Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Southeastern Orthotics and Prosthetics, Inc.
(Supplier No. 0130020002),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-315

Decision No. CR3208

Date: April 23, 2014

DECISION

Palmetto GBA National Supplier Clearinghouse (NSC), an administrative contractor for the Centers for Medicare & Medicaid Services (CMS) revoked the Medicare enrollment and billing privileges of Southeastern Orthotics and Prosthetics, Inc. (Petitioner) after it determined Petitioner did not comply with the enrollment requirements for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Petitioner requested reconsideration. An NSC hearing officer upheld the revocation of Petitioner's enrollment, citing Petitioner's noncompliance with 42 C.F.R. § 424.57(c)(7) (Supplier Standard 7). Petitioner then requested a hearing before an administrative law judge.

As explained more below, I find that Petitioner was not in compliance with the requirement at 42 C.F.R. § 424.57(c)(7) during two attempted on-site inspections. NSC, acting on behalf of CMS, was authorized to revoke Petitioner's Medicare enrollment. However, because NSC premised its reconsidered determination only on Petitioner's violation of Supplier Standard 7, I must modify the effective date of revocation to October 1, 2013. 42 C.F.R. § 424.57(d). Petitioner is, therefore, eligible to submit claims for payment of services rendered to Medicare program beneficiaries through September 30, 2013.

I. Background and Procedural History

Petitioner is located in Cleveland, Tennessee, and had been enrolled in the Medicare program as a DMEPOS supplier. As such, Petitioner was subject to a variety of rules, including the DMEPOS Supplier Standards in 42 C.F.R. § 424.57, and other requirements in 42 C.F.R. Part 424, subpart P. In order to verify compliance with these requirements, NSC attempted on-site reviews of Petitioner's location on Tuesday, July 16, 2013, at 2:08 p.m., and Tuesday, August 6, 2013, at 1:06 p.m. CMS Exhibit (Ex.) 1. On both occasions, the inspector found Petitioner's doors were locked and "dark curtains were pulled closed." CMS Ex. 1, at 6. The hours of operation posted on Petitioner's front door stated it was open from 1:00 p.m. to 5:00 p.m. on Tuesdays, from 8:00 a.m. to 5:00 p.m. on Thursdays, "By Appointment" on Mondays and Wednesdays, and closed on Fridays. CMS Ex. 1, at 7-8.

By letter dated September 16, 2013, NSC notified Petitioner that its Medicare enrollment and billing privileges were being revoked "pursuant to 42 CFR §§ 405.800, 424.57(e), 424.535(a)(1), 424.535(a)(5)(ii), and 424.535(g)," effective August 6, 2013, the date of the second attempted on-site inspection. CMS Ex. 2, at 1. NSC also imposed a two-year bar on Petitioner's re-enrollment in the Medicare program. NSC stated that Petitioner was noncompliant with Supplier Standard 7 because during the two attempted on-site inspections, Petitioner "was closed during your posted hours of operation." CMS Ex. 2.

On September 20, 2013, Petitioner requested reconsideration and submitted a corrective action plan (CAP). CMS Ex. 3. Petitioner clarified that on days when patients are not being seen, a "single clerical staff person" worked inside. CMS Ex. 3, at 2. Petitioner explained that to "ensure safety of this employee, the front door is locked when patients are not being seen." CMS Ex. 3, at 2. The clerical staff member also "closes the office mid-day for lunch." CMS Ex. 3, at 2. Petitioner also stated that it sees all patients "by appointment," and that actual hours of operation were 8:00 a.m. to 5:00 p.m., Monday through Thursday, as provided in its Medicare enrollment application. CMS Ex. 3, at 2. Petitioner stated that it would install a bell near the front door to alert staff to visitors and would post a sign on the front door when staff was out to lunch. CMS Ex. 3, at 3.

On October 25, 2013, NSC issued its reconsidered determination, which affirmed the revocation of Petitioner's billing privileges effective August 6, 2013. CMS Ex. 4. The hearing officer noted the discrepancy between the posted hours of operation and those stated in Petitioner's reconsideration request, but restated the site inspector's findings that the "facility was not open during posted hours of operation." CMS Ex. 4, at 2-3. The hearing officer also noted that Petitioner "was not afforded the rights to [a CAP], but rather a reconsideration request." CMS Ex. 4, at 3. The hearing officer went on to cite various regulatory provisions including the right of CMS to conduct on-site inspections and the definition of "operational." CMS Ex. 4, at 3. Ultimately, the hearing officer

concluded that "the facility location on record with the NSC was not open during posted hours of operation therefore the site inspector was unable to verify compliance with the supplier standards." CMS Ex. 4, at 3-4. The hearing officer found that Petitioner had not shown compliance with Supplier Standard 7. CMS Ex. 4, at 4.

On November 13, 2013, Petitioner filed a request for hearing (RFH) challenging the revocation of its enrollment. Petitioner again explained its hours of operation, namely that it is open from 8:00 a.m. to 5:00 p.m. on Monday through Thursday, but closed on Fridays. RFH at 1. Petitioner acknowledged that its "signage needed to be improved to clarify its hours of operation and we needed to ensure we have a failsafe mechanism for individuals to make their presence known who wish to enter this facility." RFH at 3. Pursuant to my Acknowledgment and Pre-hearing Order (Pre-hrg. Order), CMS filed its motion for summary judgment and supporting brief (CMS Br.) as well as six proposed exhibits (CMS Exs. 1-6). Petitioner, acting through its owner,[1] filed its "Petition for Hearing and Judgment" and supporting brief (P. Br.), which opposed summary judgment, as well as eight proposed exhibits (P. Exs. 1-8).[2] CMS subsequently filed a reply brief (CMS Reply).

II. Issues

This case presents the following issues:

1. Whether summary judgment is appropriate;

2. Whether NSC was authorized to revoke Petitioner's Medicare enrollment and billing privileges pursuant to 42 C.F.R. § 424.57; and

3. If NSC was authorized to revoke Petitioner's Medicare enrollment and billing privileges, whether NSC's basis for revocation supports a retroactive effective date for that revocation.

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[1] At one point during this proceeding (after Petitioner filed its hearing request, but prior to Petitioner filing its pre-hearing exchange), Petitioner obtained counsel. The attorney soon filed a Motion to Withdraw as counsel for Petitioner, citing the decision of Petitioner's owner to terminate the representation and to proceed without an attorney.

[2] Petitioner requested leave to file its pre-hearing exchange late due to severe winter weather and icy conditions in its region on the date its exchange was due. CMS did not oppose this request. I find Petitioner has demonstrated good cause for filing its pre-hearing exchange late and I will consider it as though it had been timely submitted.

III. Evidentiary Rulings

Because Petitioner did not object to the admission of CMS Exs. 1-6, I admit them into the record.

In its reply brief, CMS objected to admission of P. Exs. 1-8 as "new evidence" precluded under 42 C.F.R. § 498.56(e) absent a showing of good cause. CMS Reply at 3-4. I note that P. Ex. 1 and P. Ex. 3 are duplicative and need not be admitted for me to consider them. P. Ex. 1 is NSC's initial determination, previously offered as CMS Ex. 2. P. Ex. 3 is NSC's October 25, 2013 reconsidered determination, previously offered as CMS Ex. 4. Therefore, I do not admit P. Ex. 1 or P. Ex. 3.

P. Ex. 2 contains Petitioner's RFH, which is already part of the record as the initial pleading in this case, as well as several photographs that allegedly show Petitioner's current compliance with the standards in 42 C.F.R. § 424.57(c). *See* P. Ex. 2, at 4-7. The photographs demonstrate that Petitioner followed-through with its proposed CAP, but those photographs were apparently not submitted to NSC with Petitioner's reconsideration request. Petitioner has not offered any explanation as to why it did not provide these photographs to the contractor, and has not demonstrated any reason, let alone good cause, for admitting them at this level of review. *See* 42 C.F.R. §§ 405.803(e), 498.56(e)(1); Pre-hrg. Order ¶ 6. Moreover, these photographs are not relevant to whether Petitioner was compliant with Supplier Standard 7 at the time of the on-site inspections. Therefore, I do not admit P. Ex. 2. However, Petitioner's RFH remains part of the record that I consider in reaching this decision.

P. Ex. 4 contains the electronic "time records" of the employee that Petitioner alleges was present at the time of the attempt on-site inspections. Petitioner acknowledges that it did not submit these documents to NSC with its request for reconsideration. P. Br. at 3 (unnumbered). Petitioner explains that it has offered this new evidence for the first time at this level of review "to provide clarification of our intent to meet the needs of patients, including Medicare beneficiaries at this site location." P. Br. at 3. Petitioner's explanation implies that the presence of the employee behind locked doors and closed curtains demonstrated it was able to "meet the needs of patients." However, Petitioner's explanation also suggests that these documents were submitted for the first time at this level due to a strategic error in omitting them at the reconsideration level. Providing additional documents for "clarification" of an issue addressed in the initial determination is not good cause for the admission of those documents when they are presented for the first time at this level of review. Petitioner's offers no reason why these documents were not or could not have been produced to the contractor with its reconsideration request. Therefore, this evidence is precluded by regulation. I do not admit P. Ex. 4. *See* 42 C.F.R. §§ 405.803(e), 498.56(e)(1); Pre-hrg. Order ¶ 6.

P. Exs. 5–8 are declarations of various staff members and other individuals directly related to Petitioner's operations. The regulatory provision that precludes the admission of new evidence presented for the first time at this level of review (absent a showing of good cause) limits that preclusion to "documentary evidence," not testimonial evidence. *See* 42 C.F.R. § 498.56(e)(1). Therefore, because P. Exs. 5–8 represent testimonial evidence not subject to exclusion, I admit them into the record. *See Arkady B. Stern, M.D.*, DAB No. 2329 at 4 n.4 (2010) ("Testimonial evidence that is submitted in written form in lieu of live in-person testimony is not 'documentary evidence' within the meaning of 42 C.F.R. § 498.56(e) . . . .").[3]

IV. Decision on the Written Record

As mentioned above, Petitioner has offered the affidavits of several employees, one of which, when viewed in a light most favorable to Petitioner, raises a dispute about whether the NSC inspector actually attempted a site inspection on either day in question. *See* P. Ex. 8. In that affidavit, the employee that was apparently inside Petitioner's office on both days the NSC inspector attempted to gain entry stated that she did "not recall seeing anyone that I did not invite into the office those days." P. Ex. 8, at 1. She asserts that "it is very easy to observe events that are taking place outside because of the translucent quality of the material from which [the window blinds] are made." P. Ex. 8, at 2. Even though Petitioner stated in its brief that it did not dispute that NSC attempted two on-site inspections or that its door was locked on both days of the attempted inspections and it was "not being answered by [Petitioner's] staff member," the contents of that declaration, when viewed in a light most favorable to Petitioner, establish a dispute as to whether the NSC inspector actually attempted to gain entry to Petitioner's office or whether she knocked upon finding Petitioner's door locked. To set aside the declaration of Petitioner's employee and accept the assertions in Petitioner's brief, I must evaluate and weigh the evidence before me. Therefore, I cannot grant summary judgment in favor of CMS.

CMS offered the direct written testimony of the NSC site inspector. CMS Ex. 6. Petitioner offered the direct written testimony of several of its employees. P. Exs. 5-8. Neither party, however, has requested an opportunity to cross-examine any witness. *See* Pre-hrg. Order ¶ 9 ("Petitioner has the right to cross-examine any witness for whom CMS offers written direct testimony. However, I will assume that Petitioner does not wish to cross-examine any proposed CMS witness if Petitioner's brief fails to affirmatively state so."); CMS Reply at 4 ("CMS does not wish to cross-examine any of Petitioner's witnesses."). Therefore, an in-person hearing is not required, and I will issue this decision based on the written record. *See* Pre-hrg. Order ¶¶ 10-11*; see also Vandalia Park*, DAB No. 1940 (2004); *Pacific Regency Arvin*, DAB No. 1823, at 7-8 (2002)

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[3] Administrative decisions cited in this decision are accessible on the internet at: http://www.hhs.gov/dab/decisions/index.html.

(holding that the use of written direct testimony for witnesses is permissible so long as the opposing party has the opportunity to cross-examine those witnesses).

V. Discussion

To participate in the Medicare program and receive payment for services provided to program beneficiaries, a prospective supplier must enroll by completing the applicable enrollment application. *See* 42 C.F.R. §§ 424.57(b)(1), 424.510(a). CMS may perform periodic revalidations and on-site reviews to verify the enrollment information submitted to CMS, determine the supplier's compliance with Medicare enrollment requirements, and determine whether the supplier is operational. 42 C.F.R. §§ 424.510(d)(8); 424.515(c), 424.517(a). The Supplier Standards require a DMEPOS supplier to, among other things, maintain a physical facility on an appropriate site. 42 C.F.R. § 424.57(c)(7). CMS will revoke the enrollment of a DMEPOS supplier if it fails to comply with any of the Supplier Standards stated in 42 C.F.R. § 424.57(c). *See* 42 C.F.R. § 424.57(d).

1. *Petitioner was not accessible during posted hours of operation on Tuesday, July 16, 2013, or on Tuesday, August 6, 2013.*

A supplier of DMEPOS must maintain a "physical facility on an appropriate site," which includes maintaining "a permanent visible sign in plain view and post[ing] hours of operation." 42 C.F.R. § 424.57(c)(7)(i)(D). The supplier must also be "accessible and staffed during posted hours of operation." 42 C.F.R. § 424.57(c)(7)(i)(C). Although the regulations do not define "accessible," its use elsewhere in requirements for DMEPOS suppliers indicates that the regulatory drafters intended "accessible" to mean open with no restriction of entering. For example, the regulations require that a DMEPOS supplier be "in a location that is *accessible* to the public . . . ." 42 C.F.R. § 424.57(c)(7)(i)(B) (emphasis added). The regulation clarifies that the location "must not be in a gated community or other restricted area where access is restricted." *Id.* The clarification in section 424.57(c)(7)(i)(B) of what "accessible" means demonstrates that its regulatory meaning, including in section 424.57(c)(7)(i)(C), is akin to being open with unrestricted access, not merely being "accessible" to those individuals with disabilities. *See* 75 Fed. Reg. 52,629, 52,636 (Aug. 27, 2010) ("[S]uppliers should be *available* during posted business hours." (emphasis added)).

Here, an NSC site inspector attempted to conduct an on-site inspection of Petitioner's location on Tuesday, July 16, 2013 at 2:08 p.m., but found Petitioner's front door locked. CMS Ex. 1, at 6. The NSC inspector photographed the exterior of Petitioner's office, including the front door, a large window next to the door with the window shades drawn, and the posted hours of operation, which, for Tuesdays, read "1:00 PM – 5:00 PM." CMS Ex. 1, at 7. The photographs establish that the NSC inspector was at Petitioner's location. CMS Ex. 1, at 7. However, Petitioner's employee testified that she did not see anyone in the parking lot on the day of the first attempted inspection. P. Ex. 8, at 1. The

employee also suggests that she "may have been away for lunch" at the time of the inspection, which undercuts any inference that the employee would have seen the inspector in the parking lot at the time of the inspection. *See* P. Ex. 8, at 1. The site inspector testified that she knocked on the door, but no one answered. CMS Ex. 6, at 1 ¶ 5; *see* P. Br. at 2. The inspector also reported that she observed an "older couple" attempting to enter Petitioner's office, but they could not do so because the door was locked. CMS Ex. 6, at 1 ¶ 4. I accord less weight to the claim of Petitioner's employee than to the NSC's documented efforts to conduct a site visit on that date.

The NSC inspector attempted to conduct a second on-site inspection of Petitioner's location on Tuesday, August 6, 2013 at 1:06 p.m., but again found Petitioner's front door locked. CMS Ex. 1, at 6. The NSC inspector photographed the exterior of Petitioner's office, including the front door, the large window next to the door with the window shades drawn, and the posted hours of operation, which were unchanged from the first attempted inspection. CMS Ex. 1, at 7. Again, the inspector knocked "loudly enough for anyone inside to hear," but no one answered. CMS Ex. 6, at 2 ¶ 10. Petitioner concedes that the employee who should have been inside at the time of this inspection was not in the office, but on her lunch break. P. Br. at 4.

The evidence establishes that Petitioner was not accessible on either Tuesday, July 16, 2013 at 2:08 p.m., or Tuesday, August 6, 2013 at 1:06 p.m., both of which were within Petitioner's posted hours of operation.[4] Its door was locked and unanswered. There was no way for the NSC inspector, or any other member of the general public, to gain access to Petitioner's facility at those times. Even accepting that on August 6, 2013, Petitioner's employee was on a lunch break during the attempted site visit, the office's posted hours of operation did not indicate that the office would be closed for that lunch break. *See Ita Udeobong, d/b/a Midland Care Med. Supply & Equip.*, DAB No. 2324, at 6-7 (2010). A supplier may not close, even temporarily, during its posted hours of operation. *Complete Home Care Inc.*, DAB No. 2525, at 5 (2013). Petitioner, therefore, did not comply with Supplier Standard 7 (42 C.F.R. § 424.57(c)(7)) on either occasion.

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[4] As noted in NSC's reconsidered determination, there is a discrepancy between Petitioner's hours of operation as stated in its initial enrollment application and those actually posted on Petitioner's door. In its application, Petitioner stated its hours of operation were Monday through Thursday, from 8:00 a.m. to 5:00 p.m., but the posted hours were only Tuesday from 1:00 p.m. to 5:00 p.m. and Thursdays from 8:00 a.m. to 5:00 p.m., with Monday and Wednesday being "By Appointment." *Compare* CMS Ex. 5 *with* CMS Ex. 1, at 7. The applicable regulation refers to the "posted hours of operation." 42 C.F.R. § 424.57(c)(7)(i)(C). In any event, this discrepancy is ultimately not material to the outcome because both attempted site inspections were during Petitioner's hours of operations under either its reported hours in the enrollment application or its posted hours of operation.

Petitioner claims that its employee was supposed to open the door for individuals with appointments and other visitors, which notably did not happen during either attempted inspection. P. Br. at 3. Petitioner's employee states that locking the front door was implemented as a safety measure because she had an earlier traumatic encounter with a psychiatric patient. P. Ex. 8, at 1. However, even with the employee present to unlock the door for individuals with appointments, Petitioner was still not "accessible" because Petitioner's locked-door approach represented a restricted form of access contrary to the plain meaning of Supplier Standard 7. The fact that the NSC inspector twice attempted to access Petitioner's location but could not do so sufficiently demonstrates the restricted access Petitioner's approach caused. While it is understandable that Petitioner sought to protect its employee, it needed to do so in a manner that ensured that it was accessible during normal posted hours of operation. Because Petitioner did not provide that access, it violated Supplier Standard 7 and subjected itself to revocation.

2. ***CMS was authorized to revoke Petitioner's Medicare enrollment pursuant to 42 C.F.R. § 424.57(d) because Petitioner was not in compliance with Supplier Standard 7 (42 C.F.R. § 424.57(c)(7)) at the time of two attempted on-site inspections.***

CMS will revoke the Medicare enrollment if a supplier of DMEPOS "is found not to meet the standards in paragraphs (b) and (c) of this section." 42 C.F.R. § 424.57(d). Subsection (c) provides the Supplier Standards for DMEPOS suppliers. A supplier's "failure to comply with even one supplier standard is a sufficient basis for revoking a supplier's billing privileges." *1866ICPayday.com, LLC*, DAB No. 2289, at 13 (2009).

Petitioner did not meet Supplier Standard 7 at the time of the two attempted on-site inspections. Both inspections were done during Petitioner's posted hours of operation. Petitioner was not accessible because its doors were locked and no one answered when the inspector knocked. Therefore, NSC, acting on behalf of CMS, was authorized to revoke Petitioner's Medicare enrollment pursuant to 42 C.F.R. § 424.57(d).

Petitioner submitted a CAP to NSC in response to the initial determination, but the NSC hearing officer refused to consider it. CMS Ex. 4, at 3 ("[T]he supplier was not afforded the rights to a corrective action plan (CAP), but rather a reconsideration request."). In its hearing request and brief, Petitioner again attempts to demonstrate that it is now compliant with Supplier Standard 7. However, review of a revocation is limited to whether Petitioner was compliant at the time of revocation. *See Whalen Optical Lab, Inc.*, DAB CR2196, at 6 (2010). It is beyond the scope of this review to make a determination about Petitioner's current compliance with the Supplier Standards, and such compliance, even if true, cannot be a basis to reverse the revocation. Also, I have no authority to review the decision not to accept a CAP. *See DMS Imaging, Inc.*, DAB No. 2313 (2010); *see also* 42 C.F.R. § 405.809.

3. *The effective date of the revocation of Petitioner's Medicare enrollment is October 1, 2013, 15 days after NSC sent notice of the revocation, because NSC's reconsidered determination premised the revocation of Petitioner's enrollment only on a violation of Supplier Standard 7.*

NSC's initial determination stated that Petitioner was "not operational" and identified 42 C.F.R. § 424.535(a)(5)(ii) as one of the bases for revocation. Based on this finding, NSC imposed retroactive revocation to August 6, 2013, the date NSC determined that Petitioner was "not operational." CMS Ex. 2. For a revocation action taken pursuant to 42 C.F.R. § 424.535(a)(5), the regulations provide that "the revocation is effective with the date . . . that CMS or its contractor determined that the . . . supplier was no longer operational." 42 C.F.R. § 424.535(g).

However, in the reconsidered determination, NSC did not make any finding that Petitioner was "not operational," but instead relied solely on a violation of Supplier Standard 7 as the basis to revoke Petitioner. CMS Ex. 4. When a revocation is based on a failure to meet any of the Supplier Standards listed in 42 C.F.R. § 424.57(c), then the regulation provides that "revocation is effective 15 days after the entity is sent notice of the revocation." 42 C.F.R. § 424.57(d).

In a provider or supplier enrollment case, it is the reconsidered determination upon which administrative law judge review is predicated. *See Hiva Vakil, M.D.*, DAB No. 2460, at 4-5 (2012) (holding that a supplier cannot obtain administrative law judge review of the initial determination; the supplier may only obtain administrative law judge review when there is a reconsidered determination); *see also* 42 C.F.R. §§ 498.5(l), 498.20(b)(1), 498.24(c), 498.25(b)(2). My review, therefore, is of NSC's reconsidered determination and the basis for revocation stated therein.

Here, NSC issued a reconsidered determination that significantly modified the initial determination's stated reasons for revocation. NSC no longer relied on Petitioner being "not operational" or its noncompliance with 42 C.F.R. § 424.535(a)(5)(ii), but limited its determination expressly to Petitioner's violation of Supplier Standard 7. CMS Ex. 4. NSC defined "operational" in the reconsidered determination, but made absolutely no analysis concerning Petitioner's failure to meet that definition or a finding in that regard.[5] Based on that determination, the effective date for Petitioner's revocation is October 1, 2013, or 15 days from the issuance of the September 16, 2013 initial determination. Petitioner is, from an enrollment perspective, eligible to submit claims for items or services provided to Medicare beneficiaries from August 6, 2013 through September 30, 2013.

[5] Even at this level of review, CMS made one only passing citation in its brief to 42 C.F.R. § 424.535(a)(5)(ii), but never argued that Petitioner was "not operational."

VI. Conclusion

For the reasons explained above, I affirm CMS's determination to revoke Petitioner's Medicare billing privileges. The revocation is effective October 1, 2013.

/s/
Scott Anderson
Administrative Law Judge