

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**SOUTH FLORIDA DURABLE  
MEDICAL EQUIPMENT  
SUPPLIERS: RESULTS OF  
APPEALS**



Daniel R. Levinson  
Inspector General

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# *Office of Inspector General*

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## OBJECTIVES

1. To determine the number of South Florida durable medical equipment suppliers that were removed from the Medicare program (as a result of an Office of Inspector General (OIG)-led initiative) and later appealed and were reinstated by hearing officers.
2. To determine the types of evidence that hearing officers reviewed for the South Florida suppliers that were reinstated.
3. To determine the number of reinstated South Florida suppliers that were later removed from the Medicare program or indicted for fraud.

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## BACKGROUND

Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (hereinafter referred to as 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. The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC) to manage the enrollment of suppliers in the Medicare program.

Suppliers must comply with Medicare's supplier standards. If a supplier fails to comply with all supplier standards, CMS may deny or revoke the supplier's billing privileges. A supplier whose Medicare billing privileges have been denied or revoked may appeal the determination. A supplier's billing privileges can also be inactivated at any time for several reasons, such as failure to submit Medicare claims for four consecutive quarters.

A significant amount of supplier fraud and abuse has recently been identified in South Florida. The Department of Health and Human Services and the Department of Justice formed a Medicare Fraud Strike Force (Strike Force) comprised of Federal, State, and local investigators to combat fraud through the use of real-time analysis of Medicare billing data. Over a 3-month period in 2007, 56 individuals were charged in South Florida with fraudulently billing Medicare more than \$258 million. As of March 2008, the Strike Force had brought charges against 120 defendants, resulting in 101 convictions. According to CMS, as of April 2007, over three-quarters of all supplier revocations (734 of 938) nationwide during fiscal year 2007 occurred in Miami-Dade, Broward, and Palm Beach Counties.

## E X E C U T I V E   S U M M A R Y

In March 2007, OIG issued a report about South Florida suppliers. OIG staff, along with CMS and its contractor staff, conducted unannounced site visits to 1,581 suppliers located in Miami-Dade, Broward, and Palm Beach Counties. OIG found 491 suppliers that failed to maintain a physical facility or were not open and staffed during the unannounced site visits. OIG referred these 491 suppliers to CMS so that CMS could consider revocation. CMS revoked these suppliers' billing privileges.

For the suppliers that appealed their billing privileges revocations and received hearings, we reviewed the appeal files. We determined the types of evidence suppliers submitted to appeal the revocations of their billing privileges. We also reviewed CMS policies, procedures, and written responses to our questions regarding the supplier hearing process and hearing officer criteria.

NSC conducted a follow-up project to review suppliers that were reinstated as a result of appeals. We used NSC data as of March 2008 to identify the status of reinstated suppliers. We obtained information on indictments and convictions from our Office of Investigations as of April 2008.

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### FINDINGS

**Nearly half of the 491 revoked South Florida suppliers appealed and received hearings; hearing officers reinstated the billing privileges for 91 percent of these suppliers.** After our prior study, hearing officers conducted hearings for 243 of the 491 revoked South Florida suppliers. Billing privileges were reinstated for 91 percent of these suppliers (222 of 243).

**Because there are no criteria regarding the types of evidence necessary to reinstate supplier billing privileges, hearing officers reinstated billing privileges based on a variety of evidence.**

Although CMS has developed procedural guidelines for hearings, it has not provided hearing officers with criteria regarding the types of evidence revoked suppliers must submit to have their billing privileges reinstated. Therefore, hearing officers reviewed various types of evidence to reinstate the revoked South Florida suppliers' billing privileges. Examples of evidence that suppliers provided include photographs, affidavits, utility bills, and leases.

**Two-thirds of suppliers whose billing privileges were reinstated have subsequently had their privileges revoked or inactivated, and some individuals connected to reinstated suppliers have been indicted.** Half of suppliers whose billing privileges were reinstated (111 of 222) have subsequently had their privileges revoked. An additional 17 percent of suppliers (37 of 222) have had their billing privileges inactivated. As a result, two-thirds of suppliers whose billing privileges were reinstated by hearing officers (148 of 222) had their privileges revoked again or inactivated.

In addition, between April and September 2007, the U.S. Attorney's Office indicted 18 individuals connected to 15 of the 222 reinstated suppliers. As of April 2008, 10 of the 18 defendants had been convicted and were each ordered to pay between \$90,000 and \$11 million in restitution. These 10 defendants were also sentenced to jail terms ranging from 1 to 4 years.

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## RECOMMENDATION

To protect beneficiaries and the integrity of Medicare payments, CMS has developed standards that suppliers must meet to enroll in Medicare. CMS has also taken steps to ensure suppliers' compliance with these standards. For example, CMS has announced a 2-year demonstration project designed to identify noncompliant suppliers and detect potentially fraudulent supplier behavior. These efforts may result in CMS denying or revoking billing privileges for suppliers that do not meet all Medicare enrollment standards.

All suppliers whose billing privileges have been denied or revoked may appeal and request a hearing. However, there are no criteria for hearing officers regarding the types of evidence required to reinstate a supplier's billing privileges. Hearing officers generally accept all documentation submitted by suppliers as legitimate, unless they have reason to believe otherwise. Our findings suggest that a more critical review of the types of evidence submitted by suppliers is warranted to ensure that fraudulent suppliers are not reinstated.

Therefore, we recommend that CMS:

**Strengthen the appeal process by developing criteria regarding the types of evidence required for hearing officers to reinstate suppliers' billing privileges.**

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**AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In responding to our report, CMS stated that it has been taking aggressive steps to prevent fraud and abuse in the Medicare program. For example, CMS points out that all suppliers will need to become accredited by October 1, 2009, which CMS believes will ensure that only legitimate suppliers serve Medicare beneficiaries.

CMS agreed that it should consider establishing guidelines regarding the evaluation of evidence that a hearing officer will review. CMS believes that it would be useful for OIG to provide specific suggestions regarding appropriate criteria for hearing officers. However, CMS stated that any guidance provided should not impinge on a hearing officer's ability to make an independent determination or with a supplier's ability to submit any evidence that it believes will support the reversal of a revocation or denial decision.

We agree that CMS should develop criteria that maintain the independence of hearing officers and suppliers' ability to submit any evidence they wish to send. We suggest that CMS develop a list of evidence that it believes would support a decision to overturn various reasons for revocation and that such evidence should be germane to the reason for revocation. For example, if CMS revokes a supplier's billing privileges because staff was not present at the supplier's facility after multiple site visit attempts during reasonable business hours, the supplier should not be reinstated based on the submission of cell phone bills, leases, driver's licenses, or photographs. Instead, reinstatement should be based on evidence that the supplier met the Medicare standard requiring it to maintain a physical facility that is accessible to beneficiaries and CMS during reasonable business hours. CMS should also develop criteria that enable hearing officers to verify the legitimacy and credibility of documents submitted by suppliers as evidence during appeals.

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## OBJECTIVES

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2. To determine the types of evidence that hearing officers reviewed for the South Florida suppliers that were reinstated.
3. To determine the number of reinstated South Florida suppliers that were later removed from the Medicare program or indicted for fraud.

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## BACKGROUND

Medical equipment is covered under Medicare Part B and includes items such as hospital beds, wheelchairs, respirators, walkers, and artificial limbs.<sup>1</sup>

A supplier of durable medical equipment, prosthetics, orthotics, and supplies (hereinafter referred to as a supplier) is any entity or individual that sells or rents Part B-covered items to Medicare beneficiaries.<sup>2</sup> The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefits Administrators, to manage the enrollment of suppliers into the Medicare program.

### Supplier Enrollment Process

Suppliers must meet all supplier standards to receive payment for a Medicare-covered item.<sup>3</sup> Appendix A contains a complete list of the Medicare standards.

Supplier applicants must complete a Medicare enrollment application to be considered for enrollment. Applicants must certify in their applications that they meet and will continue to meet the Medicare

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<sup>1</sup> Social Security Act § 1832(a)(2)(G), 42 U.S.C. § 1395k(a)(2)(G); § 1832(a)(2)(D), 42 U.S.C. § 1395k(a)(2)(D); § 1834(a)(13), 42 U.S.C. § 1395m(a)(13); § 1861(n), 42 U.S.C § 1395x(n).

<sup>2</sup> 42 CFR § 424.57(a).

<sup>3</sup> 42 CFR §§ 424.57(b) and (c). Four new supplier standards were added to the original 21 and published in the Federal Register. 71 Fed. Reg. 48354, 48409 (Aug. 18, 2006). The additional supplier standards relate to accreditation of suppliers and are provided in Appendix A. However, CMS is phasing in the accreditation process, along with its Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program. Any supplier that wishes to participate in competitive bidding must be accredited. The deadline for all suppliers to obtain accreditation is September 30, 2009.



supplier standards. Once granted billing privileges, suppliers must reenroll in the Medicare program every 3 years to continue receiving Medicare reimbursement.<sup>4</sup>

For most suppliers, the NSC conducts an unannounced site visit before approving an applicant and granting Medicare billing privileges. NSC can also conduct an unannounced reenrollment site visit every 3 years. Unannounced site visits may take place at any other time as deemed necessary, but generally site visits occur only when suppliers enroll and reenroll in the Medicare program. According to CMS, site visits are an important component of successful oversight of supplier enrollment because they ensure that CMS conducts business only with legitimate suppliers. In many cases, site visits are the only method CMS has to ensure that suppliers actually exist and meet the requirements to participate in the Medicare program.<sup>5</sup>

#### **Revocation of Billing Privileges**

If after a reenrollment site visit, or any other unannounced site visit, NSC finds that a supplier no longer meets the supplier standards, NSC can revoke the supplier's billing privileges. When NSC revokes a supplier's billing privileges, NSC sends the supplier a letter that explains the reason for revocation, the effective date of the revocation (15 days from the date the notice is mailed), and appeal rights and procedures. The supplier cannot receive reimbursement from Medicare for medical equipment furnished on or after the effective date of the revocation.

#### **Appeal Process**

A supplier whose Medicare enrollment application has been denied or whose Medicare billing privileges have been revoked may appeal the determination. When NSC denies a supplier's application or revokes a supplier's billing privileges, the supplier has two options to contest the determination: the supplier may submit a corrective action plan or request a reconsideration (hereinafter referred to as a hearing). A supplier must submit its corrective action plan or request a hearing within 90 days from the postmark of the denial or revocation letter. A supplier may not submit a corrective action plan and request a hearing at the same time.

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<sup>4</sup> 42 CFR §§ 424.57(c) and (e).

<sup>5</sup> 71 Fed. Reg. 20754, 20755 (Apr. 21, 2006).

*Corrective Action Plan.* If a supplier chooses to submit a corrective action plan to NSC, the plan must contain evidence of compliance. The plan must also provide sufficient assurance of the supplier's intent to comply with the supplier standards. If CMS and NSC are satisfied that issues of noncompliance have been resolved, the supplier's billing privileges may be granted or reinstated.

*Hearing.* A hearing is an independent review by a hearing officer of the initial determination and the entire body of evidence, including any new information submitted by the supplier or NSC. It is the responsibility of the supplier to show that its billing privileges were denied or revoked erroneously.<sup>6</sup>

Once the supplier submits its request for a hearing, NSC has 15 days to forward the hearing package to a hearing officer. The hearing officer then has 90 days to schedule and conduct a hearing and render a decision.

#### **Fraudulent and Abusive Supplier Activity in South Florida**

The Department of Health and Human Services (HHS), the Department of Justice (DOJ), and others have recently identified and documented a significant amount of supplier fraud in South Florida. This fraud includes suppliers billing for services that are not rendered and billing for services that are not medically necessary. NSC reports that Florida led the Nation for allegations of supplier noncompliance with Medicare standards during the last two quarters of 2006, as a result of allegations in Miami-Dade and Broward Counties.<sup>7</sup> According to CMS, as of April 2007, 78 percent of all supplier revocations (734 of 938) nationwide during fiscal year 2007 occurred in Miami-Dade, Broward, and Palm Beach Counties.<sup>8</sup>

#### **Response to Fraud and Abuse in South Florida**

In March 2007, HHS and DOJ formed a Medicare Fraud Strike Force (Strike Force) made up of Federal, State, and local investigators to combat the fraudulent activities of suppliers in South Florida through the use of real-time analysis of Medicare billing data. During a 3-month

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<sup>6</sup> CMS, "Medicare Program Integrity Manual," Pub. No. 100-08, ch. 10, § 19A.

<sup>7</sup> "Supplier Audit and Compliance Unit Intelligence Report." Palmetto Government Benefits Administrators, NSC, pp. 14–15. April 19, 2007.

<sup>8</sup> HHS, "Medicare Provider Enrollment Demonstration Involving Suppliers of DMEPOS in High-Risk Areas." Available online at <http://www.hhs.gov/news/facts/medicarefraud/index.html>. Accessed on December 12, 2007.

period in 2007, 56 individuals were charged in South Florida with fraudulently billing Medicare more than \$258 million. As of March 2008, the Strike Force had brought charges against 120 defendants, resulting in 101 convictions.<sup>9</sup>

In June 2007, CMS announced a 2-year demonstration project to strengthen its ability to detect and prevent fraudulent activity in South Florida.<sup>10</sup> The demonstration was designed to detect potential fraudulent behavior at both the preenrollment stage as well as after suppliers are enrolled in Medicare. Under this demonstration, all suppliers in South Florida are required to submit a Medicare enrollment application to NSC. A supplier's Medicare billing privileges will be revoked if the supplier fails to meet certain requirements, such as reporting a change of ownership or address. Finally, suppliers whose billing privileges are not revoked will be subject to an enhanced review and will be assigned a fraud-level indicator by NSC. To determine the appropriate fraud-level indicator for each supplier, NSC will consider factors such as supplier location, fraud potential of products and services provided by the supplier, and site visit results.

#### **Office of Inspector General Site Visits**

In March 2007, OIG issued a report entitled "South Florida Suppliers' Compliance With Medicare Standards: Results From Unannounced Site Visits" (OEI-03-07-00150). OIG staff, along with CMS and its contractor staff at NSC, conducted unannounced site visits to 1,581 suppliers located in Miami-Dade, Broward, and Palm Beach Counties. OIG conducted these site visits to determine whether each supplier was in compliance with two supplier standards, which included four specific requirements:<sup>11</sup>

- 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).

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<sup>9</sup> DOJ, "Miami Jury Convicts Physician and Three Business Owners of Medicare Fraud." Available online at [http://www.usdoj.gov/opa/pr/2008/March/08\\_crm\\_183.html](http://www.usdoj.gov/opa/pr/2008/March/08_crm_183.html). Accessed on March 26, 2008.

<sup>10</sup> HHS, "Medicare Provider Enrollment Demonstration Involving Suppliers of DMEPOS in High-Risk Areas." Available online at <http://www.hhs.gov/news/facts/medicarefraud/index.html>. Accessed on December 12, 2007.

<sup>11</sup> 42 CFR §§ 424.57(c)(7) and (8).

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

If during an onsite review a facility is found closed during business hours, this becomes grounds for revocation in that the facility was found not in operation. A supplier must be operational upon site inspection to verify compliance with the Medicare supplier standards. "Operational" means the supplier has a qualified physical practice location; is open to the public for the purpose of providing health care related services; is prepared to submit valid Medicare claims; and is properly staffed, equipped, and stocked.<sup>12</sup>

***Site Visit Results.*** A total of 491 of 1,581 suppliers (31 percent) failed to maintain physical facilities or were not open and staffed during the unannounced site visits. 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. OIG referred these suppliers to CMS so that CMS could consider revocation of the suppliers' Medicare billing privileges.

Effective January 1, 2007, CMS revoked the billing privileges of these 491 suppliers. NSC sent letters to the 491 suppliers stating that a recent site visit was unsuccessful because the supplier's ". . . site was either no longer at the location on file or not open on multiple attempts. Because [NSC] could not complete an inspection of [the supplier's] facility, [NSC] could not verify [the supplier's] compliance with the standards." Therefore, NSC considered these suppliers to be out of compliance with all supplier standards.

After CMS revoked the suppliers' billing privileges, hearing officers conducted hearings and determined whether to reinstate suppliers that appealed the revocations.

#### **Follow-Up Site Visit Project**

After hearing officers conducted the supplier hearings, NSC began a follow-up project to determine suppliers' compliance with Medicare standards. NSC conducted unannounced site visits to suppliers, including those whose billing privileges were initially revoked as a result of the OIG study and then reinstated by hearing officers. Most of the suppliers that NSC visited were located in Miami-Dade County and had been in the Medicare program only for a short amount of time. NSC conducted most of the site visits between March and July 2007.

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<sup>12</sup> 42 CFR § 424.502.

Using the standard NSC site visit protocol, NSC determined whether the reinstated suppliers were in compliance with the supplier standards.

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## METHODOLOGY

### **Data Collection and Analysis**

We requested appeal files from NSC for any of the 491 suppliers whose billing privileges were revoked as a result of OIG's work in South Florida. Between April and September 2007, we received the supplier files from NSC. We reviewed the files to determine the number of suppliers that received hearings and were reinstated by hearing officers.

We reviewed the documents in the appeal files to determine the number and types of evidence submitted by suppliers. We also reviewed CMS policies and procedures, including 42 CFR § 424.57, the CMS "Medicare Program Integrity Manual," and NSC's Statement of Work.

Additionally, in December 2007, CMS provided written responses to our questions regarding hearing officer criteria and the hearing process.

We requested regular updates from NSC on its follow-up project and the status of reinstated suppliers. We used NSC data as of March 2008 to identify whether suppliers that were reinstated by hearing officers subsequently had their billing privileges revoked or inactivated. We obtained information on indictments and convictions from our Office of Investigations as of April 2008.

### **Limitations**

We requested all appeal files from NSC for the 491 revoked suppliers. We relied on NSC to provide us with complete appeal files. Our review of the suppliers' appeal files was based only on the documents NSC provided to us in response to our request.

Because our review was focused on suppliers that appealed and received hearings, we did not provide details on suppliers that submitted corrective action plans.

### **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

**Nearly half of the 491 revoked South Florida suppliers appealed and received hearings; hearing officers reinstated the billing privileges for 91 percent of these suppliers**

Hearing officers conducted hearings for 243 of the 491 South Florida suppliers whose billing privileges NSC revoked as a result of our prior

study. These suppliers appealed the revocations of their Medicare billing privileges and requested hearings. Based on submitted evidence and hearing testimony, hearing officers determined whether to reinstate the suppliers' billing privileges. Hearing officers reinstated the billing privileges for 91 percent of the suppliers that appealed and received hearings (222 of 243).

Three hearing officers conducted all of the hearings for the 243 South Florida suppliers. One of these hearing officers conducted 54 supplier hearings and reinstated billing privileges for all 54 suppliers. Another hearing officer reinstated billing privileges for 87 of 93 suppliers (94 percent), and the third hearing officer reinstated billing privileges for 81 of 96 suppliers (84 percent).

Many suppliers were represented by attorneys or consultants during the appeal process and at the suppliers' hearings. Six firms represented 60 percent of the suppliers that appealed and received hearings (145 of 243). An attorney who represented 15 suppliers during the appeal process was indicted and pled guilty to Medicare fraud in March 2007. As alleged in court documents, the attorney facilitated the fraudulent sale of 67 South Florida suppliers to nominee (or "straw") purchasers who acted in place of the true purchasers of the companies. The attorney used various legal documents to conceal the true purchasers of the companies.

**Because there are no criteria regarding the types of evidence necessary to reinstate supplier billing privileges, hearing officers reinstated billing privileges based on a variety of evidence**

Information regarding the hearing process is found in Federal Regulations, CMS's "Medicare Program Integrity Manual," and NSC's Statement of Work.<sup>13</sup> These

<sup>13</sup> CMS specifically cited the following three authorities as applicable: 42 CFR § 424.57; CMS, "Medicare Program Integrity Manual," Pub. No. 100-08, ch.10, § 19; and Statement of Work, NSC. We note that 42 CFR § 405.874 is also a key applicable regulatory section.

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documents include procedural guidelines for hearing officers, such as timeframes for conducting hearings and issuing determinations. However, these documents do not include criteria regarding the types of evidence hearing officers must receive from suppliers to reinstate their billing privileges. According to CMS, hearing officers accept all documentation submitted by suppliers, unless there is reason to believe the information is not legitimate.<sup>14</sup>

Because there are no criteria regarding the types of evidence necessary to reinstate supplier billing privileges, suppliers reinstated by hearing officers submitted various types of evidence to appeal the revocations of their billing privileges. For example, at least 75 percent of reinstated suppliers submitted photographs, licenses and permits, or evidence related to medical equipment. Suppliers also provided affidavits or statements from suppliers' owners stating that their businesses were open on the dates of the site visits. Over half of reinstated suppliers submitted evidence related to their businesses' facilities, such as leases or utility bills. The types of evidence submitted by suppliers and the percentage of reinstated suppliers that submitted each type of evidence are presented in Table 1 on the next page.

**Two-thirds of suppliers whose billing privileges were reinstated have subsequently had their privileges revoked or inactivated, and some individuals connected to reinstated suppliers have been indicted**

The billing privileges of half of the suppliers (111 of 222) that were reinstated by hearing officers have subsequently been revoked as a result of NSC's follow-up project and its continuing efforts to identify suppliers that do not meet Medicare

standards. In addition, 17 percent of suppliers (37 of 222) have had their billing privileges inactivated. As a result, two-thirds of suppliers whose billing privileges were reinstated by hearing officers (148 of 222) had their privileges revoked again or inactivated.

In addition, the U.S. Attorney's Office has indicted 18 individuals connected to suppliers whose billing privileges were reinstated by hearing officers. These 18 people were indicted between April and September 2007 and were connected to 15 of the 222 suppliers that hearing officers reinstated. As of April 2008, 10 of the 18 defendants had been convicted and each was ordered to pay between \$90,000 and

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<sup>14</sup> CMS written response to OIG questions. December 2007.

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\$11 million in restitution. These 10 defendants were also sentenced to jail terms ranging from 1 to 4 years.

<b>Table 1: Types of Evidence Submitted by Suppliers at Hearings</b>		
<b>Types of Evidence</b>	<b>Percentage of Reinstated Suppliers That Submitted at Least One Document Related to This Type of Evidence</b>	<b>Examples of Documents Submitted by Suppliers</b>
Photographs	79%	Photographs of suppliers' facilities, employees, posted hours, signs, medical equipment supplies
Licenses and permits	78%	Occupational license, driver's license, insurance certificate, State permit
Medical equipment evidence	75%	Vendor invoice, delivery slip, equipment maintenance agreement
Affidavits/statements	70%	Affidavits/statements from owners, employees, neighboring businesses
Physical facility evidence	57%	Lease, electric bill, rent receipt
Other	51%	Delivery receipt from bottled water company, business cards, "On delivery" signs
Phone evidence	46%	Land-line phone bill, cell phone bill
Banking evidence	41%	Bank statement, copy of check
Claims evidence	35%	Summary of claims, Medicare remittance notice
Fax evidence	29%	Fax cover sheet, fax confirmation sheet
Site inspection evidence	28%	NSC report on previous site inspection
Log evidence	13%	Visitor log, alarm system log
Employee evidence	13%	Employee timesheet
Patient evidence	10%	Form with patient signature



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To protect beneficiaries and the integrity of Medicare payments, CMS has developed standards that suppliers must meet to enroll in Medicare. CMS has also taken steps to ensure suppliers' compliance with these standards. For example, CMS has announced a 2-year demonstration project designed to identify noncompliant suppliers and detect potentially fraudulent supplier behavior. These efforts may result in CMS denying or revoking billing privileges for suppliers that do not meet all Medicare enrollment criteria found in 42 CFR § 424.57.

All suppliers whose billing privileges have been denied or revoked may appeal and request a hearing. This is an important process to ensure that only billing privileges for suppliers that fail to meet the supplier standards are denied or revoked.

There are no criteria for hearing officers regarding the types of evidence required to reinstate a supplier's billing privileges. For suppliers that request a hearing, hearing officers generally accept all documentation submitted as legitimate, unless they have reason to believe otherwise.

Hearing officers reinstated the billing privileges for 91 percent of the South Florida suppliers that were revoked as a result of OIG's prior study and received hearings. These billing privileges were revoked based on the results of the OIG-led unannounced site visits, yet were reinstated after suppliers submitted a wide variety of evidence to hearing officers. Two-thirds of these suppliers' billing privileges have subsequently been revoked or inactivated, and individuals connected to some of these suppliers have been indicted. Our findings suggest that a more critical review of supplier evidence is warranted to ensure that fraudulent suppliers' billing privileges are not reinstated.

Therefore, we recommend that CMS:

**Strengthen the Appeal Process by Developing Criteria Regarding the Types of Evidence Required for Hearing Officers To Reinstate Suppliers' Billing Privileges**

CMS should develop clear criteria for hearing officers on the types of evidence suppliers should submit for hearing officers to reinstate the suppliers' billing privileges. CMS could develop a list of evidence that would support the need for overturning various types of revocations. CMS or hearing officers could provide this list of documents to suppliers

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before a determination is made. Once suppliers have submitted their evidence, hearing officers could also take steps to verify the legitimacy of certain types of evidence. CMS could provide standard training to all hearing officers regarding the types of evidence required to reinstate supplier billing privileges.

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### AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In responding to our report, CMS stated that it has been taking aggressive steps to prevent fraud and abuse in the Medicare program. CMS points out that, most importantly, all suppliers will need to become accredited by October 1, 2009, which CMS believes will ensure that only legitimate suppliers serve Medicare beneficiaries. Additionally, CMS published a final rule in June 2008 which extends appeal rights to all providers and suppliers whose enrollment applications for Medicare billing privileges are denied or revoked by CMS or a Medicare contractor.<sup>15</sup> The rule also limits the submission of new evidence during an Administrative Law Judge review, requiring providers and suppliers to submit evidence and documentation at the lower levels of appeal. Finally, CMS stated that in March 2008, it established model provider enrollment letters, including letters regarding adverse provider enrollment determinations, that will help to ensure that applicants and enrolled providers and suppliers will be informed about the reason(s) for a denial or revocation and will be afforded the appropriate appeal rights.

CMS agreed that it should consider establishing guidelines regarding the evaluation of evidence that a hearing officer will review. CMS believes that it would be useful for OIG to provide specific suggestions regarding appropriate criteria for hearing officers. However, CMS stated that any guidance provided should not impinge on a hearing officer's ability to make an independent determination or with a supplier's ability to submit any evidence that it believes will support the reversal of a revocation or denial decision. For the full text of CMS's comments, see Appendix B.

We agree that CMS should develop criteria that maintain the independence of hearing officers and suppliers' ability to submit any

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<sup>15</sup> 73 Fed. Reg. 36449 (June 27, 2008).

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evidence they wish to send. We suggest that CMS develop a list of evidence that it believes would support a decision to overturn various reasons for revocation and that such evidence should be germane to the reason for revocation. For example, if CMS revokes a supplier's billing privileges because staff was not present at the supplier's facility after multiple site visit attempts during reasonable business hours, the supplier should not be reinstated based on the submission of cell phone bills, leases, driver's licenses, or photographs. Instead, reinstatement should be based on evidence that the supplier met the Medicare standard requiring it to maintain a physical facility that is accessible to beneficiaries and to CMS during reasonable business hours. CMS should also develop criteria that enable hearing officers to verify the legitimacy and credibility of documents submitted by suppliers as evidence during appeals.

## ► A P P E N D I X A

### Medicare Supplier Standards, 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 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;
- (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

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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;

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(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 been added as Medicare supplier standards in the Federal Register notice dated August 16, 2006. The additional standards relate to the accreditation of suppliers. However, CMS is phasing-in the accreditation process, along with its Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. Any supplier that wishes to participate in competitive bidding must be accredited or pending accreditation. The deadline for all suppliers to obtain accreditation is September 30, 2009.**

(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.

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Agency Comments

 DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
Office of the Administrator  
Washington, DC 20201

**DATE:** AUG 20 2008

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Kerry Weems *Kerry Weems*  
Acting Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: "South Florida Medical Equipment Suppliers: Results of Appeals," (OEI-03-07-00540)

RECEIVED  
2008 AUG 21 PM 3:00  
OFFICE OF THE INSPECTOR GENERAL

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 South Florida to determine compliance with Medicare supplier enrollment standards and to provide recommendations to improve appeals processing by the National Supplier Clearinghouse (NSC).

The Centers for Medicare & Medicaid Services (CMS) has been taking aggressive steps to prevent fraud and abuse in the Medicare program, including efforts directed to reducing the amount of fraud among suppliers in South Florida. Most importantly, all suppliers will need to become accredited by October 1, 2009 which will allow CMS to ensure that only legitimate suppliers serve Medicare beneficiaries.

Furthermore, on June 27, 2008, CMS published a final rule titled, "Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges (CMS 6003-F)" in the *Federal Register*. The effective date of this final rule is August 26, 2008.

In addition to implementing several non-appeal provisions, this final rule implements section 936 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and extends appeal rights to all providers and suppliers, including durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, whose enrollment applications for Medicare billing privileges are denied or revoked by CMS or a Medicare contractor. This final rule will also allow providers and suppliers to seek judicial review after they have exhausted the administrative appeals process.

In short, a DMEPOS supplier may appeal an adverse determination (i.e., denial of billing privileges or revocation of billing privileges) to the Medicare contractor (i.e., carrier, including NSC, fiscal intermediary, or the A/B Medicare Administrative Contractor (MAC)) making the initial determination. The process is referred to as reconsideration. Upon receipt of the reconsideration request, the Medicare contractor will assign an

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independent hearing officer to evaluate and make a determination regarding the reconsideration request.

With the implementation of this final rule, CMS or a Medicare contractor may request an Administrative Law Judge (ALJ) at the Department of Health and Human Services to review the hearing officer's decision. In addition, this final rule amends 42 CFR 489.56 to limit the submission of new evidence during an ALJ review. By requiring providers and suppliers to submit evidence and documentation at the lower levels of appeal, we believe that hearing officers will be able to make more informed determination about the appropriateness of an initial adverse determination.

**OIG Recommendation**

The CMS should strengthen the appeal process by developing criteria regarding the types of evidence required for hearing officers to reinstate suppliers' billing numbers.

**CMS Response**

While we agree that CMS should consider establishing guidelines regarding the evaluation of evidence that a hearing officer will review during the appeals process, we believe that it would be useful for OIG to provide CMS with specific suggestions regarding which criteria should be used by hearing officers during the review of a reconsideration. Any guidance should not impinge on a hearing officer's ability to make an independent reconsideration determination or impinge on a DMEPOS supplier's ability to submit any evidence that it believes supports the reversal of a revocation or denial determination issued by the NSC.

In addition to the above, CMS has the following comments:

The CMS maintains provider enrollment appeals processing guidance to its Medicare contractors, including the NSC, in Section 19 of Chapter 10 of the Program Integrity Manual (Publication 100-8).

On March 21, 2008, CMS established model provider enrollment letters via a one-time notification (CR 5832) for use by the Medicare contractors. CMS expects that use of model letters, including letters regarding adverse provider enrollment determinations, will help to ensure that applicants and enrolled providers and suppliers will be informed about the reason(s) for a denial or revocation and will be afforded the appropriate appeals rights.

**Technical Comments:**

- The draft report uses the term, "Medical Equipment Suppliers" in its title and throughout the document. Since the onsite reviews were conducted at DMEPOS suppliers, we believe that the use of the term, "durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers" or "DMEPOS supplier" is preferable.



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- The draft report uses the term “billing number” throughout the document. With the implementation of the National Provider Identifier (NPI) on May 23, 2008, CMS no longer issues billing numbers, but rather conveys billing privileges to an NPI. In addition, we believe that the term “billing privileges” is consistent with CMS’ regulatory authority found at 42 CFR 424.500 – 555.
- The Background section (page i) of the draft report states, “The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC) to manage the enrollment of suppliers in the Medicare program.” CMS contracts with NSC to manage the enrollment process for DMEPOS suppliers, not all suppliers. Accordingly, we would recommend the following change, “The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC) to manage the enrollment process for DMEPOS suppliers.”
- The Recommendation section (page iii) of the report states, “These efforts may result in CMS denying or revoking billing numbers for suppliers that do not meet Medicare standards.” We recommend the following change, “These efforts may result in CMS denying or revoking billing privileges for suppliers that do not meet all Medicare enrollment criteria found in 42 CFR 424.57.”
- In the Background section (page 1), the report states, “The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefits Administrators, to manage the enrollment of medical equipment suppliers into the Medicare program.” CMS contracts with NSC to manage the enrollment process for DMEPOS suppliers, not merely medical equipment suppliers. Accordingly, we recommend the following change, “The Centers for Medicare & Medicaid Services (CMS) contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefits Administrators, to manage the enrollment of DMEPOS suppliers into the Medicare program.”
- The second footnote on page 1 states “Four new supplier standards were added to the original 21 by Federal Register notice.” Actually, CMS promulgated rules that were published in the *Federal Register*. CMS did not issue a *Federal Register* Notice to make changes to the Code of Federal Regulations.
- The Background section (page 1) of the report suggests that an applicant completes an enrollment application and billing privileges are conveyed. However on page 2 of the report, it is stated that the NSC conducts an unannounced site visit before approving an applicant. In actuality, the NSC reviews the enrollment application and performs a site visit when it is cost efficient and reasonable to do so (e.g., the NSC does not perform site visits on large national chain drug stores). The NSC then makes a decision as to whether the applicant appears to meet all of the supplier standards prior to conveying billing privileges.

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- The Background section (page 2) of the report states that, “At any time, a supplier’s billing number can be inactivated. Reasons for inactivation include failure to reenroll and failure to submit Medicare claims for four consecutive quarters.” CMS may revoke billing privileges (see 42 CFR 424.535) when a DMEPOS supplier is not in compliance with supplier standards found in 42 CFR 424.57. CMS may also deactivate billing privileges (see 42 CFR 424.540). Accordingly, it is confusing to interject the concept of deactivation into this report because a deactivation of billing privileges does not convey appeal rights.
- The Background section (page 2) of the report states, “Unannounced site visits may take place at any other time as deemed necessary, but generally site visits occur only when suppliers enroll and reenroll in the Medicare program.” In FY 2008, CMS required that the NSC establish fraud indicators on those suppliers that pose a higher risk to the Medicare program and to conduct more frequent site visits for these suppliers.
- The Background section (page 2) of the report states, “The supplier cannot receive reimbursement from Medicare for medical equipment furnished on or after the effective date of revocation.” DMEPOS suppliers may continue to submit claims for services rendered prior to revocation for 15 – 27 months after the effective date of revocation.
- The Background section (page 3) of the report states, “If a supplier chooses to submit a corrective action plan to NSC, the plan must contain verifiable evidence of compliance.” Since CMS regulations do not require that a DMEPOS supplier submit “verifiable evidence of compliance,” we recommend that the word “verifiable” be removed from this sentence. While the NSC will verify the validity of certain documentation such as the submission of an insurance policy, the NSC will need to evaluate the probative value of some documentation (e.g., supporting statements submitted by a DMEPOS supplier, phone records, etc.) submitted by a supplier to support his or her request for reinstatement.

The CMS would like to again thank OIG for its efforts and the opportunity to review and comment on the draft report. We look forward to any additional insights that the OIG can provide so that CMS can strengthen its stewardship of Medicare Trust Funds.

## ► 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.

Emily Dolan Multari served as the project leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Consuelia McCourt; central office staff who contributed include Kevin Farber and Scott Manley.