirements billed for services rendered on or after our site visits, we requested CY 2005 claims data from the Statistical Analysis Durable Medical Equipment Regional Carrier. For each supplier, we grouped the services rendered from the day of our site visit through December 31, 2005. We then calculated the total amount of the submitted charges, and the total amount of the corresponding Medicare reimbursements for these services as of December 31, 2005.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

► FINDINGS

Of 169 DMEPOS suppliers, 10 did not exist at their business address, yet they billed Medicare almost \$393,000 in the 2 months after we had determined that they were absent

Pursuant to 42 CFR § 424.57(c)(7), DMEPOS suppliers that bill Medicare must maintain a physical facility. At the time of our site visits, 10 suppliers did not exist at

the business address listed on their enrollment application. In one instance, there was a law office at the DMEPOS business address. One of the attorneys informed us that he had been there for about 1 year, and that he was never aware of a DMEPOS business at that location.

The 10 absent suppliers should have been located in 6 of the 27 counties where we conducted our site visits. In one county, for example, we could not locate one of eight (13 percent) DMEPOS suppliers. In another county that we visited, two of five (40 percent) DMEPOS suppliers did not exist at their listed business address. We confirmed with NSC that we had conducted our site visits at the correct business addresses, and that none of the 10 absent suppliers had informed NSC that they had moved to a different location in the months preceding our visits. Because these suppliers were not randomly selected, our results are not representative of the entire six counties where the absent suppliers should have been located.

Collectively, all 10 absent DMEPOS suppliers billed Medicare \$392,720 for services rendered from the day of our site visits (October 24 – November 4) through the end of CY 2005. Of the \$392,720 in submitted claims, the businesses had received a total of \$196,842 in reimbursements as of December 31, 2005.

From our site visits, we cannot determine whether the absent suppliers were submitting claims that should not have been paid by Medicare, or were submitting legitimate claims from another location. However, as required in 42 CFR § 424.57(b)(2), DMEPOS suppliers must have a billing number for each location where they furnish supplies. Our site visits demonstrated that 10 suppliers were not at the locations associated with the Medicare billing numbers used to receive reimbursement in the 2 months after our site visits.

F I N D I N G S

Of 169 DMEPOS suppliers, 6 were closed during posted business hours at the time of our site visits

Pursuant to 42 CFR § 424.57(c)(8), DMEPOS suppliers that bill Medicare must be accessible to beneficiaries and to CMS.

Six DMEPOS suppliers existed at the business address on their enrollment application, but were closed during their posted hours of operation at the time of our single site visit. One of these businesses was in the same location as another business; the front of the room was dedicated to cell phone sales, while the DMEPOS supplier was located in the back of the room. The DMEPOS supplier was not staffed when we were onsite, and the cell phone vendor stated that the supplier “comes and goes.” In another example, the proprietor of a business adjacent to the DMEPOS establishment informed us that the DMEPOS staff were absent for months at a time. None of the six businesses were closed due to relocation, as confirmed by NSC. One of the six closed suppliers was in one of the same counties where we could not locate the suppliers previously described.

The six suppliers that were closed during their posted hours of operation collectively submitted \$101,833 in Medicare claims, and had been reimbursed \$51,948 of this amount as of December 31, 2005. These claims were for services rendered from the day of our site visits (October 24 – November 4) through the end of CY 2005.

► C O N C L U S I O N

Through out-of-cycle site visits, we found that 10 of 169 DMEPOS suppliers did not physically exist at their current business address on file with NSC. These suppliers collectively received almost \$197,000 in Medicare reimbursements in the 2 months after we had determined that they were absent. We also found that 6 of 169 DMEPOS suppliers physically existed at their business address, but were closed during their posted hours of operation at the time of our single site visit.

We conducted our DMEPOS supplier visits primarily through site observation, and found as many as 40 percent (2 of 5) of the establishments visited in one county did not physically exist at the business address on their supplier enrollment application. These results are not representative of the entire county because the suppliers we visited were not randomly selected. While this study did not uncover supplier noncompliance with Medicare requirements in all areas visited, our findings suggest that out-of-cycle site visits of targeted DMEPOS suppliers may be warranted in other areas of the country. By helping to ensure the legitimacy of DMEPOS suppliers, out-of-cycle site visits may help to prevent fraud, waste, and abuse in the Medicare program.

In August 2006, CMS issued a final rule requiring DMEPOS suppliers to go through an accreditation process. This process will utilize approved quality standards that DMEPOS suppliers must meet to participate in and bill the Medicare program. Until these changes are fully implemented, NSC will continue its enrollment responsibilities, which include conducting site visits. In the interim period before full implementation of the quality standards and accreditation, CMS may want to consider the findings of our study as they determine how and to what extent out-of-cycle site visits of DMEPOS suppliers will occur.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with the basic findings of this report. CMS agreed that out-of-cycle site visits can identify suppliers who are no longer in business or do not meet basic supplier standards. CMS also noted that there can be added value from using abbreviated protocols. However, CMS is concerned that using an abbreviated site visit protocol would not be adequate to appropriately revoke supplier numbers and ensure revocation decisions are upheld upon appeal.

CMS also stated that it is in the process of taking several aggressive actions, such as requiring DMEPOS suppliers to go through an

C O N C L U S I O N

accreditation process. CMS believes this process is another way for Medicare to ensure quality health care for beneficiaries while deterring potential fraud, waste, and abuse. In addition, CMS is drafting a proposed regulation addressing the posting of surety bonds by suppliers; enhancing the number of unannounced NSC site visits of suppliers; and developing a proposal to revise deactivation requirements for inactive Medicare billing numbers. See Appendix B for the full text of CMS's comments.

OIG is encouraged that CMS is in the process of taking additional steps to ensure that suppliers meet the required Medicare standards. Regarding CMS's concern that abbreviated site visits could hamper the process to appropriately revoke supplier numbers, this study was designed to determine if suppliers were meeting selected enrollment standards. We continue to believe that the findings of this review provide an accurate picture of how DMEPOS suppliers were doing business on the days we visited them. CMS may want to consider our findings as they determine how and to what extent out-of-cycle site visits of DMEPOS suppliers will occur.

► E N D N O T E S

¹ CMS estimate based on the Part B Extract and Statistical System, provided February 3, 2006.

² Sections 1861(n) and (s) of the Social Security Act.

³ CMS published a final rule on August 18, 2006, at 71 Federal Register 48354, entitled "Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2007; Certain Provisions Concerning Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Accreditation of DMEPOS Suppliers." In part, this final rule amends the durable medical equipment certification standards regulation at 42 CFR § 424.57(c) by adding four additional standards. See Appendix A for the standards in place at the time of evaluation, as well as the text of the new standards.

⁴ Intelligence Report: Issue 2, Palmetto GBA SACU, July 18, 2005.

⁵ Public Law 108-173, adding section 1834(a)(20) of the Social Security Act.

⁶ See 42 CFR § 424.57(c)(24) (as added by the Medicare program final rule at 71 Federal Register 48354 (August 18, 2006)). CMS has posted quality standards for suppliers of DMEPOS on its Web site at http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/downloads/CMS_DMEPOS_Quality_Standards_081406.pdf.

⁷ See the preamble to the Medicare program final rule at 71 Federal Register at 48392.

⁸ "Medical Equipment Suppliers: Assuring Legitimacy" (OEI-04-96-00240), December 1997. Available online at <http://oig.hhs.gov/oei/reports/oei-04-96-00240.pdf>. Accessed March 3, 2006.

⁹ “Medical Equipment Suppliers: Compliance with Medicare Standards” (OEI-04-99-00670), August 2001. Available online at <http://oig.hhs.gov/oei/reports/oei-04-99-00670.pdf>. Accessed March 3, 2006.

¹⁰ “More Effective Screening and Stronger Enrollment Standards Needed for Medical Equipment Suppliers” (GAO-05-656), September 22, 2005. Available online at <http://www.gao.gov/new.items/d05656.pdf>. Accessed March 3, 2006.

¹¹ We examined two requirements selected from two Medicare standards. Medicare standard seven requires DMEPOS businesses to maintain a physical facility [42 CFR § 424.57(c)(7)]. Medicare standard eight requires DMEPOS businesses to be accessible to beneficiaries and CMS [42 CFR § 424.57(c)(8)].

This appendix contains both the standards in place at the time of our review as well as standards recently added by CMS.

The following 21 Medicare standards, as outlined in 42 CFR 424.57(c), were in effect at the time of our review. Our study focused on two requirements selected from standards seven and eight. The supplier:

- (1) operates its business and furnishes Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements;
- (2) has not made, or caused to be made, any false statement or misrepresentation of a material fact on its application for billing privileges. (The supplier must provide complete and accurate information in response to questions on its application for billing privileges. The supplier must report to CMS any changes in information supplied on the application within 30 days of the change.);
- (3) must have the application for billing privileges signed by an individual whose signature binds a supplier;
- (4) fills orders, fabricates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal Government Executive Branch procurement or nonprocurement program or activity;
- (5) advises beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental durable medical equipment, as defined in section 414.220(a) of this subchapter. (The supplier must provide, upon request, documentation that it has provided beneficiaries with this information, in the form of copies of letters, logs, or signed notices.);
- (6) honors all warranties expressed and implied under applicable State law. A supplier must not charge the beneficiary or the Medicare program for the repair or replacement of Medicare covered items or for services covered under warranty. This standard applies to all

purchased and rented items, including capped rental items, as described in section 414.229 of this subchapter. The supplier must provide, upon request, documentation that it has provided beneficiaries with information about Medicare covered items covered under warranty, in the form of copies of letters, logs, or signed notices:

(7) maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location;

(8) permits CMS, or its agents to conduct onsite inspections to ascertain supplier compliance with the requirements of this section. The supplier location must be accessible during reasonable business hours to beneficiaries and to CMS, and must maintain a visible sign and posted hours of operation;

(9) maintains a primary business telephone listed under the name of the business locally or toll-free for beneficiaries. The supplier must furnish information to beneficiaries at the time of delivery of items on how the beneficiary can contact the supplier by telephone. The exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine may not be used as the primary business telephone for purposes of this regulation;

(10) has a comprehensive liability insurance policy in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations. Failure to maintain required insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed;

(11) must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(12) must be responsible for the delivery of Medicare-covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively);

(13) must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented. A supplier must refer beneficiaries with Medicare questions to the appropriate carrier. A supplier must maintain documentation of contacts with beneficiaries regarding complaints or questions;

(14) must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries. The item must function as required and intended after being repaired or replaced;

(15) must accept returns from beneficiaries of substandard (less than full quality for the particular item or unsuitable items, inappropriate for the beneficiary at the time it was fitted and rented or sold);

(16) must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item;

(17) must comply with the disclosure provisions in section 420.206 of this subchapter;

(18) must not convey or reassign a supplier number;

(19) must have a complaint resolution protocol to address beneficiary complaints that relate to supplier standards in paragraph (c) of this section and keep written complaints, related correspondence and any notes of actions taken in response to written and oral complaints. Failure to maintain such information may be considered evidence that supplier standards have not been met. (This information must be kept at its physical facility and made available to CMS, upon request.);

(20) must maintain the following information on all written and oral beneficiary complaints, including telephone complaints, it receives:

(i) the name, address, telephone number, and health insurance claim number of the beneficiary,

(ii) a summary of the complaint, the date it was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint, and

(iii) if an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(21) provides to CMS, upon request, any information required by the Medicare statute and implementing regulations.

The additional standards recently added by CMS, see endnote 3, are:

(22) All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

(23) All DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened. The accreditation organization may accredit the new supplier location for three months after it is operational without requiring a new site visit.

(24) All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare. An accredited supplier may be denied enrollment or their enrollment may be revoked, if CMS determines that they are not in compliance with the DMEPOS quality standards.

(25) All DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products.

▶ APPENDIX B : AGENCY COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

2007 FEB 20 PM 2:47

OFFICE OF INSPECTOR
GENERAL

Administrator
Washington, DC 20201

DATE: FEB 16 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medical Equipment Suppliers: Compliance with Medicare Enrollment Requirements" (OEI-04-05-00380)

Thank you for the opportunity to review the OIG's draft report entitled "Medical Equipment Suppliers: Compliance with Medicare Enrollment Requirements." In this report, the OIG evaluated whether selected durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) providers met the Medicare requirements for Medicare enrollment including maintaining a physical location. We appreciate the OIG recognizing the actions the Centers for Medicare & Medicaid Services (CMS) has taken to improve the Medicare enrollment process.

The CMS has reviewed this report, and we concur with the basic findings of the report. We agree that out-of-cycle site visits can result in identifying suppliers that are no longer in business or do not meet basic supplier standards and that there can be added value from utilizing an abbreviated protocol and quickly applying that protocol to a large number of suppliers in a short period of time. However, based on more recent experience, CMS is concerned that not utilizing site visit protocols established by the National Supplier Clearinghouse (NSC) could hamper the NSC's ability to appropriately revoke supplier numbers and ensure that the findings are upheld upon appeal. When the OIG locates or identifies such suppliers, they should immediately notify CMS so we can take the appropriate administrative action including the possible revocation of the supplier's Medicare billing number.

Finally, as the OIG is aware, CMS is in the process of taking several more aggressive actions in this area. For example:

1) Accreditation and quality standards- In August 2006, CMS published the final rule that requires DMEPOS suppliers to go through an accreditation process. The accreditation

Page 2 - Daniel R. Levinson

process will ensure that DMEPOS suppliers meet approved quality standards prior to enrolling in the Medicare program. This is yet another way for Medicare to ensure quality health care for our Medicare beneficiaries while deterring potential fraud, waste, and abuse.

2) Security bonds- CMS is in the process of drafting a proposed regulation addressing the posting of surety bonds by DMEPOS suppliers. This proposed regulation is scheduled to go out for public comment later this year.

3) Conducting more unannounced site visits of suppliers - CMS believes that the NSC should conduct more frequent and unannounced onsite visits. As such, CMS is currently revisiting the NSC's contractual requirements to enhance the number of unscheduled site visits required by the NSC.

4) Additional regulation requirements - CMS is currently developing a provider enrollment regulation that will propose revised deactivation requirements for inactive Medicare billing numbers of DMEPOS suppliers. This proposed regulation would give CMS more authority to deactivate numbers that have been inactive for a prolonged period of time.

We thank the OIG for the time and effort spent on this report.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Ann O'Connor, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office. Other principal Office of Evaluation and Inspections staff who contributed include:

Stacey Bloomer, *Co-Team Leader*

Mina Zadeh, *Co-Team Leader*

Mary-Elizabeth Harmon, *Co-Lead Analyst*

Sharon Koehler, *Co-Lead Analyst*

Mark Biagioni

Michelle Canady

Peggy Daniel

Tricia Davis

Kevin Farber

David Graf

Trevor Johnson

Scott Manley

Gerius Patterson

Rob Rutland- Brown

Barbara Tedesco

Additional analysts conducting site visits:

Rosemary Borck

Emmanuel Diacosavvas

Paul Gottlober

Camille Harper

Deborah Harvey

Michael Henry

Scott Hutchison

Jennifer Jones

Nancy Molyneaux

Linda Moscoe

Emily Multari

Kenneth Price

Mark Stiglitz

Clark Thomas

Steven Zerebecki