

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

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In the Case of:)
)
Neglex Inc., d.b.a. Latina Pharmacy &) Date: April 22, 2008
Discount (Supplier No. 5434010001),)
)
Petitioner,) Docket No. C-07-291
) Decision No. CR1776
v.)
)
Centers for Medicare & Medicaid)
Services.)
_____)

DECISION

The determination of the National Supplier Clearinghouse (NSC) and the Centers for Medicare & Medicaid Services (CMS) to revoke the supplier number of Petitioner, Neglex Inc., d.b.a. Latina Pharmacy & Discount (Neglex), reflected in the CMS notice dated December 18, 2006, was incorrect as there was no basis for revocation. The revocation action is reversed and Petitioner's supplier number is reinstated as of the effective date of the purported revocation.

I. Background

Petitioner is a retail pharmacy that, prior to the revocation in issue in this case, was enrolled in Medicare as a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). CMS notified Petitioner by letter dated December 18, 2006, that its Medicare supplier number would be revoked 15 days from the postmark of the notice. CMS stated as grounds for the revocation that Petitioner was either no longer at the location or it was not open when representatives of CMS made multiple attempts to visit Petitioner's site. Thus, CMS could not determine whether or not Petitioner was complying with the standards for participation as a supplier. CMS Exhibit (CMS Ex.) 5.

Petitioner requested a hearing by a Medicare hearing officer. On February 19, 2007, the hearing officer issued his decision in which he determined that the revocation of Petitioner's supplier number was appropriate. CMS Ex. 1, at 2. On February 22, 2007, Petitioner requested a hearing by an administrative law judge (ALJ) of the Departmental Appeals Board (DAB). The case was assigned to me for hearing and decision on March 5, 2007.

I convened a prehearing conference by telephone on March 28, 2007. The substance of the prehearing conference is contained in my Prehearing Conference Order dated March 29, 2007. I established a schedule for further development of the evidentiary record and the filing of briefs. On April 6, 2007, CMS objected to the Prehearing Conference Order arguing that the procedures established by 42 C.F.R. Part 498 should control in this case rather than those in 42 C.F.R. Part 405, based upon revisions to the Social Security Act (the Act) which have not yet been implemented by the Secretary of Health and Human Services (the Secretary) through promulgation of revised regulations.¹ On April 27, 2007, I issued an Order granting the CMS motion and establishing the procedures and schedule for hearing. I ruled that the proceedings in this case would be subject to 42 C.F.R. Part 498. On July 11, 2007, CMS moved for summary judgment. On August 2, 2007, I denied CMS' motion for summary judgment, finding that there were disputed issues of material fact and I scheduled a hearing for September 27, 2007.

I conducted a hearing in this case on September 27, 2007, in Miami, Florida. CMS offered as evidence, and I admitted, CMS exhibits 1 through 8. Transcript (Tr.) 18. Petitioner offered, and I admitted, Petitioner's exhibits (P. Ex.) 1 and 3. Tr. 47, 122. I also marked and admitted a declaration of Liliana Mederos with photographs attached as Court Ex. 1 (Tr. 28), and a copy of an email from Barry J. Bromberg to Gwendolyn L. Johnson, date/time September 26, 2007, 9:36 a.m., Subject Re: 07-291 Neglex, as Court Ex. 2 (Tr. 35). CMS presented telephonic testimony of one of the site inspectors, Patricia Snyder. Mr. Negrin testified on Petitioner's behalf. The parties filed post-hearing briefs, Petitioner filed a post-hearing reply brief, and CMS waived its post-hearing reply brief.

II. Discussion

A. Findings of Fact

The findings of fact are based upon the exhibits admitted and the witness testimony. Citations not provided here may be found in the analysis section of this decision.

¹ See 72 Fed. Reg. 9,479 (Mar. 2, 2007).

1. Petitioner's DMEPOS supplier site at 200 SW 107 Avenue, Suite 114, Miami, Florida 33174, was inspected by Lilian Mederos, an employee of the NSC contractor, on June 8, 2005.
2. Following the site inspection on June 8, 2005, Petitioner was issued a Medicare billing number as a supplier of DMEPOS.
3. Petitioner's retail pharmacy store was operational, open, and accessible to Medicare beneficiaries and the public on November 29, 2006.
4. Petitioner's retail pharmacy store was operational, open, and accessible to Medicare beneficiaries and the public on December 1, 2006.
5. Evidence that Petitioner's retail pharmacy store was not operational, open, and accessible to Medicare beneficiaries and the public on November 29, 2006 and on December 1, 2006, is not credible.

B. Conclusions of Law

1. Petitioner's request for hearing was timely and I have jurisdiction.
2. The inspections conducted on November 29 and December 1, 2006, established no basis for revocation of Petitioner's supplier billing privileges, i.e. the billing number.
3. Petitioner's billing number must be reinstated effective the date of its revocation by NSC and CMS.

C. Issue

Whether CMS had basis to revoke Petitioner's supplier privileges, i.e., the billing number.

D. Applicable Law

Section 1861 of the Act defines medical and other health services that are eligible for Medicare reimbursement to DMEPOS suppliers. Pursuant to section 1834(j)(1)(A) of the Act, a supplier of medical equipment and supplies may not be paid for items provided to an eligible beneficiary unless the supplier has a supplier number issued by the Secretary. A supplier may not obtain a supplier number unless the supplier meets the standards established by the Secretary, which must include, inter alia, the requirement to maintain a physical facility on an appropriate site. Act § 1834(j)(1)(B).

The Secretary has established special payment rules for payment of DMEPOS suppliers and the issuance of supplier billing privileges. 42 C.F.R. § 424.57. A prospective DMEPOS supplier must meet 21 standards specified at 42 C.F.R. § 424.57(c)(1) through (21) to be issued supplier billing privileges, i.e. to obtain a billing number. Revocation of a supplier's billing number is governed by 42 C.F.R. § 424.535. CMS or its contractor NSC, will revoke a supplier's billing privileges if the supplier does not meet the standards in 42 C.F.R. § 424.57(b) and (c). 42 C.F.R. § 424.57(d). CMS can use an on-site review to determine whether a "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." 42 C.F.R. § 424.535(a)(5). A supplier is operational when "the provider or 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 . . . to furnish these items or services." 42 C.F.R. § 424.502. NSC gives the supplier notice that its billing number will be revoked effective 15 days after NSC mails the notice of revocation. 42 C.F.R. § 405.874(b). A supplier cannot be paid for an item furnished during the period during which its billing privileges were revoked. 42 C.F.R. § 424.57(b)(3).

Section 1866(j) of the Act, as amended by section 936 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, requires that the Secretary establish a process for the enrollment in the Medicare program of providers of services and suppliers. Section 1866(j)(2) of the Act gives providers and suppliers equal appeal rights as described by section 1866(h)(1)(A) of the Act.² The procedures for hearings and appeals are set out in 42 C.F.R. Part 498.

The hearing before an ALJ is a de novo proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care*, DAB No. 2030 (2006); *The Residence at Salem Woods*, DAB No. 2052 (2006). The procedures for hearings and appeals pursuant to 42 C.F.R. Part 498, do not include specific provisions regarding the burden or going forward with the evidence or the burden of persuasion. However, in cases subject to Part 498 the Board has found that CMS must make a prima facie showing of a regulatory violation and the regulated entity bears the burden of persuasion by a preponderance of the evidence to show that it was compliant with the Act or regulations or that it had a defense. *Batavia Nursing and Convalescent*

² Previously, supplier appeals were governed by 42 C.F.R. § 405.874, which provided for review by a fair hearing officer and then a CMS official, designated by the Administrator of CMS. Revision of the regulations is pending. *See* 72 Fed. Reg. 9,479 (Mar. 2, 2007).

Center, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Evergreene Nursing Care Center*, DAB No. 2069, at 7-8 (2007). The Board found this allocation of the burden of going forward with the evidence and the burden of persuasion properly applied in the DMEPOS supplier case *MediSource Corporation*, DAB No. 2011, at 2-3 (2006). The parties have urged no different allocation in this case.

E. Analysis

Petitioner's billing number was revoked by NSC because two investigators determined that Petitioner was no longer operational when they allegedly went, on two separate occasions, to the address on file for Petitioner's business and found the store front location empty. The CMS notice states as grounds for revocation both that Petitioner's site was no longer open and that it was not possible for the investigators to verify compliance with all 21 supplier standards. CMS Ex. 5, at 1. The Medicare hearing officer found that on November 29, 2006 and December 1, 2006, two investigators of the NSC Supplier Audit and Compliance Unit attempted to inspect Petitioner's location. However, on both occasions Petitioner's business was closed. CMS Ex. 1, at 2. The hearing officer rejected Petitioner's testimony and other evidence and decided, based upon the report of the investigators, that there was a basis for revocation because Petitioner did not show its business was operational at the time of the visits. CMS Ex. 1, at 2. CMS argues before me that the two investigators visited Petitioner's location on November 29 and December 1, 2006, the location was closed and appeared to be vacant, and Petitioner's supplier number was revoked on that basis citing 42 C.F.R. § 424.535(a)(5).³ CMS Post-hearing Brief (CMS Brief) at 2, 6. CMS urges me to find the testimony of Patricia Snyder, her declaration at CMS Ex. 8, and her report at CMS Ex. 4 credible and Petitioner incredible. CMS Brief at 6-17. Petitioner argues that this is a case of mistaken identity, i.e. the investigators attempted to inspect the wrong address, and that he was in fact open and ready for business on the dates and at the times the investigators allege they visited his site. Petitioner's Post Hearing Brief and Reply. I find Petitioner's evidence more credible and persuasive than the CMS evidence.

³ NSC, the hearing officer, and CMS have characterized the basis for revocation both as the supplier site was closed and not accessible when the investigators attempted the visits and the site was vacant and no longer operational. I note that either the failure to comply with the 21 standards including the requirement to be accessible to both CMS and beneficiaries during posted business hours established by 42 C.F.R. § 424.57, or that Petitioner was no longer operational as indicated by a vacant store would be a sufficient basis for revocation pursuant to 42 C.F.R. § 424.535(a)(5). In this case, the investigators allege specifically that the site they visited was vacant and not operational. CMS Ex. 4, at 1, 4; CMS Ex. 8; Tr. 63, 84.

Patricia Snyder stated in her declaration that she had been employed by the CMS Office of Financial Management, Program Integrity Group, for about 13 years and that her responsibilities included conducting site inspections of DMEPOS and pharmacy suppliers. CMS Ex. 8, at 1. At hearing, she testified that she was not responsible, as part of her job, for doing site visits. In fact, she was asked to do site visits as part of a one-time special project to investigate suppliers in Miami-Dade, Broward, and Palm Beach Counties in Florida, and one of the suppliers she was assigned to investigate was Petitioner. Tr. 51. She testified that she did not actually work in the DMEPOS supplier area. Tr. 76. Thus, contrary to the impression created by her declaration, the evidence does not show that Ms. Snyder was an experienced investigator. She states in her declaration that she and Julio Hernandez attempted to visit Petitioner's site on November 30, 2006; that she could observe inside through the window; that she observed the pharmacy was vacant and did not appear operational; that she did not see any medical equipment, supplies, office equipment, or employees; that the pharmacy was vacant; that she did not observe any beneficiaries or customers attempt to access the office; and that she observed a sign with business hours. CMS Ex. 8, at 1-2. Ms. Snyder testified that her declaration was incorrect in stating that her first visit to Petitioner's site was on November 30, 2006. Rather, she would rely upon her notes from the visit as being more accurate and those notes at CMS Ex. 4 show her initial visit was actually on November 29, 2006. Tr. 51-52. Ms. Snyder also testified in conflict with her declaration that she could not recall who got out of the car to look through the windows of the site she thought was Petitioner's site. Tr. 55, 59, 70. Her declaration indicates that she and Mr. Hernandez returned to the site on December 1, 2006, and the supplier's location was vacant and not operational. CMS Ex. 8.

Ms. Snyder indicated on the record that she was from Baltimore (Tr. 49) and she testified that Mr. Hernandez was from Los Angeles (Tr. 73). Ms. Snyder testified that the special project was her first visit to Miami and she testified that she believed that it was also Mr. Hernandez's first trip to Miami. Tr. 79-80. Ms. Snyder testified that she did approximately 80 site visits in 8 days while she was in the Miami area. Tr. 53. Ms. Snyder testified that they were to do a limited inspection at each site she and Mr. Hernandez were assigned to investigate. They were instructed not to look at all 21 supplier standards. They were instructed to try to enter the facility, to look for DME supplies, and to note whether the hours of operation were posted. They were instructed not to take any pictures or ask any questions of those present at the site being inspected. Investigators were also instructed to complete for each site investigated the form at CMS Ex. 4. Tr. 52- 55. Ms. Snyder and Mr. Hernandez navigated to certain sites using a GPS (global positioning satellite) device. She testified that the GPS was used to locate Petitioner's site. Tr. 55. She testified that she was the note taker for most of the 80 sites visited and she recognized her hand-writing on CMS Ex. 4. Tr. 56. She testified that she recognized the pictures of Petitioner's pharmacy, as she visited no more than three pharmacies during the project. Tr. 59. However, when I questioned her, she could not

recall whether or not the three pharmacies were similar even in general appearance such as whether they were store fronts with signs in Spanish, such as Petitioner's. Tr. 70. She admitted on cross-examination that she checked "Office Suite in Office Building" on the form for Petitioner's site at CMS Ex. 4, at 1, and that Petitioner's site would be more accurately described as a storefront. Tr. 67. She agreed that she did not properly complete item 3 of the checklist (CMS Ex. 4, at 2) because, if she was actually at Petitioner's site, she should have observed that the name on the store sign was different than the name on the form. Tr. 67-68. She testified that there is no way they could have confused Petitioner's site with another as they "had a GPS" that they had rented with the rental car. Tr. 73. She described the GPS as one that gave audible directions to an address that was entered by the user. Tr. 80-81. She testified that she and Mr. Hernandez would verify their locations by looking at street signs and numbers, but she could not describe how streets signs were posted in the area; instead she relied upon Mr. Hernandez's navigation skills, as he was formerly a police detective in Los Angeles. Tr. 81-82.

I do not find Ms. Snyder's testimony credible or persuasive. I have no evidence that she was trained as an investigator. Rather, she accepted a special project assignment and took a trip to Miami. The inconsistencies between her declaration and her testimony and the inconsistencies in the form she completed at CMS Ex. 4 show that she was not attentive to detail. She also admitted that her recollection of events just eight or nine months previous was not good and that she had to rely upon her notes at CMS Ex. 4, which she also admitted are inaccurate and not complete. She also revealed that this was her and her partners' first visit to Miami, thus neither was familiar with the area and had to rely upon a GPS device for directions. Although she testified she could specifically recall the appearance of Petitioner's pharmacy, she could not recall whether the appearance of the other two pharmacy sites she visited were similar even in general details. Although the investigator who initially inspected Petitioner's site in 2005 took multiple photographs to support her investigation of Petitioner for approval to participate as a supplier (P. Ex. 1), Ms. Snyder and her partner were instructed to take no pictures that might have confirmed that they visited Petitioner's site and that it was vacant.

The evidence shows that Petitioner's site at 200 SW 107 Avenue, Suite 114, Miami, Florida 33174, was inspected by Lilian Mederos, an employee of the NSC contractor, on June 8, 2005. Ms. Mederos took multiple photographs of Petitioner's site, interior and exterior. Ct. Ex. 1; P. Ex. 3. There is no dispute that Petitioner was subsequently approved for billing privileges and issued a supplier billing number.

Alex Negrin, part-owner of the corporation that owns Petitioner, testified that he was motivated to obtain a supplier number so he could obtain reimbursement for test strips provided to his diabetic clients, and that otherwise he did not want to deal with Medicare. Tr. 98-99, 128-29. Mr. Negrin testified that he took the photographs admitted as P. Ex. 1,

on April 15, 2007 (Tr. 100-01, 106), which I note to be 135 days after the alleged visit by Ms. Snyder and Mr. Hernandez on December 1, 2006. The photographs in P. Ex. 1 show a pharmacy window that is nearly full of items and shelves with items such as one would find in a pharmacy. P. Ex. 1, at 1, 2, 4-6; Tr. 103. Mr. Negrin testified that the photographs taken on April 15, 2007 depict his site in much the same condition as it would have appeared on November 29 and December 1, 2006. Tr. 126. He testified that his pharmacy was open at 2:15 p.m. on November 29, 2006 and at 9:30 a.m. on December 1, 2006. Tr. 127.

I do not find credible the evidence that NSC investigators visited Petitioner's pharmacy on November 29, 2006 at about 2:15 p.m. and found that store closed or vacant. I also do not find credible the evidence that NSC investigators visited Petitioner's pharmacy on December 1, 2006 at about 9:30 a.m. and found the store closed or vacant. I do find credible the testimony of Mr. Negrin and the other evidence which shows that Petitioner's store was not vacant on June 8, 2005 and it was not vacant on April 15, 2007. I find credible the testimony of Mr. Negrin that his store appeared much the same on April 15, 2007 as it would on November 29 and December 1, 2006. I also find credible Mr. Negrin's testimony that his store was open for business at the times and on the dates the investigators allege his store was vacant. CMS argued that Mr. Negrin's testimony was uncertain and self-serving. CMS Brief at 14-17. However, while Mr. Negrin may have been uncertain as to some dates from 2004 and 2005, his demeanor and the consistency of his statements show that his testimony is credible. I also note that his un rebutted testimony is that his billing for diabetic test strips was only a small part of his business. Tr. 128. Based upon all the evidence I find that Petitioner has shown by a preponderance of the evidence that his retail pharmacy store was operational, open, and accessible to Medicare beneficiaries and the public on November 29, 2006 and on December 1, 2006.

Accordingly, I conclude that there was no basis for the revocation of his Medicare billing privileges.

III. Conclusion

For the foregoing reasons, Petitioner's supplier number was inappropriately revoked and should be reinstated effective the date of revocation.

/s/
Keith W. Sickendick
Administrative Law Judge