Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Advanced Prosthetics, Inc. (NPI: 1447342241) (PTAN: 5778960001),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-876

Decision No. CR4795

Date: February 17, 2017

DECISION

The Centers for Medicare & Medicaid Services (CMS), through an administrative contractor, revoked the Medicare billing privileges of Advanced Prosthetics, Inc. (Advanced Prosthetics or Petitioner). Advanced Prosthetics was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The CMS administrative contractor revoked Advanced Prosthetics based on a failure to meet several DMEPOS supplier standards and because Advanced Prosthetics was not operational. Advanced Prosthetics requested a hearing before an administrative law judge (ALJ) to dispute the revocation. As explained below, I affirm the revocation of Medicare billing privileges. However, because I conclude that Advanced Prosthetics was operational, I modify the effective date of revocation from April 26, 2016 to July 14, 2016.

I. Background

Advanced Prosthetics was established in 2006. Since that time, it has operated out of its facility located at 3540 Duluth Park Lane, Suite 230, Duluth, Georgia. Volley Rice and

his sister Nancy Rice own Advanced Prosthetics equally and are Advanced Prosthetics' only employees. Mr. Rice is a Georgia licensed prosthetist, and provides prosthetics and services to Advanced Prosthetics' customers. Ms. Rice handles administrative matters for Advanced Prosthetics. Petitioner (P.) Exhibit (Ex.) 1 at 1-2; P. Ex. 2 at 1-2.

Advanced Prosthetics was enrolled in the Medicare program as a DMEPOS supplier. On January 22, 2016, a CMS administrative contractor notified Advanced Prosthetics that it needed to revalidate its enrollment and submit a new CMS-855S enrollment application. CMS Ex. 2 at 1-3. In March 2016, Advanced Prosthetics submitted a CMS-855S, in which it: confirmed its Duluth Park Lane address; stated that its hours of operation were Tuesdays through Thursdays from 9:00 a.m. to 5:00 p.m.; indicated that it did not need to have a surety bond; and left blank the portions of the form where ownership information needed to be provided. CMS Ex. 2 at 4-31.

In response to the revalidation enrollment application that Advanced Prosthetics filed, the CMS administrative contractor sent an inspector to conduct a site visit at Advanced Prosthetics' facility. The inspector attempted site visits on April 19, 2016 at 2:40 p.m. and April 26, 2016, at 10:56 a.m.; however, on neither occasion was Advanced Prosthetics open. CMS Ex. 3.

In a June 14, 2016 initial determination, the CMS administrative contractor revoked Advanced Prosthetics' Medicare billing privileges. CMS Ex. 1 at 1-4. The initial determination provided several reasons for revocation:

42 CFR § 424.57(c)(2) . . . [Petitioner] failed to notify the [CMS administrative contractor] regarding ownership and hours of operation. There is currently no owner reported for this company.

42 CFR § 424.57(c)(7) . . . Recently, a representative of the [CMS administrative contractor] attempted to conduct a visit of [Petitioner's] facility on April 19, 2016 and April 26, 2016; however, the visits were unsuccessful because the business was closed during the hours of operation reported to the [CMS administrative contractor]. Per the inspector, there were no hours of operation posted, the door was locked, and a sign was posted on the door that stated [Petitioner was] either at lunch or out seeing a patient. Because we could not complete an inspection of [Petitioner's] facility, we could not verify [Petitioner's] compliance with the supplier standards. Based upon a review of the facts, we have determined that [Petitioner's] facility is not operational to furnish Medicare covered items and services. Thus, [Petitioner is] considered

to be in violation of 42 CFR §§ 424.535(a)(5), all supplier standards as defined in 42 CFR 424.57(c) and pursuant to 424.535(g), the revocation is effective the date CMS determined that [Petitioner was] no longer operational.

42 CFR § 424.57(c)(17) . . . [Petitioner] failed to disclose an owner of this company as required.

42 CFR § 424.57(c)(26) . . . [Petitioner] failed to maintain a valid surety bond as required by law.

CMS Ex. 1 at 1-2. The initial determination specified that the revocation was effective April 26, 2016, the date on which the CMS administrative contractor determined Petitioner was not operational, and that Petitioner was barred from reenrollment in the Medicare program for a two-year period commencing on July 14, 2016. CMS Ex. 1 at 1. Finally, the initial determination stated that Petitioner could file a corrective action plan (CAP) and a request for reconsideration. CMS Ex. 1 at 3.

Advanced Prosthetics filed a CAP and a reconsideration request. CMS Ex. 4. The CMS administrative contractor did not accept the CAP and forwarded the reconsideration request to a hearing officer. On August 25, 2016, the hearing officer issued an unfavorable reconsidered determination upholding all of the bases for revocation stated in the initial determination. CMS Ex. 1 at 5-11.

On September 8, 2016, Advanced Prosthetics requested a hearing before an ALJ. I issued an Acknowledgment and Pre-hearing Order (Order) on September 15, 2016. In response to my Order, CMS filed a motion for summary judgment and a pre-hearing brief, and four exhibits. Petitioner filed a pre-hearing brief that opposed summary judgment and four exhibits. Two of Petitioner's exhibits, P. Exs. 1 and 2, were written direct testimony from Mr. Rice and Ms. Rice. CMS replied to Petitioner's opposition to summary judgment and objected to two of Petitioner's exhibits.

Petitioner sought to amend its witness and exhibit list to include amended written testimony from Mr. Rice and Ms. Rice (P. Exs. 5 and 6) and new written testimony from five witnesses (P. Exs. 7-11). Petitioner also submitted a new exhibit, P. Ex. 12, which showed that Petitioner received accreditation in November 2016. CMS objected to these exhibits as untimely and immaterial.

II. Evidentiary Ruling

Petitioner did not object to any of CMS's exhibits. Therefore, I admit CMS Exs. 1-4 into the record. Order ¶ 7; Civil Remedies Division Procedures (CRDP) § 14(e).

CMS objected to P. Exs. 2, Attachment A, P. Ex. 3, P. Exs. 5-11. For the reasons explained below, I admit into the record P. Ex. 1, P. Ex. 2 at 1-4 and 11-14, P. Exs. 4-11.

CMS objected to P. Ex. 2 at 5-10 (labeled Attachment A) and P. Ex. 3. P. Ex. 2, Attachment A and P. Ex. 3 contain the same documents. The documents are Site Visit Acknowledgments from prior site visits. CMS objected to them because Petitioner did not submit them with its reconsideration request and failed to provide good cause for untimely filing them. CMS also asserted that the documents are irrelevant because they do not pertain to the attempted site visits at issue in this case. Petitioner's position is that these documents should not be subject to the requirement that they be submitted at the reconsideration level because they are CMS documents and CMS has access to them. Petitioner also stated that they are pertinent to this case because they show that CMS never previously had a concern about Petitioner's posted hours of operation. P. Br. at 9-10 n.4.

It is true that providers and suppliers must submit the evidence they wish to use to support their case before an ALJ at the reconsideration stage of the appeal process unless there is good cause for the late submission. 42 C.F.R. §§ 405.803(c), 498.56(e). However, I am uncertain if this rule would apply to CMS documents. I do not need to reach the issue of good cause because I conclude that P. Ex. 2 at 5-10 and P. Ex. 3 are not relevant or material to this case. 42 C.F.R. § 498.60(b). They relate to previous site visits not at issue here; therefore, I sustain CMS's objection to those proposed exhibits.

CMS objected to P. Exs. 5-11. P. Exs. 5 and 6 provide additional testimony from Mr. Rice and Ms. Rice. Petitioner asserts that this additional testimony from Mr. Rice and Ms. Rice is to address concerns raised by CMS regarding a lack of clarity in their prior testimony as to why their facility was closed during the attempted site visits. P. Exs. 7-11 are composed of written direct testimony from five of Petitioner's customers concerning their interaction with Petitioner. Petitioner asserts that these witnesses showed an interest in testifying after the deadline for prehearing exchanges.

I note that written direct testimony is not subject to the requirements in 42 C.F.R. §§ 405.803(c) and 498.56(e) that documents be submitted with the reconsideration request because written testimony is not documentary evidence, but simply testimony that is presented in written form. I overrule CMS's objection. I will permit Petitioner to file this testimony outside of the timeframes in my Order. CMS had sufficient time to object to these witnesses and to seek to cross-examine them. CMS is not prejudiced if I accept their testimony into the record. As discussed in this decision, I also conclude that this testimony contains material information to this case.

CMS objected to P. Ex. 12. This exhibit is a letter from November 17, 2016, indicating that Petitioner has been accredited by the American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc. CMS objected to it as untimely and irrelevant to the issues

in this case. I sustain CMS's objection. Because this letter is dated after Petitioner filed its reconsideration request, there is good cause for a late filing of the exhibit under 42 C.F.R. § 498.56(e). However, Petitioner's accreditation in November 2016 is not relevant and material to attempted site visits in April 2016 and must be excluded. 42 C.F.R. § 498.60(b).

III. Decision on the Record

I deny CMS's motion for summary judgment because there are material facts in dispute in this case.

I directed the parties to submit written direct testimony for each proposed witness. Order ¶ 8. CMS did not submit any written direct testimony. As indicated above, Petitioner submitted written direct testimony for seven witnesses. I advised the parties in my Order that an in-person hearing would only be necessary if the opposing party requested an opportunity to cross-examine a witness. Order ¶ 9 ("I will assume that Petitioner does not wish to cross-examine any proposed CMS witness if Petitioner's brief fails to affirmatively state so."); CRDP § 16(b). Because CMS did not request to cross-examine any of Petitioner's witnesses, I decide this case based on the written record. Order ¶¶ 10-11; CRDP § 19(b), (d).

IV. Issue

Whether CMS had a legitimate basis to revoke Petitioner's Medicare billing privileges.

V. Jurisdiction

I have jurisdiction to decide this issue. 42 C.F.R. §§ 498.3(b)(17), 498.5(*l*)(2); see also 42 U.S.C. § 1395cc(j)(8).

VI. Findings of Fact, Conclusions of Law, and Analysis

My numbered findings of fact and conclusions of law are set forth below in italics and bold.

The Secretary of Health and Human Services (Secretary) has the authority to create regulations that establish enrollment standards for providers and suppliers, and to create supplier requirements for DMEPOS suppliers. 42 U.S.C. §§ 1395m(j)(1)(B)(ii), 1395cc(j). The Secretary promulgated a regulation that requires providers and suppliers to be operational. 42 C.F.R. § 424.535(a)(5). To be "operational," a provider or supplier must be "open to the public for the purpose of providing health care related services" 42 C.F.R. § 424.502.

The Secretary also promulgated regulations establishing DMEPOS supplier standards, which a DMEPOS supplier must meet and maintain. 42 C.F.R. § 424.57(c). The supplier standards state that a DMEPOS supplier must be "open to the public a minimum of 30 hours per week," post its hours of operation, and be "accessible and staffed during posted hours of operation." 42 C.F.R. § 424.57(c)(7)(i), (c)(30)(i).

CMS or its contractors may conduct inspections of a supplier's premises at any time to determine if a supplier is in compliance with Medicare enrollment requirements or the supplier standards. *See* 42 C.F.R. §§ 424.57(c)(8), 424.510(d)(8), 424.515(c), 424.517(a). A supplier is subject to revocation of its Medicare billing privileges if it violates the DMEPOS supplier standards or the regulatory requirements applicable to all suppliers. 42 C.F.R. §§ 424.57(e)(1), 424.535(a).

1. On Tuesday April 19, 2016, at approximately 2:40 p.m. and Tuesday April 26, 2016, at approximately 10:56 a.m., a site inspector from a CMS administrative contractor was unable to gain entry into Advanced Prosthetics' facility at 3540 Duluth Park Lane, Suite 230, Duluth, Georgia, because the door was locked and no one answered the door when the site inspectors knocked.

On April 19, 2016, at approximately 2:40 p.m., a site inspector with a CMS administrative contractor attempted a site visit at Advanced Prosthetics' facility at 3540 Duluth Park Lane. The door was locked so the site inspector knocked on the door, but no one answered. The site inspector noted that there was a sign on the door indicating that Petitioner's personnel were either at lunch or seeing a patient. Further, the site inspector took pictures of the front door to Advanced Prosthetics' office, which show the date and time that the inspector took the pictures. CMS Ex. 3 at 1, 2, 7, 8.

On April 26, 2016, at approximately 10:56 a.m., the site inspector with the CMS administrative contractor attempted a site visit at Advanced Prosthetics' facility at 3540 Duluth Park Lane for a second time. The door was locked so the site inspector knocked on the door, but no one answered. The site inspector again noted that there was a sign on the door indicating that Petitioner's personnel were either at lunch or seeing a patient. Further, the site inspector took pictures of the front door to Advanced Prosthetics' office, which show the date and time that the inspector took the pictures. CMS Ex. 3 at 1, 2, 7, 9-10.

Petitioner admits that its facility was closed on both days at the times that the site inspector attempted to conduct the site visit. P. Ex. 1 at 2-3; P. Ex. 2 at 3; P. Ex. 5; P. Ex. 6. Therefore, I find that the site inspector's attempted site visits at Petitioner's facility on April 19 and 26, 2016, but that no one was present at Petitioner's office to allow the site inspector to enter the office.

2. CMS had a legitimate basis to revoke Petitioner's Medicare enrollment and billing privileges because Petitioner's facility was not accessible and staffed during posted hours of operation in violation of 42 C.F.R. § 424.57(c)(7).

Advanced Prosthetics informed CMS that its hours of operation were 9:00 a.m. to 5:00 p.m., Tuesday to Thursday. CMS Ex. 2 at 10. Petitioner is obligated to be accessible and staffed during its hours of operation. 42 C.F.R. § 424.57(c)(7). However, during the hours of operation on Tuesday April 19, 2016 and Tuesday April 26, 2016, Petitioner did not have staff present at its office and its office door was locked. Therefore, Petitioner violated 42 C.F.R. § 424.57(c)(7).

Petitioner asserts that it has two owners and no other employees. Mr. Rice was at home on April 19, 2016, having a new roof installed and Ms. Rice left Petitioner's office when their elderly cousin fell at their cousin's house. P. Ex. 5 at 1; P. Ex. 6 at 1. On April 26, 2016, Mr. Rice went out of town to see his first grandchild, who had been recently born, and Ms. Rice left Petitioner's office to deliver a check to someone on her cousins' behalf. P. Ex. 5 at 2; P. Ex. 6 at 2. Petitioner asserts that the age and infirmity of their cousin created an emergency situation. Further, on both days, Ms. Rice left a sign on the door of the facility with a phone number that could have been used to call her.

Petitioner's arguments are not availing. The DMEPOS supplier requirement to be staffed and accessible during normal hours of operation is a rule that has few exceptions. *See Norpro Orthotics & Prosthetics, Inc.*, DAB No. 2577, at 5 (2014) (indicating that the regulatory history of 42 C.F.R. § 424.57(c)(7) makes exceptions for disasters, emergencies, and state and federal holidays); *see also Benson Ejindu*, DAB No. 2572, at 6 (2014). A DMEPOS supplier is not "accessible" if the supplier's location is closed because the staff is out for lunch, on a break, making patient visits, or out of the office for any reason. *See Ita Udeobong*, 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). Even if the staff of a DMEPOS supplier is present at its office, but the door is locked and the staff do not hear the knock of an inspector, then the office is not accessible under 42 C.F.R. § 424.57(c)(7). *Benson Ejindu*, DAB No. 2572, at 6-7.

Although Petitioner indicates Ms. Rice was trying her best to be at Petitioner's facility, but could not do so because of her cousin's situation, their testimony does not support this. On April 19, Mr. Rice could have left his roof repairs to tend to the emergency that his cousin had or could have gone to Petitioner's facility so that Ms. Rice could go to their cousin. On April 26, Ms. Rice closed Petitioner's facility during its operating hours to deliver a check on behalf of her cousin. It is unclear how this was an emergency. Finally, Petitioner's note on the door with a telephone number is not a legal excuse for failing to provide an accessible office during the posted hours of operation. *See Complete Home Care*, DAB No. 2525, at 5-6.

I conclude that Petitioner violated 42 C.F.R. § 424.57(c)(7) because its office was not accessible on April 19 and 26, 2016.

3. CMS did not have a legitimate basis to revoke Petitioner's Medicare billing privileges based on a finding that Petitioner was not operational under 42 C.F.R. § 424.535(a)(5).

Suppliers must be operational or they are subject to revocation. 42 C.F.R. § 424.535(a)(5). A supplier is operational if 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 (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered), to furnish these items or services.

42 C.F.R. § 424.502. Although the requirement to be operational has significant similarities to the DMEPOS supplier standard that requires a DMEPOS's facility be staffed and accessible to the public during posted hours of operation (i.e., 42 C.F.R. § 424.57(c)(7)), it is important to note that the requirement to be "operational" is not a DMEPOS supplier standard. Instead, it applies to all suppliers. Therefore, a DMEPOS supplier could be "operational," but still not meet all of the strict requirements of the DMEPOS supplier standards.

In the present case, there is sufficient evidence that Petitioner was operational. The site inspector confirmed that Petitioner's address exists and that signs show that Petitioner occupies the address Petitioner provided in its revalidation enrollment application. CMS Ex. 3 at 2, 8-10. Petitioner had liability insurance that was in effect from September 20, 2015 to September 20, 2016. CMS Ex. 2 at 18. Petitioner had a City of Duluth Occupational Tax Certificate that was valid until January 30, 2017, for "Manufacturing Prosthetics." CMS Ex. 4 at 3. The American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. had accredited Petitioner in 2013 as a Prosthetics facility. CMS Ex. 4 at 4. Georgia licensed Mr. Rice to be a prosthetist and that license did not expire until June 30, 2016. CMS Ex. 4 at 5. The American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. certified Mr. Rice as a prosthetist and the certification did not expire until December 31, 2016. CMS Ex. 4 at 6. Mr. Rice and Ms. Rice testified to the fact that Petitioner is operational and sees customers. P. Ex. 1 at 1-2; P. Ex. 2 at 4. Finally, five witnesses who have been customers of Petitioner for many years testified that they have been happy with the services Petitioner has provided and that they never had difficulty contacting Petitioner. P. Exs. 7-11. This testimony is uncontroverted and I accept it as true.

I conclude that while Petitioner was not always open during its hours of operation, it was still open and staffed to provide health care related services sufficiently to avoid a violation of 42 C.F.R. § 424.535(a)(5).

4. I do not need to determine whether Petitioner violated 42 C.F.R. § 424.57(c)(2), (17), and (26).

I have concluded that Petitioner was not staffed and accessible during its hours of operation in violation of 42 C.F.R. § 424.57(c)(7). This violation is sufficient to uphold the revocation of Petitioner's Medicare billing privileges. 42 C.F.R. § 424.57(e)(1). Therefore, I do not need to adjudicate the other violations of the DMEPOS supplier standards that the CMS administrative contractor believed that Petitioner committed.

5. Petitioner's Medicare enrollment and billing privileges must be revoked, but the effective date of revocation is changed to July 14, 2016.

CMS imposed a retroactive revocation effective date in this case due to its finding that Petitioner was not operational. CMS Ex. 1 at 1, 8; 42 C.F.R. § 424.535(g). However, based on my conclusion that Petitioner was not properly revoked for being non-operational, I must modify the effective date of revocation.

Because Petitioner violated 42 C.F.R. § 424.57(c)(7), CMS was required to revoke Petitioner 30 days after the date that CMS sent the revocation notice to Petitioner. 42 C.F.R. § 424.57(e)(1). CMS sent Petitioner the initial determination to revoke on June 14, 2016 (CMS Ex. 1 at 1); therefore, the effective date of Petitioner's revocation is July 14, 2016. Petitioner may seek reimbursement for items and services provided to Medicare beneficiaries through July 13, 2016.

VII. Conclusion

I affirm CMS's revocation of Advanced Prosthetics' Medicare enrollment and billing privileges. I modify the effective date of revocation from April 26, 2016 to July 14, 2016.

______/S/ Scott Anderson Administrative Law Judge