Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Peoples Pharmacy, Inc.
(Supplier No. 5108320001),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-08-509

Decision No. CR2111

Date: April 12, 2010

DECISION

I affirm the revocation of Petitioner, Peoples Pharmacy, Inc.'s, supplier number.

I. Background

Petitioner, a community pharmacy located in Miami, Florida (licensed by the Florida Department of Health Board of Pharmacy and authorized to dispense medications by the Board of Pharmacy), is an oxygen supplier, pharmacy, and medical supply company with prosthetic/orthotic personnel and a registered pharmacist. CMS Exhibit (Ex.) 9 at 8. Petitioner also is a supplier of items that include: commodes; diabetic equipment and supplies; diabetic footwear; drugs and pharmaceuticals; durable medical equipment; manual and electric hospital beds with accessories; nebulizers; custom-fabricated and non-custom orthotics; oxygen; patient lifts and seat lift mechanisms; power mobility devices, including power operated vehicles (or scooters) and power wheelchairs; prosthetics; respiratory equipment, including bi-level positive airway pressure and continuous positive airway pressure; surgical dressings; urinals and bedpans; walkers; canes and crutches; and manual wheelchairs. *Id.* at 9.

By letter, dated October 31, 2007, the National Supplier Clearinghouse (NSC)[1] notified Petitioner that CMS had initiated a demonstration project, entitled "Medicare Provider Enrollment Demonstration for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) in High Risk Areas." NSC advised Petitioner that it was required to re-enroll with NSC within 30 days. CMS Ex. 8.

By letter, dated February 14, 2008, NSC notified Petitioner that its supplier number was revoked 15 days from the postmark on the letter. The letter stated that Petitioner was not in compliance with supplier standard eight, specifically,

> Supplier standard number *eight* states that a supplier "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." *Recently a representative of the SACU[2] attempted to conduct a visit of your facility; however, the visit was unsuccessful because no one was available to conduct the inspection on multiple attempts. Because we could not complete an inspection of your business, we could not verify your compliance with the standards. Thus, you are considered to be in violation of all 21 standards.*

CMS Ex. 5 at 1 (emphasis in original). The letter informed Petitioner it could request reconsideration or complete a corrective action plan (CAP). Petitioner requested reconsideration. CMS Exs. 3, 5.

By letter, dated April 18, 2008, following a hearing conducted on April 4, 2008, a hearing officer for the NSC rendered a decision unfavorable to Petitioner. She found that because "the pharmacist was not available during the site inspection attempts, and the prescription department of People's Pharmacy was unavailable to Medicare beneficiaries, the facility was non-compliant." CMS Ex. 3 at 2-3. The decision noted that "[i]f during on-site review a facility is found closed this becomes grounds for revocation because the facility was found not in operation. A supplier must be found 'operational' upon the site inspection in order to verify compliance with the Medicare Enrollment requirements."

---

[1] NSC is the entity authorized by CMS to issue, revoke, and reinstate DMEPOS supplier numbers. *MediSource Corp.*, DAB No. 2011 at 1 n.1 (2006).

[2] SACU is an acronym for the Supplier Audit and Compliance Unit of the NSC.

Id. at 2. The letter informed Petitioner that it could appeal the hearing officer's decision to an administrative law judge (ALJ) of the Departmental Appeals Board.[3] *Id.* at 3.

By letter, dated May 30, 2008, Petitioner requested a hearing. The case was assigned to me for hearing and decision on June 18, 2008. I held a pre-hearing conference on July 17, 2008. During the conference, the parties agreed that the only issues left to be resolved were legal issues and that the case could be decided based on written submissions without the need for an in-person hearing. I set a schedule for the parties to brief the case. I also informed Petitioner that it had the option to re-apply for its Medicare supplier number at any time during the hearing process.

CMS filed its brief (CMS Br.) on August 22, 2008, accompanied by CMS Exs. 1-13. Petitioner filed its brief on September 19, 2008, accompanied by Petitioner's Exhibits (P. Exs.) 1-10. Neither party filed a reply. In the absence of objection, I admit CMS Exs. 1-13 and P. Exs. 1-10 into evidence.

II. Applicable Law

Under section 1834(j)(1)(A) of the Act, a supplier may not be paid for items provided to an eligible beneficiary unless the supplier has a supplier number issued by the Secretary of the Department 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:

---

[3] During the NSC hearing, Petitioner argued that the pharmacist's not being at the pharmacy during business hours was the fault of the company with which Petitioner contracted to provide pharmacists and that the pharmacist's failure to be there was thus beyond Petitioner's control. CMS Ex. 3. Petitioner did not make this argument in the briefing before me. However, had Petitioner made the argument, I would have found the argument without merit. It was Petitioner who had the supplier agreement with CMS, and it is Petitioner's responsibility to make sure that it is in compliance with all supplier requirements.

[4] 42 C.F.R. § 405.874 was amended effective August 26, 2008. Under the amended regulation, 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).

> (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.

A supplier is "operational" when "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 . . . 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 CAP 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 ALJ.

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 Corp.*, DAB No. 2011 at 2-3.

III. Findings of Fact and Conclusions of Law

1. The NSC inspector attempted to complete an inspection of Petitioner on January 14, 2008 at 2:30 p.m., and on January 16, 2008 at 9:40 a.m. CMS Ex. 4 at 1, 6; P. Br. at 2-3.

2. Petitioner was out of compliance with supplier standard eight, because the site inspector could not determine whether Petitioner was in or out of compliance with supplier standards, as the pharmacist was not on the premises when the site inspector arrived, and the inspector could not complete an inspection. *Id*.

3. Petitioner had to be in compliance with all supplier standards to retain Medicare billing privileges. 42 C.F.R. § 424.57(b) and (c).

4. CMS had a basis upon which to revoke Petitioner's Medicare billing privileges. 42 C.F.R. §§ 424.57(d); 405.874.

IV. Analysis

It is undisputed that Petitioner timely filed its re-enrollment application. A site inspection to verify Petitioner's compliance with supplier standards is part of the enrollment process. It is undisputed that Petitioner's posted hours of operation were from 9:00 a.m. to 5:00 p.m. Monday through Friday. CMS Ex. 4 at 2; CMS Ex. 12; P. Br. at 9. It is also undisputed that on January 14, 2008 at 2:30 p.m., and on January 16, 2008 at 9:40 a.m., an NSC site inspector arrived at Petitioner's pharmacy to inspect the facility. CMS Ex. 4 at 1, 6; P. Br. at 2-3. Petitioner does not dispute that on both occasions the pharmacist was not present, and the inspector left without inspecting the facility. *Id*. The site inspector found during the first visit that the drug door was locked and a "pharmacy closed sign [was] posted on [the] interior door." An employee stated to the investigator that "it would be at least ½ hr until pharmacist returned, and probably 1 full hr." Further, the employee "did not want to do inspection himself, preferred to wait until a later date." CMS Ex. 4 at 6. On the second visit, the inspector found "[p]harmacist was not here again. Lady states he doesn't come in usually until 10 am (pharmacy hours are 9-5). I reminded the employees this was my 2nd visit, if not completed, the Medicare # would be revoked. Supplier stated the pharmacist was always late & comes/goes as he pleases. He had no way to contact him (not an employee, contracted pharmacist), so he had no idea when he would show up. I did not wait." *Id.*

In a sworn affidavit (CMS Ex. 13), Petitioner's Administrator does not materially dispute the site inspector's comments, stating that during the first site visit the pharmacist was at lunch, and, during the second site visit, a pharmacist had not been dispatched from the staffing company to the facility as of 9:40 a.m. CMS Ex. 13 at 1. Petitioner's Administrator also stated in his affidavit that "[b]y law I am prohibited from opening the prescription department to allow any non-pharmacist in the area without the pharmacist being on-site." *Id*. Petitioner's Administrator states that after the second site visit, he

fired the staffing company and hired another company to provide a full-time pharmacist until Petitioner itself was able to hire a full-time pharmacist and pharmacy manager. As of February 12, 2008, Petitioner passed an on-site Board of Pharmacy inspection. *Id*. Petitioner's Administrator also stated that Petitioner's corporate culture is that regardless of whether a pharmacist is late for an emergency beyond the Administrator's control that the pharmacy is open 40 hours a week, five days a week. *Id*. at 2.

Petitioner asserts that on the dates in question it was "operational" as defined by 42 C.F.R. § 424.502, and that the site inspector unilaterally decided not to conduct a site visit even though neither state nor federal law requires a pharmacist to be on-site for a survey to be performed. P. Br. at 2.

Petitioner asserts that federal law is silent on the on-site inspection issue, other than for the language at supplier standard eight. Petitioner asserts, however, that the Florida Administrative Code at 64B16-28.101, "Prescription Area Accessible to Inspection," states:

> (1) The prescription department compounding room or any other place where prescriptions are . . . filled . . . dispensed . . . shall be so situated and located that authorized agents and employees of the Department or other persons authorized by law to enter and inspect, can observe and survey the confines of said department, room or area and can enter into said department . . . for the purposes of inspection at a reasonable hour or when the practice of the profession of pharmacy is being carried on . . . without having been previously detained or announced."

P. Ex. 3; P. Br. 6. Petitioner asserts that, pursuant to Florida law, the NSC investigator thus had the authority to perform the inspection regarding the drugs and pharmaceuticals and the many other items and services provided by Petitioner not required to be dispensed by a registered pharmacist and provided outside the confines of the prescription department. Petitioner echoes the Administrator's comment that on February 12, 2008, a state inspection for compliance with Board of Pharmacy regulations passed Petitioner without a single deficiency. P. Ex. 4.

That Petitioner passed a Board of Pharmacy inspection after January 16, 2008 is irrelevant with regard to whether, on the two visits in question, it was in compliance with supplier standards. Compliance at a later date does not prove compliance with participation requirements at the time of the attempted inspections. Moreover, Petitioner's argument that the inspector could have performed an inspection in the absence of the pharmacist either at a reasonable hour or when the profession of pharmacy is being carried on (P. Br. at 6) is curious in light of the fact that its own Administrator submitted a sworn affidavit that he was prohibited from opening the prescription department to allow a non-pharmacist in the area without the pharmacist being on site. Moreover, the pharmacy employees the site inspector encountered were apparently not

willing to have an inspection done without the pharmacist present. CMS Ex. 4 at 6. While the Florida law cited by Petitioner would allow an inspection, it does not compel the federal site inspector to conduct an inspection under these circumstances where, in the absence of the pharmacist, the inspection cannot be completed. Petitioner also asserts that although Florida law requires Petitioner to be open 40 hours and 5 days a week, it does not specify what those hours might be. *See* P. Br. at 5-6. However, Petitioner chose to post its business hours as from 9:00 a.m. to 5:00 p.m. Monday through Friday, and it was required to be open those hours. If not, a sign should have been placed letting people know when the pharmacist was out and when he would return. Petitioner did not do so.

Petitioner also asserts that NSC's action is in violation of the Fifth and Fourteenth Amendments to the United States Constitution. P. Br. at 7-8. Petitioner asserts that in an unnamed case where a pharmacist was not on-site during an NSC inspection attempt the NSC did not revoke the supplier number but allowed the provider to provide documentation explaining the deficiency. P. Ex. 5. Even if I had the authority to decide Constitutional issues (which I do not), the facts of the case cited by Petitioner are not analogous to the case here. That case involves a different supplier standard, standard one (42 C.F.R. § 424.57(c)(1)), which references whether a supplier operates its business and furnishes Medicare-covered items in compliance with applicable federal and state licensure and regulatory requirements. Specifically, that case concerned whether the company involved had a current Florida Medical Oxygen Retailer license, or specific proof that oxygen was only being dispensed as a drug by the pharmacist. *Id*.

Petitioner also asserts that the NSC site investigation form, CMS Ex. 4, refers only to DME, and the only question on the form requiring the NSC inspector to do something is for the inspector to view the prescription department area and that has nothing to do with drugs and pharmaceuticals. Petitioner asserts the measure of the pharmacy's compliance should be a Florida inspection form, not the NSC site investigation form. P. Br. at 8. As Petitioner's employees did not want the site inspector to inspect in the absence of the pharmacist, this is a moot point. However, as sworn to by Petitioner's Administrator, the site inspector was precluded from even viewing the prescription area in the absence of the pharmacist.

Finally, Petitioner asserts that it was "operational" in that it had a qualified physical practice location at 907 SW 87th Avenue, Miami, was open to the public from Monday through Friday, 9:00 a.m. to 5:00 p.m., submitted valid Medicare claims, is now properly staffed and had been staffed in January 2008 to provide pharmacists 40 hours a week and five days a week, and was properly equipped and stocked. P. Br. at 9. However, during the two site visits, Petitioner was not properly staffed, and the pharmacy was not fully open for business as anything requiring dispensing by a pharmacist could not be dispensed. If the pharmacy was not open during lunch without posted explanation, or opened at a later time than the hours of operation posted on the door without posted explanation, Petitioner was not operational on those days.

V. Conclusion

Based on my review of all the evidence and arguments advanced by the parties, and for the reasons discussed above, I affirm the revocation of Petitioner's supplier number.

/s/
Alfonso J. Montaño
Administrative Law Judge