

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

_____)	
In the Case of:)	
)	
Sky Medical Services,)	Date: May 4, 2009
(Supplier No. 5816230001),)	
)	
Petitioner,)	
)	
- v. -)	Docket No. C-09-107
)	Decision No. CR1946
Centers for Medicare & Medicaid)	
Services.)	
_____)	

DECISION

I affirm the revocation of Sky Medical Services' supplier number.

I. Background

Petitioner, Sky Medical Services, was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), effective January 9, 2008. On May 15, 2008, the Supplier Audit and Compliance Unit, National Supplier Clearinghouse, Palmetto GBA (NSC), a CMS contractor,¹ sent a letter to Petitioner stating that its supplier number would be revoked 15 days from the postmark of the letter. CMS Ex. 2, at 58-59.² Petitioner was informed that the basis for the revocation was its failure to be operational or open on more than one occasion when an

¹ NSC, a division of Palmetto GBA, LLC, has been delegated the responsibility to review supplier enrollment applications to determine if an entity requesting a Medicare supplier billing number meets the requirements of 42 C.F.R. Part 424 before issuing billing privileges. CMS Pub. 100-108, Medicare Program Integrity Manual, Chapter 10. Once a billing number is issued, NSC has the responsibility to ensure that the DMEPOS supplier continues to meet the standards set forth in the applicable regulations. *Id.*; CMS Pre-hearing Brief (PH Br.) at 2.

² I refer to CMS's exhibits as "CMS Ex." I refer to Petitioner's exhibits as "P. Ex."

NSC investigator attempted to complete an inspection to verify Petitioner's compliance with supplier standards. Petitioner submitted a corrective action plan on or about May 21, 2008. CMS Ex. 2, at 10-41. On June 10, 2008, CMS notified Petitioner that it had reviewed the corrective action plan but determined that Petitioner was still out of compliance with supplier standards. CMS Ex. 2, at 8. On July 10, 2008, Petitioner submitted a request for reconsideration. CMS Ex. 2, at 6. On September 12, 2008, a telephone hearing was held before a Hearing Officer. The Hearing Officer upheld the decision to revoke Petitioner's supplier number. CMS Ex. 1, at 1-3. On November 17, 2008, Petitioner submitted a hearing request and, on December 1, 2008, the case was assigned to me for hearing and decision.

I held a prehearing conference in the case on December 15, 2008, at which time I determined that, because material facts were in dispute, a hearing was necessary. Specifically, the issue of fact to be determined is whether Petitioner's owner, Christine Okezie, was at Petitioner's premises when the NSC investigator came to the facility on April 16, 2008. I held the hearing in Houston, Texas, on February 18, 2009. Testifying for CMS was Mark D. Porter, the NSC investigator who conducted the inspections of Petitioner at issue here. Testifying for Petitioner were: Christine Okezie, Petitioner's owner; Odoemelem Okezie, Christine Okezie's husband; and Kate Koko, Christine Okezie's friend. A 103-page transcript (Tr.) of the hearing was prepared. CMS offered five exhibits. I admitted CMS Exs. 1-5, except that I reserved ruling on CMS Ex. 4, at 8-10, which consists of photographs taken at the on-site survey in December 2008. Petitioner objected to the authenticity of these photographs. Tr. at 8. I now admit these photographs, as I find that Mr. Porter, the NSC witness, has shown that the photographs were taken in the usual course of business (although signing and dating the photos was only a requirement of the December inspection). Tr. at 6-8, 25, 37-38, 44-48, 64; CMS Ex. 5, at 2. Petitioner offered three exhibits. I admitted P. Exs. 1-3.³ Tr. at 9-10. I also marked and admitted ALJ exhibit (ALJ Ex.) 1. Tr. at 93-94. Both parties filed pre-hearing briefs (CMS and P. PH Br.) and post-hearing briefs (CMS and P. Br.). By e-mail dated April 13, 2009, CMS notified Maxine Winerman, the staff attorney assigned to assist me in this case, that it did not intend to file a reply brief. Petitioner filed a reply on April 13, 2008 (P. Reply).

³ Following the hearing, I found that page 5 of P. Ex. 2 was missing from the record copy of the exhibit submitted during the hearing. The same page was missing when Petitioner filed its pre-hearing exchange. Petitioner faxed three copies of page 5 to me on February 5, 2009 to complete its pre-hearing exchange. In the absence of objection, I have placed one of the copies of page 5 sent to me on February 5, 2009 in the record copy of the exhibit. E-mail dated March 9, 2009.

II. Applicable Law

Section 1861(n) of the Social Security Act (Act) defines medical and other health services that are eligible for Medicare reimbursement for DMEPOS suppliers. Under section 1834(j)(1)(A) of the Act, a DMEPOS supplier may not be paid for items provided to an eligible beneficiary unless the supplier has a supplier number issued by the Secretary of Health and Human Services (Secretary). A supplier may not obtain a supplier number unless the supplier meets the standards prescribed by the Secretary. Act, section 1834(j)(1)(B). A prospective DMEPOS supplier must meet all of the standards specified at 42 C.F.R. § 424.57(b) and (c) to be issued supplier billing privileges. Once billing privileges are issued, CMS or NSC may revoke a supplier's billing privileges for failure to meet all of the standards specified. 42 C.F.R. § 424.57(d); 42 C.F.R. § 405.874. CMS or NSC must send notice by certified mail of the revocation and the revocation becomes effective 15 days after the entity is sent notice of the revocation. 42 C.F.R. § 405.874(b).⁴ Supplier standard eight, the standard at issue in this case, states:

(c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards. The supplier: . . . (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.

42 C.F.R. § 424.57(c)(8). CMS has the right to conduct on-site inspections to confirm compliance with supplier standards. 42 C.F.R. § 424.535(a) states,

(a) *Reasons for revocation.* CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges . . . for the following reasons: . . . (5) *On site review.* CMS determines upon on-site review, that the provider or supplier is no longer operational to furnish Medicare covered items or services, or is not meeting Medicare enrollment requirements under statute or regulation to supervise treatment of, or to provide Medicare covered items or services for, Medicare patients. Upon on-site review, CMS determines that – . . . (ii) A Medicare Part B supplier is no longer operational to furnish Medicare covered items or services, or the supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations.

⁴ 42 C.F.R. § 405.874 was amended effective August 26, 2008. Under the amended regulations, the effective date of revocation is 30 days after CMS or the CMS contractor mails the notice of its determination to a supplier. 42 C.F.R. § 405.874(b)(2).

A supplier is “operational” when “the . . . supplier has a qualified physical 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 . . . to furnish these items or services. 42 C.F.R. § 424.502.

A supplier has the right to request reconsideration of a determination to deny or revoke its billing privileges (or to submit a corrective action plan for a denied or revoked billing number, 42 C.F.R. § 405.874(e)). 42 C.F.R. § 405.874(c)(2). If the hearing request is timely, a fair hearing officer not involved in the original determination to revoke the billing number will schedule a hearing in which both the entity and the carrier may offer evidence. A supplier has the right to appeal the reconsidered determination to an administrative law judge.

Once CMS has established a prima facie case that a supplier is not in substantial compliance with relevant statutory or regulatory provisions, the supplier must prove substantial compliance by the preponderance of the evidence. *MediSource Corporation*, DAB No. 2011, at 2-3 (2006).

III. Findings of Fact and Conclusions of Law

1. Mr. Mark D. Porter, the NSC investigator, attempted to complete an inspection of Petitioner on April 2 and April 16, 2008, to verify Petitioner’s compliance with DMEPOS supplier standards, but was unable to do so because Petitioner’s office was not open and thus not operational. Tr. at 24-65, 94-97; CMS Exs. 3, 5.
2. Petitioner was out of compliance with supplier standard eight, and the site investigator could not determine whether Petitioner was in or out of compliance with other supplier standards because the site investigator could not access Petitioner’s office.
3. A DMEPOS supplier must be in compliance with all supplier standards in order to retain Medicare billing privileges.
4. CMS had a basis to revoke Petitioner’s Medicare billing privileges.

IV. Analysis

CMS asserts that Petitioner failed to be operational because it was not open during two attempted site inspections, on April 2, 2008 and April 16, 2008, in violation of supplier

standard eight.⁵ CMS asserts that to be in compliance with supplier standard eight, the physical facility of the supplier must be accessible during reasonable business hours, and, during the posted hours of operation, staff must be available, so that beneficiaries, CMS, or NSC can contact the supplier directly and visit the supplier's location. *See MediSource Corp.*, DAB No. 2011, at 9. ["The physical facility required of suppliers is the place where patients can contact the supplier directly . . . Staff must be available at the facility during posted hours of operation."] CMS asserts Petitioner was not in compliance here because, on April 2 and 16, 2008, the NSC investigator was unable to complete an on-site visit to verify compliance with supplier standards because Petitioner was not open.

Petitioner asserts that CMS and the NSC Hearing Officer misstated the law. Specifically, Petitioner refers to the statement in the Hearing Officer decision that:

According to 42 CFR § 424.515(d), "the NSC reserves the right to perform on-site inspections as a means of verifying information on file with the NSC and confirm compliance with the supplier standards. If during on-site review a facility is found closed this becomes grounds for revocation because the facility was found not in operation."

Hearing Officer decision dated September 27, 2008, attached to Petitioner's November 17, 2008 Hearing Request. Petitioner notes that counsel for CMS made an almost identical statement at hearing:

According to 42 C.F.R. Section 515(d), the NSC, the National Supplier Clearinghouse, reserves the right to perform on-site inspections as a means of verifying information on file with the NSC and confirm compliance with supplier standards. If, during on-site review, a facility is found closed, this becomes grounds for revocation because the facility was found not in operation.

Tr. at 14. Petitioner argues that the language of 42 C.F.R. § 424.515(d) (a copy of which is in the record at CMS Ex. 2, at 62) does not reflect this language. It states,

(d) *Off Cycle revalidations.* (1) CMS reserves the right to perform off cycle revalidations in addition to the regular 5-year revalidations and may request that a provider or supplier recertify the accuracy of the enrollment information when warranted to assess and confirm the validity of the enrollment information

⁵ CMS also notes that Petitioner failed to be open or operational on two additional site inspections on December 8 and 9, 2008. CMS Br. at 2. It is not necessary for me to address these alleged failures to decide the case, and I thus limit my analysis to the April visits.

maintained by CMS. Off cycle revalidations may be triggered as a result of random checks, information indicating local health care fraud problems, national initiatives, complaints, or other reasons that cause CMS to question the compliance of the provider or supplier with Medicare enrollment requirements. Off cycle revalidations may be accompanied by site visits. . . .

Petitioner's argument that the Hearing Officer and CMS made "gross misstatements" of law (P. Reply at 1) is overblown. The regulation cited by CMS refers not to the second half of these statements, but to the first half, and addresses only the right to perform off cycle revalidations on site visits such as the ones that took place in this case. That CMS does not reference the second half of the statements is not a mis-statement. Other sections of the regulations, noted above, support the second half of the statement.⁶ It is axiomatic that if a facility is not open an investigator cannot determine whether or not it is otherwise operational. In regard to Petitioner's assertion that the statement at section 424.515(d) refers to CMS and not to NSC, and to Petitioner's inference that there is something wrong in referring only to CMS and not specifically referring to NSC, that fact is insignificant. NSC is CMS's contractor and the regulations permit CMS or its agents (such as NSC) to verify compliance with supplier standards.

Petitioner also asserts that supplier standard eight does not address the temporary absence of a supplier's staff from the supplier's location. Instead, Petitioner asserts that the standard mandates that suppliers will "permit" on-site inspections and be accessible during business hours. Petitioner asserts that CMS cannot establish a prima facie case by proving that no staff was available on the dates in question, but must prove instead that Petitioner was not operational (inferring that a temporary absence of staff does not show that Petitioner was not operational at the time of the inspections).

The evidence shows, however, that Petitioner was not open at the time of the inspections, and, by not being open, was not operational at the time that the NSC investigator attempted to conduct his site investigations. By not being open, the NSC investigator was unable to find out whether or not Petitioner was in compliance with all supplier standards and beneficiaries were not able to access Petitioner's services. CMS has established a prima facie case, unrebutted by Petitioner, that Petitioner was not operational (because it was not open) on more than one occasion when the NSC investigator attempted to complete an investigation to verify compliance.

⁶ Petitioner also asserts that the reliance of the Hearing Officer and CMS on what it terms this "gross misstatement" of law has detrimentally affected it and denied it due process of law. Although I disagree, Petitioner's Constitutional argument is saved for later appeal, as I do not have the authority to decide Constitutional issues.

Specifically, I find the testimony and the affidavit of Mark D. Porter, the NSC investigator, to be credible and determinative. Tr. at 24-65, 94-97; CMS Ex. 5. Mr. Porter is a trained and experienced investigator with an extensive background and familiarity with Medicare supplier regulations and requirements. *Id.* His investigation was conducted in the course of his business as an investigator.

Mr. Porter's affidavit, CMS Ex. 5, states, at page 2, his general practice in conducting an on-site visit:

I conduct the initial phase of on-site visits the same for all locations. When I receive a request for a site inspection, I drive to the location. I find the suite/office. I make note on the site visit questionnaire if there is a sign for the business name and if there are posted hours of operation. I will turn the doorknob and if the door is unlocked, I will enter, announce myself and conduct the site inspection. If the door is locked, I make a note on the site visit questionnaire indicating I made a first attempt, and I leave the location. I physically turn the knob each time with force enough to open the door. I do not leave a notice that I was at the location. We are no longer required to leave notices of attempts; however, a couple years ago we were required to leave notices of all attempts. This was discontinued because it became evident applicants would only appear at the office after notices of attempts were left. Site visits are all unannounced. I will later make a second attempt to conduct an on-site investigation during the posted hours of operation, if there are any; if none, I make the attempt during reasonably assumed business hours. I will go through the same steps. If the door is locked when I turn the knob, I make a note on the site visit questionnaire. If this is the second attempt that the office was closed during the posted hours of operation, I will annotate only the sections of the site visit questionnaire II (sic) was able to complete and fail the site inspection. I am required to make only two attempts of a supplier site visit for a particular location before failing the site inspection.

I will also take photographs of the location during a site inspection. Photos are mandatory for every site inspection. The photos are required to substantiate my visit to a particular location. I am required to take photos of the business sign and hours of operation (if any), and if I enter the office, photos of the layout of the office, any and all inventory, paths to show the location is handicap accessible (if above the 1st floor, include photos of elevator), and any other item that would be relevant to substantiate any statements and/or findings.

I completed the applicable sections of the document entitled Site Investigation for – Durable Medical Equipment (DME) Suppliers identified and marked as CMS Exs. 3 and 4. this questionnaire is used in the regular course of my duties as an investigator for NSC. It was in the regular course of my duties that I completed the applicable section of the document related to Sky Medical Services.

CMS Ex. 5, at 2-3. Mr. Porter’s affidavit further states at page 3 that:

I received notification on March 31, 2008 to conduct an ad hoc⁷ site inspection on Sky Medical Services located at 2650 Fountain View, Ste. 124, Houston, Texas 77057. Documentation shows I made the 1st attempt at conducting this site inspection on April 2, 2008 at 10:20 AM and the office was closed. There was no other sign, notice or indication as to why this supplier was closed during posted hours of operation. A 2nd attempt at conducting this site inspection was made on April 16, 2008 at 11:55 AM. There was no other sign, notice or indication as to why this supplier was closed during posted hours of operation. On April 16, 2008, I failed this site inspection because two attempts were made at conducting this site inspection. The office was closed on each attempt during posted hours of operation. No further attempts were required. The supplier was found to be not operational based on noncompliance with supplier standards #1-21.

Mr. Porter’s hearing testimony is consistent with his affidavit. Tr. at 35-38. Mr. Porter testified with regard to investigator practice that when he attempts to enter a DMEPOS supplier in an executive office building (and he does not only survey DMEPOS suppliers in office buildings, but also surveys suppliers such as CVS, Wal-Mart, or The Scooter Store, testifying that all DMEPOS suppliers must meet the same standards), if the supplier has a sign with posted hours, he “turn[s] the knob and walk[s] in.” Tr. at 34. He testified that investigators do not expect to knock. Although, he acknowledged that for companies in “problematic” areas that keep their doors locked there might be a sign to knock. He testified that,

Typically, no. We don’t knock, unless there is a specific sign that says please knock or ring the bell. But if there’s no such sign . . . then we typically will just turn the doorknob and expect to walk in because the standards say that they must be open and accessible to beneficiaries during reasonable business hours.

Tr. at 35. Mr. Porter documented his site visit on April 16, 2008 with photographs. CMS Ex. 3, at 9-11; Tr. at 36-37, 47. The sign he photographed on the door on April 16, 2008,

⁷ Mr. Porter explained that the NSC does three types of inspections. An initial on-site inspection when an entity applies for a supplier number; a re-enrollment inspection every three years; and an “ad-hoc” request for an out-of-sequence inspection. Tr. 32-33, 55.

stated “Sky Medical Services Hours of Operation Mon - Fri 9am - 5 pm” and “No Soliciting” CMS Ex. 3, at 9; Tr. at 38. Mr. Porter noted as comments on his site visits “2 attempts; office closed on each attempt; no further attempt necessary” (CMS Ex. 3, at 2), and “2 attempts during parties hours of operation – office closed on each attempt – no further attempts necessary.” CMS Ex. 3, at 8. Mr. Porter did not call the number listed on the Site Investigation Request (CMS Ex. 3, at 1), because it is not a requirement to do so and investigators are prohibited from calling a supplier to tell the supplier they are coming to make a site visit. Tr. at 59, 62. In fact, to do so would defeat one purpose of the visit, which is to find out if the supplier is open during stated business hours.

Petitioner seeks to impeach Mr. Porter’s credibility by pointing to Mr. Porter’s testimony that he did not leave a notice of attempted visit on April 2, 2008, because investigators were no longer required to, when he did, in fact, do so. That notice read:

A representative of the National Supplier Clearinghouse attempted to conduct an inspection of your company, Sky Medical Services. The first attempt was made today, April 2, 2008; however, the visit was unsuccessful because the facility was closed or an authorized representative was not available. A second unannounced attempt will be made soon during your posted hours of operation. If we are unable to complete the inspection, it may be concluded that this company is not open for business. In addition, the company will be determined to be in non-compliance with the 21 Medicare DMEPOS Supplier Standards as listed in 42 CFR 424.57(c), and it will be subject to denial or revocation of its Medicare DMEPOS supplier number.

ALJ Ex. 1. During CMS’s rebuttal case, Mr. Porter testified that he thought he had been given the instruction not to leave a notice prior to the April 2 visit, but was mistaken. Tr. at 46-47, 94-97; ALJ Ex. 1. I do not find that Mr. Porter’s failure to recall leaving this notice impeaches the credibility of his well-documented and consistent testimony that, on two occasions, April 2 and 16, 2008, he attempted to enter Petitioner’s offices but could not because the door was not open. Moreover, having been notified on April 2, 2008, that an investigator was attempting a site visit, Petitioner was on notice that someone needed to be available during its posted business hours for inspection (or at least a notice left on the door as to when someone would be back).

Petitioner also seeks to impeach Mr. Porter’s credibility by referring to earlier site visits made to Petitioner’s office by Mr. Porter in connection with Petitioner’s initial site inspection. Mr. Porter conducted a site inspection at Petitioner’s facility on July 5, 2007. Mr. Porter found Petitioner noncompliant. NSC later found Petitioner in compliance and issued a billing number, but Mr. Porter did not know why the number was issued, as he testified that he is not involved after his site inspection. Tr. at 56-57. Ms. Okezie, Petitioner’s owner, testified that Mr. Porter failed to forward all documentation to the

person processing Petitioner's application and testified that she did so and received her supplier number. Tr. at 75, 77. Petitioner stated that such errors are likely given the vast territory covered by Mr. Porter. P. Br. at 9, citing Tr. at 48. Petitioner thus infers that given the large territory covered by Mr. Porter, Mr. Porter may have made mistakes with regard to the two site investigation visits here. Given the documentation at CMS Ex. 3, and the fact that the only action Mr. Porter took was to try to enter Petitioner's facility, Petitioner's suggestion does not, in any way, diminish Mr. Porter's credible testimony.

Petitioner admits that no-one was in Petitioner's office on April 2, 2008, when Mr. Porter attempted his site visit. Tr. at 68. Thus, the office was not open on that date. Ms. Okezie testified that, after April 2, 2008 (and her receipt of Mr. Porter's notice, ALJ Ex. 1) she made it a point to be in her office during business hours. Tr. at 69. Petitioner asserts that the testimony of Ms. Okezie, Mr. Okezie and Ms. Koko, and telephone records from April 16, 2008, show that Petitioner was open (and thus operational) on April 16, 2008.

Ms. Okezie testified that she was present on April 16, 2008, when Mr. Porter made his second attempt to conduct a site inspection during Petitioner's regular business hours of 9:00 a.m. to 5:00 or 5:15 p.m. Tr. at 69. Petitioner asserts this testimony is corroborated by Ms. Koko, who testified that she visited Ms. Okezie at Petitioner's offices, arriving around 10:30 or 11:00 a.m. and left to get lunch around 11:30, returning before noon. Tr. 20-21. Petitioner also refers to telephone records showing that telephone calls were made from Petitioner's landline phone on that date, reflecting a call from Petitioner's number at 1:28:37 p.m. and a call to Petitioner's number at 3:02:31 p.m. P. Ex. 2, at 11; Tr. at 71. Additionally, Mr. Okezie testified that it was Ms. Okezie's custom and habit to keep office hours and that Ms. Okezie was there on April 16, 2008, because he called to get her lunch, but her friend was there. Tr. at 87. Ms. Okezie does not explain, however, why her door would have been locked when Mr. Porter arrived.

The evidence adduced by Petitioner does not show that Petitioner was open when Mr. Porter attempted to enter Petitioner's facility at 11:55 a.m. on April 16, 2008. The telephone calls were made on the afternoon of April 16, 2008, after Mr. Porter attempted to enter. And, I find the testimony of Mr. Porter, and the site report and attached photographs at CMS Ex. 3, to be more credible than the evidence adduced by Petitioner. In sum, I find that Mr. Porter attempted to enter Petitioner's premises twice, was unable to enter because the door was locked, took the photographs included in CMS Ex. 3 on April 16, 2008, and left, all in the ordinary course of his business. Because Petitioner's office was not open: Petitioner's office was not accessible during the reasonable business hours Mr. Porter sought to enter; CMS was not able to conduct the on-site inspection to ascertain Petitioner's compliance with supplier standards; and Petitioner was not in compliance with supplier standard eight.

V. Conclusion

A supplier must comply with all supplier standards. NSC was unable to access Petitioner's office on two occasions in April, during posted hours of operation, to verify compliance with all surveyor standards. Petitioner's noncompliance with supplier standard eight is a sufficient basis for the revocation of its Medicare billing privileges.

/s/

Alfonso J. Montano
Administrative Law Judge