

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**LOS ANGELES COUNTY 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 Los Angeles County to (1) determine their compliance with selected Medicare supplier standards and (2) identify their atypical characteristics.

BACKGROUND

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 submit claims for Medicare reimbursement. DMEPOS suppliers are required to comply with 5 conditions and 25 supplier standards to enroll in the Medicare program and receive payment for a Medicare-covered item. The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC) to manage the enrollment and reenrollment of suppliers in the Medicare program.

According to the Department of Health and Human Services, Los Angeles is a high-risk area for fraudulent activity involving DMEPOS suppliers. Supplier site inspections conducted by NSC underscore the risks in Los Angeles County. In 2006, NSC conducted 401 inspections in Los Angeles County and revoked the billing privileges of 95 suppliers.

In the 12 months beginning July 1, 2006, Medicare allowed approximately \$245 million for DMEPOS provided in Los Angeles County and \$8.6 billion nationwide.

We focused on four requirements with which compliance could be verified quickly through direct observation: suppliers must (1) maintain physical facilities, (2) be accessible during business hours, (3) have visible signs, and (4) post hours of operation. We conducted unannounced site visits of 905 suppliers in Los Angeles County in late 2007. In addition, we analyzed the suppliers' billing patterns.

FINDINGS

In Los Angeles County, 115 of 905 suppliers (13 percent) did not maintain physical facilities or were not open during unannounced site visits. Thirteen percent of the suppliers we visited (115 of 905) did not maintain physical facilities or were not open during our unannounced

site visits. Thirty suppliers did not maintain physical facilities, and 85 suppliers were not accessible during business hours. Medicare allowed \$21 million in the 12 months beginning July 1, 2006, for these suppliers' claims.

Another 79 suppliers (9 percent) were open but did not meet at least one of the two additional requirements for the standards we reviewed.

Seventy-eight suppliers did not post hours of operation, but were open during reasonable business hours (10 a.m. to 4 p.m.). Five suppliers did not post signs indicating a business name. Four suppliers did not meet either requirement.

An additional 124 suppliers (14 percent) met the requirements for the standards we reviewed, but their claims had in common an atypical characteristic. More than half of the Medicare beneficiaries for these 124 suppliers did not receive other Medicare services (such as an office visit) from the ordering physician within a 6-month period preceding the DMEPOS claim. Eighty-nine percent of these suppliers have the primary specialty "Medical Supply Company—Other."

RECOMMENDATION

Our findings in this report, along with past Office of Inspector General (OIG) work in Florida, demonstrate that noncompliant suppliers are enrolled in the Medicare program. We recognize that CMS recently has taken action to address vulnerabilities in the DMEPOS benefit, particularly in Florida and California, including initiating a 2-year DMEPOS demonstration project in November 2007. Although this demonstration project has potential to prevent fraud, permanent corrective action is warranted to prevent fraudulent providers from entering and participating in Medicare. Therefore, we recommend that CMS:

Strengthen the Medicare DMEPOS supplier enrollment process and ensure that suppliers meet Medicare supplier standards. OIG presented a number of options to CMS in its March 2007 report, "South Florida Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits" (OEI-03-07-00150). CMS has made progress toward implementing some of those options for strengthening the Medicare DMEPOS supplier enrollment process and compliance with supplier standards. We continue to recommend that CMS:

- conduct more unannounced site visits to suppliers, which could include full site inspections and abbreviated site inspections, to

supplement, not replace full site inspections and to determine whether suppliers still exist at the addresses on record;

- perform more rigorous background checks of applicants and currently enrolled high-risk suppliers (including business owners and managing employees);
- assess the fraud risk of suppliers and focus monitoring and enforcement on high-risk suppliers;
- increase prepayment review of DMEPOS claims, especially claims from new suppliers and suppliers deemed high risk;
- require suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years; and
- strengthen the Medicare supplier standards by establishing a minimum number of hours of operation and establishing minimum inventory requirements for product and service types.

In addition, we recommend that CMS:

- require all suppliers to pay a Medicare enrollment application fee to cover the costs of: (1) full site inspections or abbreviated site inspections to monitor suppliers' compliance with Medicare standards and (2) criminal background checks;
- require a supplier to pay an additional Medicare enrollment fee if, during a site visit (conducted during business hours), the supplier's facility is closed or inaccessible, necessitating an additional site visit; and
- seek legislative authority to impose temporary moratoriums, on an as-needed basis, on supplier enrollment in high-fraud areas.

In addition, we sent to CMS information about the suppliers we visited that did not meet one or more of the four requirements. Based on our findings and its own followup, CMS should take appropriate action.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS stated that it believes that it has already addressed the majority of the options we recommend in this report that also appear in "South Florida Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits" (OEI-03-07-00150). Specifically, CMS modified its

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scope of work with NSC to increase the frequency of unannounced site visits and to assess the fraud risk of suppliers in certain high fraud areas. CMS will consider increasing prepayment review of suppliers' claims and is in the process of conducting "targeted background checks on suppliers." CMS may consider establishing more frequent reenrollment requirements for suppliers. CMS is seeking public comment on a proposed rule that would establish a minimum number of hours of operation required for suppliers.

Regarding the new recommendations in this report, CMS stated that suppliers must pay a fee to the accrediting organization for an initial site visit and that "criminal background checks are conducted as required by State standards." We note that our new recommendations regarding site inspections and application fees pertain to NSC's actions to enforce compliance with Medicare supplier standards: the fees we suggest would be paid to the Federal Government. The accrediting organization and NSC are independent of one another and address different standards. We have modified our recommendation to clarify this point. Finally, CMS will consider seeking legislative authority to impose temporary moratoriums on supplier enrollment.

CMS did not indicate whether it concurred with our recommendation to establish minimum inventory requirements. We ask that, in its final management decision, CMS more clearly indicate whether it concurs with this recommendation and what steps, if any, it will take to implement it.

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BACKGROUND

Medicare Coverage of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Pursuant to Title XVIII of the Social Security Act, DMEPOS are covered under Medicare Part B and include such items as hospital beds, wheelchairs, respirators, walkers, artificial limbs, and wound care supplies.¹ Medicare pays for DMEPOS that are necessary and reasonable for the treatment of a beneficiary's illness or injury or to improve the function of a malformed body member. Medicare covers medical equipment only when it is ordered for a beneficiary by a physician or, in some cases, a nonphysician practitioner.

Medicare Enrollment of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Suppliers

The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefits Administrator (Palmetto GBA), to manage the enrollment of suppliers. Suppliers must enroll in Medicare to submit claims for reimbursement.² The enrollment process involves obtaining a National Provider Identifier (NPI), completing a Medicare enrollment application, and satisfying the Medicare DMEPOS conditions and supplier standards.

Supplier conditions and standards. Pursuant to 42 CFR § 424.57(b), DMEPOS suppliers must meet five conditions to be eligible to receive payment for a Medicare-covered item. (See Appendix A for a list of these conditions.) In addition to meeting these conditions, suppliers must meet and certify that they meet and will continue to meet the

¹ Social Security Act §§ 1832, 1834, and 1861.

² 42 CFR § 424.505.

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25 standards imposed pursuant to 42 CFR § 424.57(c).³ (See Appendix B for a list of the standards.) CMS can revoke suppliers' billing privileges if they fail to meet the conditions and standards.⁴

Application. New applicants must obtain their NPIs before they can complete an application.⁵ The NPI is a unique identifier for health care providers that is assigned by the National Plan and Provider Enumeration System. Suppliers also must submit supporting documentation with every application.⁶ A supplier must complete and submit the Medicare Enrollment Application when:

- enrolling in Medicare for the first time,
- reporting certain changes from the initial application,
- adding another business location,
- verifying the accuracy of information on an original application, or
- reenrolling or deactivating a billing number.⁷

Site visits. NSC can inspect a supplier's site to ascertain compliance with the conditions and standards⁸ and to verify enrollment information.⁹ After a supplier submits an enrollment application, NSC conducts an unannounced site visit to ensure that the supplier complies with the conditions and standards. Following the inspection, NSC notifies the supplier in writing, generally within 60 days, whether it has

³ Initially there were 21 supplier standards. Four additional supplier standards were added by a Federal Register notice dated April 10, 2007. The additional supplier standards relate to competitive bidding and supplier accreditation. However, applicable suppliers had until September and October 2007, respectively, to meet the competitive bidding and accreditation requirements.

⁴ 42 CFR § 424.57(d).

⁵ Centers for Medicare & Medicaid Services (CMS), "Medicare Enrollment for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers," May 2007. Available online at <http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DurableMedicalEquip.pdf>. Accessed November 5, 2007.

⁶ 42 CFR § 424.510.

⁷ Palmetto Government Benefits Administrator (Palmetto GBA), "Helpful Hints on Completing the 855S for an Additional Location," revised February 5, 2007. Available online at [http://www.palmettogba.com/palmetto/providers.nsf/Attachments/2343214C3D5F4CE68525734E0048000C/\\$FILE/Helpful+Hints+on+completing+the+855S++Additional+Locations.pdf](http://www.palmettogba.com/palmetto/providers.nsf/Attachments/2343214C3D5F4CE68525734E0048000C/$FILE/Helpful+Hints+on+completing+the+855S++Additional+Locations.pdf). Accessed November 5, 2007.

⁸ 42 CFR § 424.57(c)(8).

⁹ 42 CFR § 424.510(d)(8).

approved the application. To continue billing Medicare, the supplier must renew its application every 3 years.¹⁰ NSC then may conduct an additional site visit to confirm whether the supplier complies with the conditions and standards. (See Appendix C for more details on the site visit process.)

Vulnerabilities in the Site Inspection Process

Generally, once a DMEPOS supplier has had an enrollment or reenrollment site visit, NSC does not revisit the supplier for 3 years. NSC may conduct additional site visits if it suspects that a supplier is in violation of one or more Medicare standards. Recent Office of Inspector General (OIG) findings¹¹ suggest that suppliers can defraud Medicare by establishing businesses that are not maintained or staffed after NSC conducts the initial or reenrollment site visit.

Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Vulnerabilities in South Florida and Los Angeles County

This report is one of a series of recent OIG reports on vulnerabilities in the Medicare DMEPOS benefit, including the March 2007 report, “South Florida Suppliers’ Compliance With Medicare Standards: Results From Unannounced Visits” (OEI-03-07-00150). OIG reviewed suppliers in three South Florida counties (Miami-Dade, Broward, and Palm Beach) to assess their compliance with selected Medicare supplier standards. The review focused on three supplier standards with which compliance could be verified quickly through direct observation and desk review. OIG conducted 1,581 unannounced site visits and identified 491 suppliers (31 percent) that did not maintain physical facilities or were not accessible during reasonable business hours. OIG referred these suppliers to CMS to consider revoking their Medicare billing numbers.

Recent work by NSC indicates that DMEPOS suppliers in Los Angeles County may have characteristics similar to those of suppliers in South Florida. In 2006, NSC conducted 401 inspections in Los Angeles County and revoked the billing privileges of 95 suppliers.¹² From 2002

¹⁰ 42 CFR § 424.57 (e).

¹¹ Office of Inspector General (OIG), “Medical Equipment Suppliers: Compliance With Medicare Enrollment Requirements” (OEI-04-05-00380), March 2007.

¹² CMS, “Medicare Provider Enrollment Demonstration Involving Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies in High-Risk Areas, July 2, 2007.” Available online at <http://www.hhs.gov/news/facts/medicarefraud/index.html>. Accessed July 19, 2007.

through 2006, the number of DMEPOS suppliers, the amount of DMEPOS billing, and the number of revocations all increased in Los Angeles County.¹³ In the 12 months beginning July 1, 2006, Medicare allowed approximately \$245 million for DMEPOS provided in Los Angeles County and \$8.6 billion nationwide.¹⁴

Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Demonstration Project

On November 1, 2007, CMS began a 2-year demonstration project¹⁵ involving all DMEPOS suppliers located in Miami-Dade, Broward, and Palm Beach Counties in Florida and Los Angeles, Orange, Riverside, and San Bernardino Counties in California. CMS designed the project to improve its ability to detect and prevent fraud. In the first 3 months of the demonstration, NSC required all suppliers in these seven counties to submit new Medicare Enrollment Applications. If a supplier does not submit an application within 30 days, NSC will immediately revoke its billing privileges. For suppliers that submit new applications, NSC will conduct new site inspections. In addition, NSC will revoke suppliers' billing privileges if suppliers:

- fail to report changes in ownership or addresses within 30 days of the effective date of the change,
- are required by NSC to obtain accreditation and fail to do so within 90 days,
- have owners or managing employees who were convicted of felonies in the last 10 years, or
- no longer meet each requirement for enrollment.

Suppliers covered under the demonstration project will be subject to additional, enhanced review designed to detect fraud.

Related Office of Inspector General Studies

In 1997, OIG issued "Medical Equipment Suppliers: Assuring Legitimacy" (OEI-04-96-00240). OIG examined Medicare supplier enrollment practices in 12 large metropolitan areas in five States.

¹³ Ibid.

¹⁴ OIG analyses of Medicare National Claims History, 2007.

¹⁵ Palmetto GBA, "Medicare Provider Enrollment Demonstration Project," October 2007. Available online at [http://www.palmettogba.com/palmetto/providers.nsf/Attachments/85256D580043E75485257360004A7023/\\$FILE/NSC+News++October+2007.pdf](http://www.palmettogba.com/palmetto/providers.nsf/Attachments/85256D580043E75485257360004A7023/$FILE/NSC+News++October+2007.pdf). Accessed November 5, 2007.

Based on unannounced site visits, OIG found that the enrollment process—desk review and verification of applicants—was unreliable for detecting unethical and improper practices of suppliers, particularly because supplier enrollment at the time did not involve onsite verification of supplier application data. One of the options OIG recommended for ensuring the integrity of Medicare suppliers was for CMS to conduct onsite visits at applicants’ physical locations. CMS concurred but stated that limited resources allowed onsite visits to be conducted only in high-risk areas.

In August 2001, OIG issued a follow-up report entitled “Medical Equipment Suppliers: Compliance With Medicare Standards” (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.

In March 2007, OIG issued “Medical Equipment Suppliers: Compliance With Medicare Enrollment Requirements” (OEI-04-05-00380). OIG conducted unannounced site visits in 2005 and found that 10 of the 169 DMEPOS suppliers that were reviewed did not exist at their business addresses. However, these 10 suppliers billed Medicare almost \$393,000 in the 2 months after OIG had determined that they were nonexistent and received almost \$197,000 in reimbursements. The report concluded that out-of-cycle site visits may help to prevent fraud, waste, and abuse in the Medicare program.

METHODOLOGY

Scope of Review

We focused on two supplier standards with which compliance could be verified quickly through direct observation. These standards include four specific requirements:

- The supplier must maintain a physical facility (Standard 7).
- The facility must be accessible during reasonable business hours (Standard 8).
- The facility must have a visible sign (Standard 8).

- The supplier's hours of operation must be posted (Standard 8).

Sample

Our review focused on 905 suppliers in Los Angeles County. Using NSC enrollment data as of August 22, 2007, we identified all active DMEPOS suppliers in Los Angeles County. NSC enrollment data are updated each day as additions and changes are received from suppliers. From this list, we selected seven primary specialty supplier types for inclusion in our review. Appendix D lists the primary specialty supplier types. To be consistent with our 2006 review of South Florida DMEPOS suppliers, we excluded large chain suppliers (25 stores or more) from our review. We also excluded suppliers under investigation by OIG and suppliers whose Medicare billing numbers had been revoked by NSC.

Data Collection and Analysis

We conducted unannounced site visits to all 905 suppliers to determine whether suppliers complied with the four requirements related to Standards 7 and 8. We recorded all observations using a standardized protocol. OIG staff conducted all site visits in September and October 2007. We developed the following 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 it did not exist at the business address on file with NSC.
- We determined that a supplier was not accessible during business hours if it was closed during site visits that occurred on two different weekdays (Monday through Friday). We considered the facility closed if (1) the door was locked (and there was no doorbell) or (2) the door was locked and no one responded to the doorbell (if there was a doorbell). We conducted all visits during the suppliers' posted business hours. If a supplier did not post business hours, we conducted the visits during reasonable business hours (10 a.m. to 4 p.m., Monday through Friday).
- We also determined that a supplier was not accessible during business hours on multiple visits if it (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 or had posted the same sign during a third site visit.

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In total, we conducted more than 1,200 unannounced visits. We aggregated the site visit results to determine the number of suppliers that were not in compliance with the four requirements. We reviewed and categorized our direct observations of the physical facilities to provide more detailed information about the site visits and to compare and contrast the suppliers' observable features. During our site visits, we took photographs of selected suppliers.

In addition, we analyzed the Medicare claims patterns of the suppliers we visited and the national population of active and revoked suppliers. (See Table 1 on page 12.)¹⁶ Data for the suppliers' claims came from Medicare's National Claims History. Supplier enrollment information came from NSC's supplier enrollment files. We used SAS analytical software to analyze all data.

Limitations

We designed this review to collect data about DMEPOS suppliers while remaining undetected during unannounced site visits. Our review was limited to providing compliance data on two Medicare supplier standards that include four requirements. We did not conduct full compliance reviews that would address all 25 standards.

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.

¹⁶ For this analysis, we limited the population to suppliers that billed more than \$10,000 for DMEPOS in the 12 months beginning July 1, 2006.

► FINDINGS

In Los Angeles County, 115 of 905 suppliers (13 percent) did not maintain physical facilities or were not open during unannounced site visits

Thirteen percent of the suppliers we visited (115 of 905) did not maintain physical facilities or were not open during our unannounced site visits to their locations in Los Angeles County.

These suppliers did not maintain appropriate physical facilities, or their facilities were not open during posted or reasonable business hours on at least two visits. In the 12 months beginning July 1, 2006, Medicare allowed \$21 million for these suppliers' claims.¹⁷

"Medical Supply Company—Other" was the primary specialty supplier type listed in NSC enrollment data for the majority of suppliers that did not maintain physical facilities or were not accessible during posted or reasonable business hours (99 of 115). Suppliers with this primary specialty accounted for 45 percent of all Los Angeles County suppliers in our review but accounted for 86 percent of suppliers in this category. (See Appendix D for a breakout of all 115 suppliers by primary specialty supplier type.)

Three percent of suppliers (30 of 905) did not maintain physical facilities

Medicare requires all DMEPOS suppliers to maintain "a physical facility on an appropriate site."¹⁸ However, 30 of the suppliers we visited did not maintain physical facilities. Instead of finding operational facilities, we found vacant facilities or facilities in which other types of businesses were operating.

Twenty facilities were vacant. These facilities were vacant and closed for business. Although these suppliers have active enrollment files and most have recent paid Medicare claims, we found no operational businesses at the suppliers' locations. For all but 5 of these 20 suppliers, Medicare allowed claims in the 12 months beginning July 1, 2006. In total, Medicare allowed approximately \$3 million for these suppliers in the 12 months beginning July 1, 2006. For example, one supplier associated with a vacant facility was allowed \$301,687 in the 12 months beginning July 1, 2006. We observed the same two signs stating "out for delivery" and "return at 2:15 p.m." in the facility's window on two visits on different weekdays. The signs appeared to be permanent fixtures, and the facility was devoid of medical supplies or

¹⁷ At the time that we issued this report, the most recent Medicare claims data available to us covered the 12 months beginning July 1, 2006.

¹⁸ 42 CFR § 424.57(c).

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any evidence suggesting that it was an operational business. (See Photo 1 below.)

PHOTO 1
The supplier was actively enrolled in Medicare, but the facility was vacant.



Source: OIG unannounced site visits to DMEPOS facilities in Los Angeles County, September 2007.

Eight facilities did not appear to be DMEPOS facilities. Instead of finding medical equipment suppliers, we found other businesses operating at the addresses on record with NSC. In six instances, the businesses were an art gallery, a tutoring business, a trucking company, an insurance sales office, a vitamin supplement company, and physicians' offices. Two additional locations were private residences, with no business signs or posted business hours.

For the supplier whose facility is now an art gallery, Medicare allowed approximately \$5 million in the 12 months beginning July 1, 2006. Suppliers have 30 days from the date of an address change to inform NSC.¹⁹ However, at the time of our visits, the art gallery had been open at the supplier's address for about 5 months. Medicare allowed more than \$1 million during the first 3 months of this 5-month period.²⁰ The only other address listed in NSC files for this supplier is a post

¹⁹ 42 CFR § 424.57(c)(2).

²⁰ At the time we issued this report, we did not have access to the last 2 months of DMEPOS claims for the 5-month period.

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office box, which is shared by two other suppliers. These other two suppliers failed NSC site inspections and currently are not enrolled with NSC as active suppliers. For all three suppliers, the post office box is listed as the “pay to” address—the address to which Medicare sends reimbursement checks.

The addresses listed with NSC were not valid for two suppliers, and we could not confirm the suppliers’ existence. In both cases, the street addresses existed; however, the suite numbers associated with the suppliers did not. There was no sign indicating that the supplier had moved, or that the supplier occupied another suite in the building.

Nine percent of suppliers (85 of 905) were not open during business hours

Nine percent of the 905 DMEPOS suppliers were not open during posted or reasonable business hours. The average weekly hours of operation posted for these suppliers was 30 hours compared to 44 hours among the suppliers that were open during business hours.²¹ When business hours were not posted, we considered 10 a.m. to 4 p.m. on weekdays to be reasonable business hours and conducted our visits accordingly.

In the 12 months beginning July 1, 2006, Medicare allowed approximately \$11 million for these 85 suppliers’ claims. The median allowed per supplier was \$82,314. For example, Medicare allowed \$219,226 for one supplier we found inaccessible during its posted business hours. This supplier appeared to share space with a tax return preparation service and a notary public. We photographed the facility during its posted business hours. (See Photo 2 on the next page.) We visited another supplier three times during reasonable business hours, but the supplier changed its posted business hours prior to each of our visits and was closed during each visit. During each visit, we observed no DMEPOS visible through the facility’s windows. Medicare allowed \$152,485 for that supplier’s claims in the 12 months beginning July 1, 2006.

²¹ To calculate the average hours of operation, we included only the suppliers that posted hours of operation. Five of the eighty-five suppliers that were closed did not post hours of operation. Of the 790 suppliers that were open during business hours, 78 did not post hours of operation.

FINDINGS

PHOTO 2
The supplier was actively enrolled in Medicare but not accessible during its posted business hours on two unannounced visits.



Source: OIG unannounced site visits to DMEPOS facilities in Los Angeles County, September 2007. Supplier-identifying information was redacted.

Another 79 suppliers (9 percent) were open but did not meet at least one of the two additional requirements for the standards we reviewed

Nine percent of suppliers (79 of 905) were open but did not post hours of operation and/or did not post signs with their business names.

Seventy-eight suppliers did not post hours of operation but were open during reasonable business hours. Five suppliers did not post signs indicating a business name. Four suppliers did not meet either requirement.

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The remaining 79 percent of suppliers we visited (711 of 905) met all four of the requirements included in our review.²²

An additional 124 suppliers (14 percent) met the requirements for the standards we reviewed, but their claims had in common an atypical characteristic

Fourteen percent of the suppliers we visited met the four requirements, but more than half of the Medicare beneficiaries for these 124 suppliers did not receive other Medicare services (such as an office visit) from

the physicians who ordered the DMEPOS within the 6-month period preceding the DMEPOS claims²³ (see Table 1). Generally, physicians provide services prior to ordering medical equipment for their patients. However, Medicare does not require physicians to conduct face-to-face examinations of patients to write a prescription for any DMEPOS except power mobility devices.²⁴

TABLE 1
More than half of the beneficiaries for whom the suppliers billed did not receive other Medicare services (such as an office visit) from the physicians who ordered the DMEPOS.

DMEPOS Suppliers (Allowed more than \$10,000 in Medicare claims for DMEPOS)	Suppliers Whose Claims Had An Atypical Characteristic		
	Population	Number	Percentage
Los Angeles Review Population			
-Met the four requirements we reviewed	427	124	29%
-Did not meet one or more of the requirements we reviewed	119	63	53%
National Population			
-Actively billing suppliers	54,913	4,415	8%
-Revoked suppliers (July 1, 2006, to present)	919	619	67%

Source: OIG analysis of Medicare National Claims History, 2007.

²² The percentage of suppliers that met the requirement plus the percentage of suppliers that did not meet the requirements does not total 100 percent because of rounding.

²³ We reviewed Medicare claims data to determine that the beneficiaries did not see the ordering physician within a 6-month period preceding the DMEPOS claim. The total Los Angeles review population is 905 suppliers. One hundred and seven suppliers had no allowed DMEPOS claims in 12 months beginning July 1, 2006, and were excluded from this table. Two hundred and fifty-two suppliers were allowed less than \$10,000 in the same period and also were excluded from the table. Therefore, we analyzed 546 of the 905 suppliers in the Los Angeles review population.

²⁴ “Power mobility device means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home.” 42 CFR § 410.38(c)(2)(i).

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This characteristic is prevalent among noncompliant suppliers. Sixty-seven percent of suppliers nationally whose billing privileges were revoked by NSC had a majority of claims for beneficiaries who did not receive other Medicare services from the ordering physicians during the 6 months prior to the DMEPOS claim. Similarly, in this review, 53 percent of the suppliers that we found to be noncompliant with Medicare standards exhibited this characteristic. In contrast, only 8 percent of actively billing suppliers nationally exhibited this pattern.

One primary specialty supplier type stands out among suppliers that exhibited this characteristic. Eighty-nine percent of these suppliers (110 of 124) have the primary specialty “Medical Supply Company—Other.” Similarly, 86 percent of the suppliers that did not maintain physical facilities or were not open during unannounced site visits have the primary specialty “Medical Supply Company—Other.” However, this specialty accounts for only 45 percent of the Los Angeles County suppliers in our review.

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In total, 194 of the 905 suppliers (22 percent) that we visited did not meet one or more of the requirements for the Medicare DMEPOS standards we reviewed. These suppliers did not maintain physical facilities, were not accessible to beneficiaries during posted or reasonable business hours, and/or failed to post signs indicating a business name and/or hours of operation. An additional 124 suppliers (14 percent) met the requirements for the standards we reviewed but more than half of their Medicare beneficiaries did not receive other Medicare services (such as an office visit) from the physicians who ordered the DMEPOS within the 6-month period preceding their DMEPOS claims.

These findings show continued vulnerabilities in the Medicare DMEPOS benefit. In March 2007, OIG reported the results of our unannounced visits to 1,581 suppliers in South Florida. We identified 491 suppliers that did not maintain physical facilities or were not accessible during business hours. Our work in Florida and California demonstrates that noncompliant suppliers are enrolled in the Medicare program. Our work also demonstrates that abbreviated site visits may be an efficient use of limited resources to identify suppliers that do not meet the most basic of supplier standards—existing at the locations they report to CMS.

We recognize that CMS recently has taken action to address vulnerabilities in the DMEPOS benefit, particularly in Florida and California, including initiating a 2-year DMEPOS demonstration project in November 2007. Although this demonstration project has potential to prevent fraud, permanent corrective action is warranted to prevent fraudulent providers from entering and participating in Medicare. Therefore, we recommend that CMS:

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

OIG presented a number of options to CMS in its March 2007 report, “South Florida Suppliers’ Compliance With Medicare Standards: Results From Unannounced Visits” (OEI-03-07-00150). CMS has made progress toward implementing some of those options for strengthening the Medicare DMEPOS supplier enrollment process and compliance with supplier standards. We continue to recommend the following:

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- conduct more unannounced site visits to suppliers, which could include full site inspections and abbreviated site inspections, to supplement, not replace full site inspections and to determine whether suppliers still exist at the addresses on record;
- perform more rigorous background checks of applicants and currently enrolled high-risk suppliers (including business owners and managing employees);
- assess the fraud risk of suppliers and focus monitoring and enforcement on high-risk suppliers;
- increase prepayment review of DMEPOS claims, especially claims from new suppliers and suppliers deemed high risk;
- require suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years; and
- strengthen 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.

In addition, we recommend that CMS:

- require all suppliers to pay a Medicare enrollment application fee to cover the costs of: (1) full site inspections or abbreviated site inspections to monitor suppliers' compliance with Medicare standards and (2) criminal background checks;
- require a supplier to pay an additional Medicare enrollment fee if, during a site visit (conducted during business hours), the supplier's facility is closed or inaccessible, necessitating an additional site visit; and
- seek legislative authority to impose temporary moratoriums, on an as-needed basis, on supplier enrollment in high-fraud areas.

In addition, we sent to CMS information about the suppliers we visited that did not meet one or more of the four requirements. Based on our findings and its own followup, CMS should take appropriate action.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS stated that it believes that it has already addressed the majority of the options we recommend in this report that also appear in “South Florida Suppliers’ Compliance With Medicare Standards: Results From Unannounced Visits” (OEI-03-07-00150). Specifically, CMS modified its scope of work with NSC to increase the frequency of unannounced site visits and to assess the fraud risk of suppliers in certain high fraud areas. Once NSC applies fraud risk indicators to suppliers, CMS will consider increasing prepayment review of suppliers’ claims. CMS stated that it is in the process of conducting “targeted background checks on suppliers.” Depending on the outcome of the DMEPOS demonstration project, CMS may consider more frequent reenrollment requirements for suppliers. In addition, CMS is seeking public comment on a proposed rule that would establish a minimum number of hours of operation required for suppliers.

For the first two new recommendations—(1) to establish an application fee to cover the costs of site visits and rigorous background checks and (2) to require a supplier to pay an additional fee if, during a site visit (conducted during business hours), the supplier’s facility is closed or inaccessible, necessitating an additional site visit—CMS referred to the new accreditation process for DMEPOS suppliers. CMS stated that suppliers must pay a fee to the accrediting organization for an initial site visit and that “criminal background checks are conducted as required by State standards.” We note that our new recommendations regarding site inspections and application fees pertain to NSC’s actions to enforce compliance with Medicare supplier standards: the fees we suggest would be paid to the Federal Government. The accrediting organization and NSC are independent of one another and address different standards. We have modified our recommendation to clarify this point.

For the third new recommendation, CMS stated that it will consider seeking legislative authority to impose enrollment moratoriums, depending on the outcome of its enrollment demonstrations.

CMS did not indicate whether it concurred with our recommendation to establish minimum inventory requirements. We ask that, in its final management decision, CMS more clearly indicate whether it concurs with this recommendation and what steps, if any, it will take to

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implement it. The full text of CMS's comments is provided in Appendix E.

Conditions for Medicare Payments for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

The following conditions appear in 42 CFR § 424.57(b):

1. The supplier has submitted a completed application to CMS to furnish Medicare-covered items including required enrollment forms. (The supplier must enroll separate physical locations it uses to furnish Medicare-covered DMEPOS, with the exception of locations that it uses solely as warehouses or repair facilities.)
2. The item was furnished on or after the date CMS issued to the supplier a DMEPOS supplier number conveying billing privileges. (CMS issues only one supplier number for each location.) This requirement does not apply to items furnished incident to a physician's service.
3. CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished has not been revoked or excluded.
4. A supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs. (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician's license.)
5. The supplier has furnished to CMS all information or documentation required to process the claim.

Medicare DMEPOS Supplier Standards

The following standards appear in 42 CFR § 424.57(c):

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 § 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 § 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 § 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.
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.



A P P E N D I X ~ C

Supplier Site Visit Process

According to Palmetto Government Benefits Administrator (Palmetto GBA), supplier site inspections are unannounced and inspectors generally will attempt to conduct a second site visit if the supplier is inaccessible during the initial visit.

Unannounced Site Visits. The following appears on the Palmetto GBA Web site, in the supplier-guidance document, “Can I make an appointment for my site visit?”

Site visits are unannounced and will take place during your posted hours of operation. Supplier Standard #8 requires the location must be accessible during reasonable business hours. If a site inspector comes to your location outside of the posted hours of operation, the inspector will attempt a subsequent site visit during the posted hours.

If, during the second attempt, a site inspector reports the facility is not open for business or could not complete the visit during the posted hours of operation, a denial shall not be issued. In these cases, the applicant will receive a letter stating a site visit was unable to be conducted and informing the applicant to submit a new application at such a time when a site inspection can be completed. If the site visit could not be completed for an existing supplier, the supplier number may be revoked as appropriate.²⁵

Attempts To Complete a Site Visit. The following appears on the Palmetto GBA Web site, in the supplier-guidance document, “How many attempts are made to complete a visit?”

Generally, two attempts are made to complete a visit. However, if on the first attempt the inspector finds the facility is still under construction or other obvious indications the facility is not a true operating location, or there is no visible sign or office hours posted, the site inspector will not make a second attempt and the NSC will be notified the visit could not be completed.

²⁵ Available online at

<http://www.palmettogba.com/palmetto/providers.nsf/44197232fa85168985257196006939dd/85256d580043e75485256d5f00624eb1?OpenDocument>. Accessed November 6, 2007.

If an attempt is made outside of the posted hours of operation, the inspector may leave a notice and will make a second attempt during the posted hours of operation. However, if the business is still inaccessible during the second attempt, the site inspector will not make any further attempts.

The hours of operation indicate when a supplier is open and available. During these hours, a beneficiary, CMS or its agents should be able to visit the facility. If a supplier goes to lunch from 1:00 pm to 2:00 pm, then this needs to be posted along with the hours of operation. If your posted hours state you are open from 9:00 am to 5:00 pm, then the supplier should be available from 9:00 am to 5:00 pm.

An initial application will not be denied because of the NSC or its subcontractor's inability to conduct a site visit. In these cases, the applicant will receive a letter stating a site visit was unable to be conducted and to submit a new application at such time when a site visit can be completed.²⁶

²⁶ Available online at

<http://www.palmettogba.com/palmetto/providers.nsf/44197232fa85168985257196006939dd/85256d580043e7548525734800479abb?OpenDocument>. Accessed November 6, 2007.

▶ A P P E N D I X ~ D

Primary Specialty Supplier Types Visited in Los Angeles County

Primary specialty	Number Of Suppliers	Percentage Of Suppliers*	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 Accessible*
Pharmacy	452	49.9%	13	11.3%
Medical Supply Company—Other	405	44.8%	99	86.1%
Medical Supply Company With Respiratory Therapist	23	2.5%	1	0.9%
Medical Supply Company—Certified Orthotist/Prosthetist	11	1.2%	0	0.0%
Medical Supply Company—Certified Prosthetist	8	0.9%	1	0.9%
Medical Supply Company—Certified Orthotist	5	0.6%	1	0.9%
Medical Supply Company—Registered Pharmacist	1	0.1%	0	0.0%
Total	905	100.0%	115	100.1%**


Source: Office of Inspector General analysis of primary specialty types listed in August 22, 2007, National Supplier Clearinghouse enrollment data.

* Percentages are rounded.

** Column does not total 100 percent because of rounding.

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Agency Comments

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

Office of the Administrator
Washington, DC 20201

RECEIVED
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OFFICE OF INSPECTOR GENERAL

DATE: JAN 28 2008

TO: Daniel R. Levinson
Inspector General

FROM: Kerry Weems
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Los Angeles County Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits," (OEI-09-07-00550)

Thank you for the opportunity to review and respond to this OIG draft report. We appreciate the OIG's efforts to conduct unannounced site visits in Los Angeles County to determine compliance with Medicare supplier enrollment standards. Most of the recommendations contained in this report are similar to previous OIG reports on this issue in the South Florida area (OEI-03-07-00150), and the Centers for Medicare & Medicaid Services (CMS) believes it has already addressed the majority of these recommendations. However, this report allows us the opportunity to highlight the significant actions CMS has taken to reduce vulnerabilities in the Medicare supplier enrollment process.

OIG Recommendation

Strengthen the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Supplier Enrollment Process and Ensure that Suppliers Meet Medicare Supplier Standards. As part of this recommendation, the OIG presented 6 options for CMS to consider:

- OIG Option 1: Conducting more unannounced site visits of suppliers;

CMS Response: The CMS recently modified the National Supplier Clearinghouse's (NSC) current Scope of Work (SOW) in September, 2007 to increase the frequency of unscheduled site visits required by the NSC. The NSC has also significantly increased its staff to address this additional workload.
- OIG Option 2: Performing more rigorous background checks of supplier applicants;

CMS Response: We have started the process of conducting targeted background checks on suppliers (both applicants and currently enrolled suppliers) in certain high fraud areas.

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- **OIG Option 3: Assessing the fraud risk of suppliers and targeting monitoring and enforcement on high risk suppliers;**

CMS Response: The CMS has already modified the NSC’s SOW to incorporate the assessment of a supplier’s fraud risk targeting, monitoring and enforcement efforts in certain high fraud areas.

- **OIG Option 4: Increasing prepayment review of DMEPOS claims especially claims from new suppliers and suppliers deemed high risk;**

CMS Response: The CMS currently has procedures to put DMEPOS claims on prepayment review when payment aberrancies or evidence of a high risk exist. Once the NSC assigns the fraud risk indicators to suppliers, we will conduct the appropriate analysis to determine the necessity and feasibility of instructing the contractors to increase prepayment review of DMEPOS claims.

- **OIG Option 5: Require suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years;**

CMS Response: Depending on the outcome of CMS’ enrollment demonstrations, CMS will consider implementing more frequent reenrollment requirements in certain high fraud areas. In addition, CMS will require all newly enrolling DMEPOS suppliers (except large chain suppliers) to obtain and submit an accreditation approval on or after March 1, 2008, and that all DMEPOS suppliers obtain accreditation by September 30, 2009.

- **OIG Option 6: 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;**

CMS Response: On January 25, 2008, CMS published a proposed rule (CMS-6036-P) which seeks public comment regarding a minimum number of hours of operation.

OIG Recommendation

Require all suppliers to pay an application fee to cover the costs of site visits and criminal background checks. Require a supplier to pay an additional fee if, during a site visit (conducted during business hours), the supplier’s facility is closed or inaccessible, necessitating an additional site visit.

CMS Response

The CMS has recently announced a mandatory accreditation process for DMEPOS suppliers. In order to be accredited, a DMEPOS supplier must submit an application and pay a fee to the Accrediting Organization (AO) for the initial unannounced site visit. Additional unannounced site visits may occur at the discretion of the AO. Through onsite personnel reviews the AOs

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verify that the DMEPOS suppliers have conducted employee background checks, i.e. education, personnel qualifications, training, licensure and/or certification. The suppliers must conduct these background checks on an ongoing basis. Criminal background checks are conducted as required by State standards.

OIG Recommendation

Seek legislative authority to impose temporary moratoriums, on an as-needed basis, on supplier enrollment in high fraud areas.

CMS Response

Depending on the outcome of CMS' enrollment demonstrations, CMS will consider seeking legislative authority to impose temporary moratoriums on supplier enrollment in high fraud areas.

CMS thanks the OIG for their efforts on this report. We look forward to continuing to work with you in the future to strengthen our Medicare enrollment process and to identify and 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 Timothy S. Brady, Regional Inspector General for Evaluation and Inspections in the San Francisco regional office, and Deborah W. Harvey, Deputy Regional Inspector General.

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