

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SOUTH FLORIDA SUPPLIERS'
COMPLIANCE WITH MEDICARE
STANDARDS: RESULTS FROM
UNANNOUNCED VISITS**



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OBJECTIVE

To conduct unannounced site visits of suppliers of Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in three South Florida counties (Miami-Dade, Broward, and Palm Beach) to determine their compliance with selected Medicare supplier standards.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) reported that payments for DMEPOS reached \$10 billion in fiscal year 2005. DMEPOS are covered under Medicare Part B and include items such as hospital beds, wheelchairs, respirators, walkers, and artificial limbs. DMEPOS suppliers must enroll in the Medicare program to sell or rent medical equipment and supplies to Medicare beneficiaries and to submit claims for Medicare reimbursement. At the time of our review, DMEPOS suppliers had to comply with 21 Medicare DMEPOS supplier standards to enroll in the Medicare program.

CMS contracts with the National Supplier Clearinghouse (NSC) to manage the enrollment of suppliers in the Medicare program. According to NSC supplier enrollment data, Miami-Dade County has the highest concentration of suppliers per Medicare beneficiary of any county in the nation. Broward and Palm Beach Counties also have high concentrations of suppliers. As a result of allegations in Miami-Dade and Broward Counties, NSC reported that, during the last two quarters of 2005, Florida led the nation for allegations of supplier noncompliance with Medicare standards. We undertook a review of the suppliers in three South Florida counties to assess their compliance with Medicare supplier standards.

We focused on three supplier standards that could be verified quickly through direct observation and desk review. These three standards include five specific requirements, which state that suppliers must: (1) maintain a physical facility, (2) be accessible (open and staffed) during business hours, (3) have a visible sign, (4) have hours of operation posted, and (5) maintain a primary business telephone listed under the name of the business. We conducted unannounced site visits in late 2006 to determine whether 1,581 DMEPOS suppliers in Miami-Dade, Broward, and Palm Beach Counties were in compliance with these 5 requirements.

FINDINGS

Thirty-one percent of suppliers in three South Florida counties did not maintain a physical facility or were not open and staffed during unannounced site visits. A total of 491 of 1,581 suppliers (31 percent) failed to maintain a physical facility or were not open and staffed during our unannounced site visits. Suppliers located in Miami-Dade County represented 64 percent of the suppliers we visited, but accounted for 80 percent of suppliers that did not maintain physical facilities or were not accessible during business hours.

Six percent of the suppliers we visited (98 of 1,581) did not maintain physical facilities. Instead of finding operational facilities, site reviewers found vacant facilities or facilities in which another type of business was operating.

An additional 25 percent of suppliers (393 of 1,581) were not accessible during reasonable business hours. Of these suppliers, 385 were closed during unannounced site visits on a minimum of 2 weekdays during reasonable or posted business hours. Eight suppliers were open but not staffed during a minimum of two unannounced site visits. These suppliers' doors were unlocked, but site reviewers saw no one in the facilities.

Another 14 percent of suppliers were open and staffed but did not meet at least one of three additional requirements for the standards we reviewed. Fourteen percent of suppliers (216 of 1,581) were open and staffed but did not meet at least 1 of the 3 remaining requirements we reviewed (having posted hours of operation, a visible sign, and a listed telephone number). Two hundred and six of these suppliers did not comply with 1 of these requirements and 10 suppliers did not comply with 2 or more of these requirements.

The remaining 55 percent of suppliers we visited met all of the 5 requirements included in our review.

RECOMMENDATION

Based on unannounced site visits to 1,581 Medicare DMEPOS suppliers in 3 counties in South Florida, we identified 491 suppliers (31 percent) that did not maintain physical facilities or were not accessible during reasonable business hours. We referred these suppliers to CMS so that it could consider potential revocation of the suppliers' Medicare billing numbers. Another 216 suppliers (14 percent) were open and staffed but

failed to meet at least 1 of the other 3 requirements included in our review.

Because nearly half of the suppliers we visited were not in compliance with the Medicare supplier standards we reviewed, our findings warrant further attention by CMS to protect the integrity of the Medicare DMEPOS benefit. Therefore, we recommend that CMS:

Strengthen the Medicare DMEPOS Supplier Enrollment Process and Ensure That Suppliers Meet Medicare Supplier Standards

Options to implement this recommendation could include:

- conducting more unannounced site visits to suppliers;
- implementing an enhanced review of all new enrollment applications by DMEPOS suppliers in South Florida;
- prioritizing processing reenrollment applications for current suppliers over processing new supplier applications;
- performing more rigorous background checks of applicants;
- assessing the fraud risk of suppliers and targeting monitoring and enforcement on high-risk suppliers;
- increasing prepayment review of DMEPOS claims;
- requiring all DMEPOS suppliers to post a surety bond;
- implementing a competitive bidding acquisition program for DMEPOS within high-vulnerability areas; if a competitive bidding program is implemented in these areas, the number of suppliers should be limited to those that demonstrate compliance with Medicare standards and that can provide the best value to the Medicare program and its beneficiaries;
- requiring suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years;
- strengthening the Medicare supplier standards by establishing a minimum number of hours of operation required for each supplier and establishing minimum inventory requirements for product and service types provided by a supplier; and
- deactivating the Medicare billing numbers of DMEPOS suppliers that have been inactive for a 90-day period.

AGENCY COMMENTS

CMS agreed with or will consider the options we recommended for strengthening the Medicare DMEPOS supplier enrollment process and ensuring that suppliers meet Medicare supplier standards. CMS noted that it is taking several steps to strengthen DMEPOS supplier standards. Some of these steps include requiring suppliers to become accredited, drafting a proposed regulation requiring suppliers to post surety bonds, revisiting NSC contract requirements to increase unannounced supplier site visits, and developing a proposal to revise deactivation requirements for inactive Medicare billing numbers. CMS stated that it appreciated working collaboratively with NSC and the Office of Inspector General (OIG) to conduct unannounced site visits in South Florida to determine compliance with Medicare supplier enrollment standards. CMS noted that the data collection protocol used for the South Florida supplier site visits was valuable, but provided less information than the NSC-established site visit protocol to support supplier number revocation decisions when suppliers submit appeals.

OFFICE OF INSPECTOR GENERAL RESPONSE

Previous work conducted by OIG has demonstrated that the Medicare DMEPOS benefit is highly vulnerable to fraud and abuse. These vulnerabilities can only be reduced by ensuring that Medicare does business with legitimate DMEPOS suppliers.

The findings of this review detail the business practices of more than 1,500 DMEPOS suppliers that were the subject of our review during visits to suppliers. We found that 45 percent of the suppliers we visited did not meet at least one of the five requirements that we reviewed, raising substantial concerns as to whether DMEPOS suppliers in South Florida are in compliance with the most basic of supplier standards.

As CMS states in its comments, we worked closely with CMS and NSC staff in developing the protocol for this study. This joint effort allowed for unannounced site visits to a large population of DMEPOS suppliers during a several week period. Visiting a large number of suppliers without forewarning in a short period of time was crucial to ensuring that suppliers were not alerted to our efforts.

Given the overwhelming evidence of noncompliance with supplier standards in South Florida, it is essential that our recommendations be promptly implemented to ensure the integrity of the Medicare program and to protect beneficiaries from potentially unscrupulous suppliers.

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OBJECTIVE

To conduct unannounced site visits of suppliers of Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in three South Florida counties (Miami-Dade, Broward, and Palm Beach) to determine their compliance with selected Medicare supplier standards.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) reported that Medicare payments for DMEPOS reached \$10 billion in fiscal year 2005. DMEPOS are covered under Medicare Part B and include items such as hospital beds, wheelchairs, respirators, walkers, and artificial limbs.¹ Medicare pays for DMEPOS that are necessary and reasonable for the treatment of a beneficiary's illness or injury, or to improve the functioning of a malformed body member. Medicare only covers medical equipment when it is ordered for a beneficiary by a physician or in some cases a nonphysician practitioner.

Medicare Enrollment of DMEPOS Suppliers

CMS contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefits Administrators, to manage the enrollment of suppliers. Suppliers must complete applications and comply with 21 Medicare DMEPOS supplier standards to enroll in the program.² CMS requires DMEPOS suppliers to comply with these supplier standards to ensure that only qualified suppliers are enrolled in the Medicare program. A supplier must report to CMS any changes in the information provided in the application (including change of address) within 30 days of the change.

If DMEPOS suppliers operate businesses at multiple physical locations, they are required to apply for a different Medicare billing number for each location.

¹ Social Security Act, §§ 1832, 1861.

² 42 CFR § 424.57(c). This citation refers to 25 supplier standards because 4 additional supplier standards were added by Federal Register notice dated August 18, 2006. The additional supplier standards relate to accreditation of suppliers and are provided in Appendix A. However, CMS has not set a deadline for DMEPOS suppliers to become accredited in order to retain/obtain a billing number. At the time of this review, suppliers needed to comply with only 21 standards to enroll in the Medicare program.

Standards. Federal regulations state that DMEPOS suppliers must meet the Medicare DMEPOS supplier standards to receive payment for a Medicare-covered item. If a supplier fails to comply with all standards, CMS may revoke the supplier's billing privileges (42 CFR § 424.57(d)). Appendix A contains a complete list of the Medicare standards.

Application. DMEPOS applicants must complete the Medicare enrollment application (Form CMS-855S) to be considered for enrollment. Before the application can be completed, however, new applicants must first obtain their National Provider Identifier (NPI), a unique identifier for health care providers that is assigned by the National Plan and Provider Enumeration System. Only after obtaining this NPI can applicants submit Form CMS-855S and supporting documents to NSC.³

Site visit. NSC must conduct a site visit to verify that a DMEPOS supplier applicant complies with the 21 Medicare supplier standards before approving an applicant and assigning a Medicare billing number.⁴ NSC or its contractor conducts unannounced site visits while the application is being processed.⁵ During these site visits, inspectors complete a questionnaire based on the standards. In addition to this questionnaire, site inspectors review files, request copies of required licenses, and document the supplier's inventory. Generally, if the supplier is not in compliance, NSC denies the application. However, if the deficiency is very minor, NSC educates the provider about the required change(s) rather than denying the application. After the initial enrollment site visit, suppliers are generally not visited by NSC inspectors until they are due for reenrollment every 3 years.

³ Supporting documents include, but are not limited to, copies of Federal, State, and/or local professional and business licenses, certifications, and/or registrations; liability insurance policies; written confirmation from IRS confirming Tax Identification Number; completed Authorization Agreement for Electronic Funds Transfer (Form CMS-588); and NPI notification.

⁴ Available online at: <http://www.palmettogba.com/palmetto/providers.nsf/44197232fa85168985257196006939dd/85256d580043e75485256fe20049923e?OpenDocument>. Accessed on October 19, 2006.

⁵ In South Florida, two inspectors from the NSC Supplier Audit and Compliance Unit conduct all the site visits. The processing time for initial enrollment of a DMEPOS supplier is approximately 60 days.

Reenrollment. DMEPOS suppliers are required to reenroll in the Medicare program every 3 years to continue receiving Medicare reimbursement (42 CFR § 424.57 (e)). Prior to their reenrollment date, suppliers receive a reenrollment package from NSC. Suppliers have 35 days from the date on the reenrollment letter to submit the completed CMS-855S and required documentation. A one-time extension can be requested by suppliers; however, suppliers failing to reenroll within the given timeframe are subject to deactivation of their Medicare billing number. NSC conducts an unannounced reenrollment site visit to ensure that a supplier continues to meet Medicare standards. Generally, if the supplier is not in compliance during the reenrollment visit, NSC issues a revocation notice. However, if the deficiency is very minor, NSC educates the provider about the required change(s) rather than issuing a revocation notice.

Appeals Process. When NSC denies or revokes a supplier's billing number, the supplier has two options to contest the determination: the supplier may submit a corrective action plan (CAP) or request a hearing. CMS and NSC negotiate the terms of the CAP with the supplier to ensure that the supplier complies with current supplier standards. If CMS and NSC are satisfied that issues of noncompliance have been resolved, the supplier's billing number may be reissued or reinstated. If CMS and NSC uphold the denial or revocation, the supplier may request a formal hearing before a Hearing Officer. This hearing can be conducted by telephone or in person. The next level of appeal is review of the case by an Administrative Law Judge.⁶

Vulnerabilities in the Current Medicare Enrollment Process in South Florida

According to NSC supplier enrollment data, Miami-Dade County has the highest concentration of suppliers per Medicare beneficiary of any county in the nation. Broward and Palm Beach Counties also have high concentrations of suppliers. As a result of allegations in Miami-Dade and Broward Counties, NSC reported that, during the last two quarters of 2005, Florida led the nation for allegations of supplier noncompliance with Medicare standards.

⁶ 42 CFR § 405.874; also available online at: <http://www.palmettogba.com/palmetto/providers.nsf/ViewTemplate+for+Docs?ReadForm&Providers/National+Supplier+Clearinghouse/Supplier+Enrollment/Appeals+Process>. Accessed on January 30, 2006.

Once a DMEPOS supplier has received an enrollment or reenrollment site visit, the supplier generally is not visited again outside the 3-year cycle. Though an unannounced, out-of-cycle site visit may occur if NSC becomes aware that a supplier may be in violation of one or more Medicare standards, typically DMEPOS suppliers are only visited at the end of their 3-year reenrollment period.

Out-of-cycle site visits have proven to be effective in detecting noncompliant suppliers. According to NSC, in the first quarter of 2006 it initiated a project to conduct out-of-cycle visits to approximately 500 DMEPOS suppliers in Miami-Dade, Broward, and Palm Beach Counties. As a result of this project, NSC revoked the Medicare billing numbers for 286 of these suppliers. Many of these suppliers' facilities were found to be vacant or occupied by some other business. This suggests that DMEPOS suppliers may take advantage of the standard site visit cycle by establishing businesses that are not maintained or staffed after NSC conducts the initial or reenrollment site visit.

Related Studies

A September 2005 Government Accountability Office (GAO) report (GAO-05-656) examined the procedures NSC uses to ensure that DMEPOS suppliers are legitimate businesses and are qualified to bill Medicare. GAO found that the screening procedures used by NSC, including on-site visits and checking State licensure, were insufficient to prevent illegitimate businesses from enrolling in the Medicare program. GAO estimated that NSC did not conduct 605 required on-site visits to suppliers in Florida, Illinois, Louisiana, and Texas. GAO made several recommendations, including establishing a minimum number of out-of-cycle, on-site inspections that NSC must perform each year as part of its contract. CMS generally concurred with the report's findings and stated that, beginning in fiscal year 2006, the requirement to perform out-of-cycle, on-site visits would be added to NSC's contractual duties.

In 1997, OIG issued the report "Medical Equipment Suppliers: Assuring Legitimacy" (OEI-04-96-00240). In this study, OIG examined Medicare supplier enrollment practices in 12 large metropolitan areas in 5 States, including Florida. Based on unannounced site visits, the study concluded that the enrollment process was unreliable for detecting unethical and improper practices of suppliers, particularly because supplier enrollment at that time did not involve on-site verification of supplier application data. One of the options OIG

recommended for ensuring the integrity of Medicare suppliers was for CMS to conduct on-site visits at applicants' physical locations. CMS concurred, but stated that limited resources allowed on-site visits to be conducted only in high-risk areas.

In 2001, OIG issued a follow-up report (OEI-04-99-00670) that assessed how well DMEPOS suppliers were meeting the Medicare standards. OIG found that the expansion of the CMS site inspection program improved supplier compliance with the Medicare standards. OIG made several recommendations to increase the compliance rates further, such as instituting random, unannounced site visits. CMS concurred with the recommendations.

METHODOLOGY

Scope of Review

We focused on three supplier standards that could be verified quickly through direct observation and desk review. These three standards (7, 8, and 9 in Appendix A) include five specific requirements:

- The supplier must maintain a physical facility (Standard 7).
- The facility must be accessible during business hours (Standard 8).
- The facility must have a visible sign (Standard 8).
- The supplier's hours of operation must be posted (Standard 8).
- The supplier must maintain a primary business telephone listed under the name of the business (Standard 9).

Our review focused on 1,581 suppliers in the South Florida area, specifically in Miami-Dade, Broward, and Palm Beach Counties. We identified all active DMEPOS suppliers in these counties using NSC enrollment data as of October 16, 2006. NSC enrollment data are updated each day as additions and changes are received from suppliers. From this list, we selected 10 primary specialty supplier types for inclusion in our review. Appendix B lists the primary specialty types. We excluded large chain suppliers (25 stores or more) from our review. We also excluded suppliers under investigation by OIG and suppliers that had, or were in the process of having, their Medicare billing numbers revoked by NSC. This resulted in a total of 1,581 suppliers for our review. The number of suppliers located in each county is presented in Appendix C.

Data Collection and Analysis

We conducted unannounced site visits to all 1,581 suppliers to determine whether suppliers were in compliance with the 4 requirements related to Standards 7 and 8. We recorded all observations using a standardized protocol. OIG staff, along with CMS and its contractor staff, conducted all site visits in late 2006.

Working with CMS, we developed parameters to define supplier compliance with the requirements to maintain a physical facility and be accessible to beneficiaries during business hours:

- We determined that a supplier did not maintain a physical facility if the supplier did not exist at the business address on file with NSC.
- We determined that a supplier was not accessible during business hours if the supplier was closed (i.e., the door was locked) or not staffed during site visits that occurred on two different weekdays (Monday through Friday). The first visit was conducted during reasonable business hours (9 a.m. to 5 p.m.) and the second visit was conducted during the supplier's posted business hours or during reasonable business hours (9 a.m. to 5 p.m.) if no business hours were posted.
- We also determined that a supplier was not accessible during business hours if the supplier (1) was closed (i.e., the door was locked) during the first site visit; (2) had posted a sign indicating that the supplier was "out on delivery" or "out to lunch" during the second site visit; and (3) was closed, not staffed, or had posted the same sign during a third site visit. The second and third visits were conducted during the supplier's posted business hours or during reasonable business hours (9 a.m. to 5 p.m.) if no business hours were posted.

We aggregated site visit results to determine the number of suppliers that had visible signs and hours of operation posted. We also reviewed and categorized site reviewers' observations about the physical facilities.

In addition to site visits, we conducted Internet searches to determine whether each supplier had a listed telephone number as specified in Standard 9. The searches included WhitePages.com, YellowPages.com, and SuperPages.com. We used the supplier's

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business name or alias (i.e., an alternate name the supplier uses to conduct business) to conduct the Internet searches.

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

Thirty-one percent of suppliers in three South Florida counties did not maintain a physical facility or were not open and staffed during unannounced site visits

A total of 491 of 1,581 DMEPOS suppliers (31 percent) failed to maintain a physical facility or were not open and staffed during our unannounced site visits to

suppliers' locations in 3 South Florida counties. These suppliers did not maintain appropriate physical facilities or their facilities were not accessible to beneficiaries during reasonable or posted business hours on at least two visits. As of November 30, 2006, the 491 suppliers billed Medicare for almost \$237 million and Medicare allowed over \$97 million for services provided between January 1 and November 30, 2006.

Of the 491 suppliers, 394 were located in Miami-Dade County, 59 were located in Broward County, and 38 were located in Palm Beach County. Suppliers located in Miami-Dade County represented 64 percent of the suppliers we visited, but accounted for 80 percent of suppliers that did not maintain physical facilities or were not accessible during business hours. Appendix C provides the number of suppliers visited in each county.

“Medical supply company—other” was the primary business specialty listed in NSC enrollment data for the majority of suppliers that did not maintain physical facilities or were not accessible during reasonable business hours (413 of 491). Suppliers with this primary specialty accounted for 53 percent of all South Florida suppliers in our review, but accounted for 84 percent of suppliers that did not maintain physical facilities or were not open and staffed during business hours. The remaining specialty types for suppliers are provided in Appendix B.

Six percent of suppliers (98 of 1,581) did not maintain physical facilities

Medicare requires all medical equipment suppliers to maintain “a physical facility on an appropriate site.” However, 98 of the suppliers we visited did not maintain physical facilities. Instead of finding operational facilities, site reviewers found vacant facilities or facilities in which another type of business was operating.

Twenty-five percent of suppliers (393 of 1,581) were not accessible during reasonable business hours

One-quarter of the 1,581 medical equipment suppliers we visited were not accessible during reasonable or posted business hours. When business hours were not posted, we considered reasonable business hours to be between 9 a.m. and 5 p.m. on weekdays.

F I N D I N G S

Of the 393 suppliers, 385 were closed during site visits on a minimum of two weekdays during reasonable or posted business hours. Eight suppliers were open but not staffed during a minimum of two site visits. These suppliers' doors were unlocked, but site reviewers saw no one in the facilities.

Site reviewers visited some locations housing multiple suppliers that were not open and staffed during posted or reasonable business hours. At one building, 15 suppliers were not open and staffed. On the same street, another building housed nine suppliers that were not open and staffed. Other locations often had two to six suppliers that were not open and staffed.

Some of these 393 suppliers also failed to meet 1 or more of 3 additional requirements. Site visits revealed that 41 of the 393 suppliers did not meet the requirement that suppliers' hours of operation be posted. Based on signs at their facilities, all suppliers with posted business hours were open an average of 35 hours per week. However, those found to be closed or open and not staffed posted business hours that averaged only 26 hours per week. Ten of these 393 suppliers also failed to meet the requirement that visible signs be posted at their facilities. Finally, Internet searches revealed that 14 of the 393 suppliers did not have listed telephone numbers.

Another 14 percent of suppliers were open and staffed but did not meet at least one of three additional requirements for the standards we reviewed

Fourteen percent of suppliers (216 of 1,581) were open and staffed but did not meet at least 1 of the 3 remaining requirements we reviewed (having posted hours of operation, a visible sign, and a listed telephone number). Two hundred and six of these suppliers did not comply with 1 of these requirements and 10 did not comply with 2 or more of these requirements.

Of the 216 suppliers that were open and staffed but failed to meet 1 or more of three additional requirements in our review, 204 suppliers did not have posted hours of operation. Thirteen suppliers did not meet the requirement of having a visible sign, and 10 suppliers did not have listed telephone numbers.

The remaining 55 percent of suppliers we visited (874 of 1,581) met all of the 5 requirements included in our review.

Based on unannounced site visits to 1,581 Medicare DMEPOS suppliers in 3 counties in South Florida, we identified 491 suppliers (31 percent) that did not maintain physical facilities or were not accessible during reasonable business hours. We referred these suppliers to CMS so that it could consider potential revocation of the suppliers' Medicare billing numbers.

An additional 14 percent of suppliers, while maintaining facilities that were open and staffed, did not meet at least 1 additional requirement from the Medicare standards that we reviewed.

Because nearly half of the suppliers we visited were not in compliance with the Medicare supplier standards we reviewed, our findings warrant further attention by CMS to protect the integrity of the Medicare DMEPOS benefit. Therefore, we recommend that CMS:

Strengthen the Medicare DMEPOS Supplier Enrollment Process and Ensure That Suppliers Meet Medicare Supplier Standards

Options to implement this recommendation could include:

- conducting more unannounced site visits to suppliers;
- implementing an enhanced review of all new enrollment applications by DMEPOS suppliers in South Florida;
- prioritizing processing reenrollment applications for current suppliers over processing new supplier applications;
- performing more rigorous background checks of applicants;
- assessing the fraud risk of suppliers and targeting monitoring and enforcement on high-risk suppliers;
- increasing prepayment review of DMEPOS claims;
- requiring all DMEPOS suppliers to post a surety bond;
- implementing a competitive bidding acquisition program for DMEPOS within high-vulnerability areas; if a competitive bidding program is implemented in these areas, the number of suppliers should be limited to those that demonstrate compliance with Medicare standards and that can provide the best value to the Medicare program and its beneficiaries;

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- requiring suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years;
- strengthening the Medicare supplier standards by establishing a minimum number of hours of operation required for each supplier and establishing minimum inventory requirements for product and service types provided by a supplier; and
- deactivating the Medicare billing numbers of DMEPOS suppliers that have been inactive for a 90-day period.

AGENCY COMMENTS

CMS agreed with or will consider the options we recommended for strengthening the Medicare DMEPOS supplier enrollment process and ensuring that suppliers meet Medicare supplier standards. Specifically, CMS is revisiting the NSC's contract requirements to increase the number of unannounced supplier site visits; considering targeted background checks of supplier applicants; incorporating targeted monitoring and enforcement for high-risk suppliers into future contract solicitations; drafting a proposed regulation requiring suppliers to post surety bonds; requiring suppliers to become accredited as meeting DMEPOS quality standards; considering proposing more general minimum inventory and business hours requirements in a future rulemaking document; and developing a proposal to revise deactivation requirements for inactive Medicare billing numbers. CMS has already begun conducting enhanced reviews of new supplier applicants and prioritizing the processing of reenrollment applications over new supplier applications in South Florida and other high vulnerability areas.

CMS stated that it appreciated working collaboratively with NSC and the Office of Inspector General (OIG) to conduct unannounced site visits in South Florida to determine compliance with Medicare supplier enrollment standards. CMS believes that projects such as the one conducted in South Florida are both worthwhile and cost-effective, and states that the results of the project show there can be added value from quickly applying an abbreviated protocol to a large number of suppliers in a short period of time. CMS further noted that it believes the data collection protocol used for the South Florida supplier site visits was valuable, but provided less information than the NSC-established site visit protocol to support supplier number revocation decisions when

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suppliers submit appeals. The full text of CMS's comments is provided in Appendix D.

OFFICE OF INSPECTOR GENERAL RESPONSE

Previous work conducted by OIG has demonstrated that the Medicare DMEPOS benefit is highly vulnerable to fraud and abuse. These vulnerabilities can only be reduced by ensuring that Medicare does business with legitimate DMEPOS suppliers.

The findings of this review detail the business practices of more than 1,500 DMEPOS suppliers that were the subject of our review during visits to suppliers. We found that 45 percent of the suppliers we visited did not meet at least one of the five requirements that we reviewed, raising substantial concerns as to whether DMEPOS suppliers in South Florida are in compliance with the most basic of supplier standards.

As CMS states in its comments, we worked closely with CMS and NSC staff in developing the protocol for this study. This joint effort allowed for unannounced site visits to a large population of DMEPOS suppliers during a several week period. Visiting a large number of suppliers without forewarning in a short period of time was crucial to ensuring that suppliers were not alerted to our efforts.

Given the overwhelming evidence of noncompliance with supplier standards in South Florida, it is essential that our recommendations be promptly implemented to ensure the integrity of the Medicare program and to protect beneficiaries from potentially unscrupulous suppliers.

► A P P E N D I X A

Medicare DMEPOS Supplier Standards

- (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 Sec. 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 Sec. 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 multisite supplier, records may be maintained at a centralized location;
- (8) Permits CMS, or its agents to conduct on-site 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;

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(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 Sec. 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.

(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 following items have recently been added as Medicare suppliers standards in the Federal Register notice dated August 18, 2006. However, CMS has not set a deadline for DMEPOS suppliers to become accredited in order to retain/obtain a billing number. Therefore, at the time of our review, suppliers needed to comply with only 21 standards to enroll in the Medicare program.

(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 3 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.

▶ A P P E N D I X B

Primary Specialty Types for Suppliers Visited in South Florida				
Primary specialty	Number of suppliers	Percentage of suppliers¹	Number of suppliers that did not maintain physical facilities or were not accessible	Percentage of suppliers that did not maintain physical facilities or were not accessible¹
Medical Supply Company—Other	836	52.88	413	84.11
Pharmacy	410	25.93	41	8.35
Podiatry	234	14.80	21	4.28
Medical Supply Company With Respiratory Therapist	34	2.15	8	1.63
Medical Supply Company—Certified Orthotist	18	1.14	4	0.81
Independently Practicing Occupational Therapist	17	1.08	1	0.20
Independently Practicing Physical Therapist	14	0.89	2	0.41
Medical Supply Company—Certified Prosthetist	9	0.57	0	0.00
Medical Supply Company—Certified Orthotist/ Prosthetist	6	0.38	0	0.00
Unknown Physician Specialty	3	0.19	1	0.20
Total	1,581	100	491	100

Source: Office of Inspector General analysis of suppliers' primary specialty types listed in October 16, 2006, National Supplier Clearinghouse enrollment data.

¹Percentages are rounded.

▶ A P P E N D I X C


County Locations for Suppliers Visited in South Florida				
County	Number of suppliers	Percentage of suppliers¹	Number of suppliers that did not maintain physical facilities or were not accessible	Percentage of suppliers that did not maintain physical facilities or were not accessible¹
Miami-Dade	1,013	64.07	394	80.24
Broward	311	19.67	59	12.02
Palm Beach	257	16.26	38	7.74
Total	1,581	100	491	100

Source: Office of Inspector General analysis of suppliers' addresses listed in October 16, 2006, National Supplier Clearinghouse enrollment data.

¹Percentages are rounded.

▶ A P P E N D I X D

Agency Comments


 DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

RECEIVED
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, Jr.
Acting Administrator 

SUBJECT: Office of Inspector General (OIG) Draft Report: "South Florida Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits" (OEI-03-07-00150)

Thank you for the opportunity to review the subject Office of Inspector General (OIG) draft audit report. We appreciate the OIG's collaborative efforts in working with the Centers for Medicare & Medicaid Services (CMS) and its contractor, the National Supplier Clearinghouse (NSC), to conduct unannounced site visits in South Florida to determine compliance with Medicare supplier enrollment standards. These types of projects are both worthwhile and extremely cost-effective.

As part of this project, CMS and the OIG mutually agreed to modify the normal protocol the NSC uses when evaluating suppliers for possible revocation. CMS viewed this project as an opportunity to see the results of a widespread effort which would test the effectiveness of using an abbreviated protocol. The results of the project showed 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, this approach did highlight vulnerabilities in the abbreviated protocol, specifically having less information available which could support the revocation recommendation during the hearings and appeals process. CMS believes that utilizing NSC-established site-visit protocols on future projects would strengthen the NSC's ability to appropriately revoke supplier numbers and ensure that the findings are upheld upon appeal.

It is in this context that we address the recommendation and specific options in the draft report.

OIG Recommendation

The CMS should strengthen the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier enrollment process and ensure that suppliers meet Medicare supplier standards. Options to implement this recommendation could include:

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- 1) Conducting more unannounced site visits of suppliers;
- 2) Implementing an enhanced review of all new enrollment applications by DMEPOS suppliers in South Florida;
- 3) Prioritizing processing reenrollment applications for current suppliers over processing new supplier applications;
- 4) Performing more rigorous background checks of supplier applicants;
- 5) Assessing the fraud risk of suppliers and targeting monitoring and enforcement on high risk suppliers;
- 6) Increasing pre-payment review of DMEPOS claims;
- 7) Requiring all DMEPOS suppliers to post a surety bond;
- 8) Implementing a competitive bidding acquisition program for DMEPOS within high vulnerability areas. If a competitive bidding program is implemented, the number of suppliers should be limited to those that gave demonstrated compliance with Medicare standards and that can provide the best value to the Medicare program and its beneficiaries;
- 9) Requiring suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years;
- 10) Strengthening the Medicare supplier standards by establishing a minimum number of hours of operation required for each supplier and establishing minimum inventory requirements for product and service types provided by a supplier; and
- 11) Deactivating the Medicare billing numbers of DMEPOS suppliers that have been inactive for a significant period of time.

CMS Response

- 1) Conducting more unannounced site visits of suppliers

The 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.

- 2) Implementing an enhanced review of all new enrollment applications by DMEPOS suppliers in South Florida

The CMS agrees with this recommendation and has already begun enhanced review of new DMEPOS enrollment applications in South Florida and other high vulnerability areas of the country.

- 3) Prioritizing processing reenrollment applications for current suppliers over processing new supplier applications

The CMS has already begun implementing this recommendation in high vulnerability areas of the country.

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- 4) Performing more rigorous background checks of supplier applicants

Due to the potentially high costs associated with nationwide implementation of this recommendation, CMS is considering targeted background checks.

- 5) Assessing the fraud risk of suppliers and targeting monitoring and enforcement on high risk suppliers

The CMS concurs with this recommendation and is in the process of incorporating this recommendation into future contract solicitations.

- 6) Increasing pre-payment review of DMEPOS claims

The CMS currently has procedures in place where DMEPOS claims are put on pre-payment review where payment aberrancies or evidence of a high likelihood of fraud exist. In coordination with its Program Safeguard Contractors, CMS will continue to pursue using pre-payment review as an effective tool for fraud deterrence.

- 7) Requiring all DMEPOS suppliers to post a surety bond

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

- 8) Implementing a competitive bidding acquisition program for DMEPOS within high vulnerability areas. If a competitive bidding program is implemented, the number of suppliers should be limited to those that gave demonstrated compliance with Medicare standards and that can provide the best value to the Medicare program and its beneficiaries

The CMS published DMEPOS quality standards on the CMS Web site in August 2006. Suppliers must comply with these quality standards to participate in the competitive acquisition program. CMS has also approved 11 organizations that will accredit DMEPOS suppliers as meeting quality standards. These deemed accreditation organizations are in the process of accrediting those suppliers who may be in the initial group of Metropolitan Statistical Areas for the competitive acquisition program.

- 9) Requiring suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years

The CMS is considering implementing more frequent reenrollment requirements in high vulnerability areas. However, CMS does not believe that establishing a more frequent reenrollment process nationwide will necessarily ensure that DMEPOS suppliers are maintaining compliance with the 21 supplier standards. CMS feels that conducting more frequent onsite

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visits for high risk providers would yield an equal, if not higher, benefit. Additionally, the new CMS accreditation process will also help to ensure the validity of suppliers.

- 10) Strengthening the Medicare supplier standards by establishing a minimum number of hours of operation required for each supplier and establishing minimum inventory requirements for products and service types provided by a supplier

The CMS believes that determining minimum inventory amounts by product and service types is impractical as there are an extremely large number of products and services which can be furnished by DME suppliers. In addition, since DMEPOS suppliers also maintain inventory for other payers, including Medicaid and private health plans, the NSC may not be able to effectively monitor this proposed recommendation. CMS will consider proposing more general minimum inventory amounts and a minimum number of business hours in a future rulemaking document.

- 11) Deactivating the Medicare billing numbers of DMEPOS suppliers that have been inactive for a significant period of time

The NSC already adheres to deactivation provisions found in Federal regulations at 42 CFR 424.540 which provide for deactivation when a “provider or supplier does not submit any Medicare claims for 12 consecutive calendar months.” CMS concurs with this recommendation and is currently planning on proposing revised deactivation requirements in a forthcoming provider enrollment regulation later this year. This would give CMS more authority to deactivate numbers that have been inactive for a prolonged period of time.

The CMS thanks the OIG for their efforts on this report. We look forward to working together with you in the future as we continue to prevent fraud, waste, and abuse in the Medicare program.



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

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General.

Tanaz Dutia and Amy Sernyak served as the team leaders for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to this report include Jessica Demko, Diane Epstein, Cynthia Hansford, Maria Johnson, Conswelia McCourt, Emily Multari, Roman Strakovsky, and Stephanie Yeager; other regional and central office staff who contributed include Suzanne Bailey, Mark Biagioni, Diane Caves, Peggy Daniel, Jaime Durley, Deborah Harvey, Michael Henry, Scott Hutchison, Scott Manley, Gerius Patterson, Steven Zerebecki, and Mina Zadeh.

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