

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Shree Pharmacy, Inc.

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-711

Decision No. CR3015

Date: November 27, 2013

DECISION

Palmetto GBA National Supplier Clearinghouse (NSC), an administrative contractor acting on behalf of the Centers for Medicare & Medicaid Services (CMS), revoked the Medicare supplier number and billing privileges of Petitioner, Shree Pharmacy, Inc., a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). NSC determined that Petitioner was not in compliance with 42 C.F.R. § 424.57(c)(7), which requires suppliers to maintain an operational physical location that is accessible to the public, Medicare beneficiaries, the government, and its inspectors. Petitioner appealed. CMS argues the revocation was proper and requests summary judgment to affirm it. For the reasons stated below, I grant CMS's motion for summary judgment.

I. Background and Procedural History

Petitioner was enrolled in the Medicare program as a DMEPOS supplier. During the fall of 2012, it is undisputed that Petitioner's physical address of record was 1624 W. Montrose Ave., Chicago, Illinois. CMS Exhibit (Ex.) 1, at 2; Petitioner's Exhibit (P. Ex.) 1, at 8. An NSC compliance inspector working on behalf of CMS attempted to conduct site inspections at Petitioner's location on Monday, September 24, 2012, at

approximately 12:10 p.m., and on Friday, October 19, 2012, at approximately 12:47 p.m. CMS Ex. 1, at 2.

According to CMS, at the time of the first site inspection, the NSC inspector observed the words “Pharmacy” and “Medical Center” on the entrance door to Petitioner’s location. CMS Exs. 2, 8. On the left of the entrance door, closer to the word “Pharmacy” than “Medical Center,” there was a sign that posted hours of operation as 12:00-6:00 p.m. Monday and Tuesday, closed on Wednesday, 12:00-7:00 p.m. on Thursday and Friday, and 12:00-5:30 p.m. on Saturday. CMS Br. at 3; CMS Ex. 1, at 3. There were no other operating hours posted on the entrance door or any other observable indication that the pharmacy and the medical center had separate hours of operation. The door to the building was locked and no person answered when the NSC inspector knocked, and no person answered the phone when the NSC inspector called. CMS Ex. 1, at 7; CMS Ex. 8. The NSC inspector returned on Friday, October 19, 2012, to attempt a site inspection and was again unable to complete the site inspection because the building was closed. CMS Ex. 8.

On November 5, 2012, NSC sent a letter notifying Petitioner that its supplier number was revoked, retroactive to October 19, 2012, the date of the second attempted site inspection, when CMS determined that Petitioner’s practice location was not operational. CMS Ex. 4, at 1. NSC barred Petitioner from re-enrolling in the Medicare program for two years from October 19, 2012. CMS Ex. 4, at 1. The notice letter explained that the basis for Petitioner’s revocation was because Petitioner was closed during its posted hours of operation on September 24, 2012, and October 19, 2012, when a NSC inspector attempted to complete site inspections to verify Petitioner’s compliance with supplier standards. CMS Ex. 4, at 2. The notice letter further informed Petitioner of its right to request reconsideration of the revocation determination within 60 days of the postmark of the notice. CMS Ex. 4, at 2.

On December 4, 2012, Petitioner requested that NSC reconsider its revocation decision. Petitioner disagreed with CMS’s revocation determination and asserted:

That on both occasions, September 24, 2012 and October 19, 2012 the pharmacy was open to the public during its posted hours of operation. Within the medical building that the pharmacy is located, there are two separate hours posted in the building entryway, both for the clinic, and the pharmacy. The hours of operation for both practices are different. The pharmacy posted hours are 1:30 p.m. - 9:30 p.m. Monday, Tuesday, Thursday and Friday and Saturday from 12:00 p.m.-8:00 p.m.

CMS Ex. 5, at 1-2.

Petitioner also included three affidavits from individuals who asserted that they were present and working at the pharmacy on September 24, 2012 and October 19, 2012. CMS Ex. 5, at 3-5.

On February 22, 2012, NSC issued a reconsideration decision affirming the revocation. The hearing officer stated that NSC was authorized to perform revalidation site inspections in order to verify the information that NSC had on file for suppliers and to confirm compliance with all supplier standards. CMS Ex. 7, at 2. The hearing officer observed that the NSC inspector's photographs of the entrance to the building at 1624 W. Montrose Ave., Chicago, Illinois, do not show separate hours of operation for the pharmacy and the medical center and that the posted hours are closer to the sign for the pharmacy than to the sign for the medical center. CMS Ex. 7, at 3. The hearing officer also noted that because the door was locked at the time of both attempted site visits, there was no method of determining if additional hours were posted inside of the building. CMS Ex. 7, at 3. The hearing officer concluded that the pharmacy was closed during its posted hours of operation on the dates of the attempted inspections and that the NSC inspector was unable to verify compliance with supplier standards and, thus, affirmed the revocation.

Petitioner filed a request for a hearing with the Departmental Appeals Board, Civil Remedies Division, by letter dated April 15, 2013. The case was assigned to me, and I issued an Acknowledgment and Pre-hearing Order (Pre-hearing Order). In accordance with my May 2, 2013 Pre-hearing Order, CMS timely filed its pre-hearing exchange, consisting of a motion for summary judgment and brief (CMS Br.), along with eight proposed exhibits, CMS Exs. 1-8. Petitioner then filed its pre-hearing exchange, which included a response brief (P. Br.) and three proposed exhibits, P. Exs. 1-3. Because neither party objected to any of the proposed exhibits, I admit them all to the record.

The Pre-hearing Order also advised the parties that they must submit written direct testimony for each proposed witness and that an in-person hearing would only be necessary if the opposing party requested an opportunity to cross-examine a witness. Pre-hearing Order ¶¶ 8, 9, and 10; *Vandalia Park*, DAB No. 1940 (2004); *Pacific Regency Arvin*, DAB No. 1823, at 8 (2002) (holding that the use of written direct testimony for witnesses is permissible as long as the opposing party has the opportunity to cross-examine those witnesses). CMS listed one witness and submitted an affidavit of written direct testimony for this witness. CMS Ex. 8. Petitioner did not request cross examination. Petitioner did not list any proposed witnesses and filed one affidavit of Dilip N. Desai, RPh. P. Ex. 3. CMS did not request to cross-examine Mr. Desai. I find, therefore, that an in-person hearing in this case is unnecessary.

II. Applicable Law

To receive Medicare payments for items furnished to a Medicare-eligible beneficiary, the Secretary of the U.S. Department of Health and Human Services must issue a supplier billing number to a DMEPOS supplier.¹ Social Security Act (Act) § 1834(j)(1)(A); 42 U.S.C. § 1395m(j)(1)(A). To receive direct-billing privileges, a DMEPOS supplier must also meet and maintain the Medicare application certification standards set forth in 42 C.F.R. § 424.57(c). Among other requirements, a DMEPOS supplier must permit CMS or its agent to conduct on-site inspections to ascertain supplier compliance with the Medicare enrollment standards. 42 C.F.R. § 424.57(c)(8). In addition, a DMEPOS supplier must be in a location accessible to the public and CMS and must be accessible and staffed during posted hours of operation. 42 C.F.R. § 424.57(c)(7)(i)(B),(C). Moreover, the supplier must maintain a permanent visible sign in plain view, and, if the supplier's place of business is located within a building complex the sign must be visible at the main entrance of the building, or the hours can be posted at the entrance of the supplier. 42 C.F.R. § 424.57(c)(7)(i)(D). A supplier must also be "operational," which means it "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.

CMS will revoke a currently-enrolled Medicare supplier's billing privileges if CMS or its agent determines that the supplier is not in compliance with any supplier enrollment standard. *See* 42 C.F.R. § 424.57(d); *A to Z DME, LLC*, DAB No. 2303, at 3 (2010); *see also 1866ICPayday.com*, DAB No. 2289, at 13 (2009) ("[F]ailure to comply with even one supplier standard is a sufficient basis for revoking a supplier's billing privileges."). If an on-site inspection reveals that a supplier is no longer operational, or otherwise fails to meet one of the supplier standards, CMS may revoke the supplier's Medicare billing privileges. 42 C.F.R. § 424.535(a)(5)(ii). Suppliers who have had their billing privileges revoked "are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar," which is "a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation." 42 C.F.R. § 424.535(c). The effective date of revocation is the date that CMS determined the supplier was no longer operational. *See* 42 C.F.R. § 424.535(g).

¹ Petitioner, as a supplier of DMEPOS, is considered a "supplier" for Medicare purposes. *See* 42 C.F.R. § 498.2 (definition of "Supplier").

III. Analysis

A. Issue

The issue in this case is whether CMS is entitled to summary judgment on the grounds that the undisputed evidence establishes CMS had a legitimate basis to revoke Petitioner's Medicare enrollment and billing privileges, effective October 19, 2012.

B. Applicable Standard

Summary judgment is appropriate when a case presents no issue of material fact, and its resolution turns on questions of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *Livingston Care Ctr. v. U. S. Dep't of Health and Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004); *see also Illinois Knights Templar Home*, DAB No. 2274, at 3-4 (2009) (*citing Kingsville Nursing Ctr.*, DAB No. 2234, at 3-4 (2009)). The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Ctr.*, 388 F.3d at 173 (*quoting Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); *see also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing and Rehab. Ctr.*, DAB No. 1918 (2004).

To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs but must furnish evidence of a dispute concerning a material fact. *Illinois Knights Templar*, DAB No. 2274, at 4; *Livingston Care Ctr.*, DAB No. 1871, at 5 (2003). In examining the evidence to determine the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *See Brightview Care Ctr.*, DAB No. 2132, at 2, 9 (2007); *Livingston Care Ctr.*, 388 F.3d at 168, 172; *Guardian Health Care Ctr.*, DAB No. 1943, at 8 (2004); *but see Cedar Lake*, DAB No. 2344, at 7 (2010); *Brightview*, DAB No. 2132, at 10 (noting entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). Also, the role of an administrative law judge (ALJ) in deciding a summary judgment motion differs from the ALJ's role in resolving a case after a hearing. The ALJ should not assess credibility or evaluate the weight of conflicting evidence. *Holy Cross Vill. at Notre Dame*, DAB No. 2291, at 4-5 (2009).

C. Findings of Fact and Conclusion of Law

1. CMS had legitimate basis to revoke Petitioner's Medicare enrollment because an NSC inspector was not able to access Petitioner's location, on September 24, 2012 and October 19, 2012, during the sole posted hours of operation.

In summary, CMS contends that Petitioner was not open and accessible during the sole posted business hours outside of Petitioner's entrance door, which were 12:00-6:00 p.m. on Monday, September 24, 2012 and 12:00-7:00 p.m. on Friday, October 19, 2012. CMS argues that while Petitioner asserts that different hours were posted inside of the building, Petitioner's business could not be accessed for the NSC inspector to see whether a sign was posted, as the outside door was locked, when NSC attempted a site inspection. CMS argues that the signage on the exterior of the building at 1624 W. Montrose Avenue, Chicago, Illinois, suggests that the posted hours are Petitioner's hours and it was reasonable for the NSC inspector and the public to reach this conclusion. CMS Br. at 6. CMS believes the site inspector reasonably concluded, based upon available evidence, that Petitioner was not open to the public and accessible during its posted hours of operation. Thus, CMS argues that Petitioner's Medicare billing privileges were properly revoked and summary judgment is appropriate.

Petitioner argues it has come forward with specific facts to overcome the CMS motion and summary judgment should be denied and Petitioner's revoked Medicare supplier number should be reinstated. P. Br. at 1-2. Petitioner does not dispute that on Monday, September 24, 2012, at approximately 12:10 p.m., and on Friday, October 19, 2012, at approximately 12:47 p.m., the pharmacy was closed and locked, with no staff on site when the NSC inspector visited the premises. P. Br. at 3. However, Petitioner argues the NSC inspector improperly inferred that the posted hours outside of the building at 1624 W. Montrose Avenue reflected Petitioner's actual hours of operation. Instead, Petitioner states that the hours posted outside reflect the hours of operation for only the medical clinic which is also located inside the building. P. Br. at 2. Petitioner states that it posted separate hours outside of its entrance within the clinic building, which the inspector could not access on September 24th at 12:10 p.m. and October 19th at 12:47 p.m. P. Br. at 2; P. Exs. 2, 3; CMS Ex. 5, at 2. Petitioner further argues that on August 1, 2011, Petitioner's authorized official signed and submitted to CMS a Medicare enrollment application indicating hours of operation of Monday 1:30-8:30 p.m., Tuesday 1:30-8:30 p.m., Wednesday Closed, Thursday 1:30-8:30 p.m., Friday 1:30-8:30 p.m., and Saturday 1:30-8:00 p.m. P. Ex. 1, at 16. Petitioner believes that the NSC inspector's reliance on a sign posted on the entrance to 1624 W. Montrose Ave., Chicago, Illinois, rather than the hours of operation stated on Petitioner's previously submitted Medicare enrollment application, was not reasonable and Petitioner's Medicare enrollment was erroneously revoked.

On summary judgment, I will not make credibility determinations, weigh the evidence, or decide which inferences to draw from the evidence, as would be done when finding facts after a hearing on the record. Rather, I will construe the evidence in a light most favorable to the non-movant and avoid deciding which version of the facts is more likely true. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291, at 5. Moreover, I will apply the plain meaning of the regulatory text to the facts in this case. The regulation at 42 C.F.R. § 424.57(c)(7)(i)(D) states that the supplier must maintain “a permanent visible sign in plain view” and post hours of operation. If the supplier’s place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the supplier. 42 C.F.R. § 424.57(c)(7)(i)(D). In addition, a DMEPOS supplier must be in a location accessible to the public, Medicare beneficiaries, CMS, NSC, and its agents, and must be accessible and staffed during posted hours of operation. 42 C.F.R. § 424.57(c)(7)(i)(B),(C). The regulation also notes that the location must not be in a gated community or other area where access is restricted. 42 C.F.R. § 424.57(c)(7)(i)(B). Petitioner does not dispute that the only hours posted outside the entrance door near the word “pharmacy” at 1624 W. Montrose Avenue in Chicago were 12:00-6:00 p.m. Monday and Tuesday, closed on Wednesday, 12:00-7:00 p.m. on Thursday and Friday, and 12:00-5:30 on Saturday. CMS Ex. 1, at 3; P. Br. at 2. Petitioner also does not dispute that on Monday, September 24, 2012, at approximately 12:10 p.m., and on Friday, October 19, 2012, at approximately 12:47 p.m., the entrance door to 1624 W. Montrose Avenue was closed and locked and no staff was present on site. P. Br. at 2-3. Further, Petitioner does not dispute that the NSC inspector was “denied access” to the “clinic building” on both of the dates the NSC inspector attempted to conduct a site inspection at Petitioner’s business. P. Br. at 2.

For purposes of summary judgment, I will infer that Petitioner posted separate hours of operation outside of a door within the clinic building and disclosed these hours of operation to CMS, as Petitioner alleges. However, the fact remains that the “permanent visible sign in plain view” near the entrance door which could be accessed by the public, Medicare beneficiaries, CMS, and NSC listed hours of operation of 12:00-6:00 p.m. on Mondays and 12:00-7:00 p.m. on Fridays. CMS Exs. 2, 8. Although Petitioner contends that the pharmacy had different hours of operation, Petitioner undisputedly did not post these hours outside the main entrance door near the exterior signage for the business, and the NSC inspector could not gain access to the pharmacy to ascertain whether Petitioner had posted separate hours of operation, or whether Petitioner was in fact operational. Additionally, any Medicare beneficiary who may have tried to access Petitioner’s business at the same times as the inspector would not have had any notice of a different set of hours for the pharmacy posted beyond the locked doors of the medical center.

I find Petitioner did not maintain all the Medicare supplier standards set forth in 42 C.F.R. § 424.57(c) because Petitioner was not accessible to the public, Medicare beneficiaries, and NSC, and it was not staffed during its posted hours of operation on two separate occasions. On Monday, September 24, 2012, and on Friday, October 19, 2012,

during the posted hours of operation, NSC was unable to conduct an on-site inspection, in accordance with 42 C.F.R. § 424.57(c)(8), of Petitioner because the main entrance door at 1624 W. Montrose Avenue in Chicago was locked and no staff was present. After evaluating the submissions of both parties, I determine that this case presents no genuine issues of material fact and grant CMS's motion for summary judgment on the grounds that Petitioner was not operational within the meaning of 42 C.F.R. §§ 424.57(c)(7),(8) and 424.502 and that CMS had the authority to revoke Petitioner's Medicare supplier number and billing privileges pursuant to 42 C.F.R. §424.535(a)(5)(ii) effective October 19, 2012.

/s/

Joseph Grow
Administrative Law Judge