Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Superior Medical Products
(PTAN: 6514330001),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-432

Decision No. CR3224

Date: May 7, 2014

DECISION

The Medicare enrollment and billing privileges of Petitioner, Superior Medical Products, are revoked pursuant to 42 C.F.R. §§ 424.57(d) and 424.535(a)(1),[1] effective August 24, 2013, based on violation of 42 C.F.R. § 424.57(c)(7)(i)(C) (supplier standard 7).

I. Procedural History and Jurisdiction

The Medicare contractor, Palmetto GBA (Palmetto),[2] notified Petitioner by letter dated August 9, 2013, that its Medicare billing privileges and provider agreement were revoked effective July 19, 2013. Centers for Medicare & Medicaid Services (CMS) exhibit

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[1] The 2012 revision of the Code of Federal Regulations (C.F.R.) is cited, unless otherwise indicated.

[2] The notice was issued by the National Supplier Clearinghouse Supplier Audit and Compliance Unit (SACU), which is operated by Palmetto.

(Ex.) 1 at 6. Palmetto cited 42 C.F.R. §§ 405.800, 424.57(e),[3] 424.535(a)(1), 424.535(a)(5)(ii), and 424.535(g), as the authority for revocation based on Petitioner's noncompliance with 42 C.F.R. § 424.57(c)(7).[4] CMS Ex. 1 at 6-7. Palmetto also notified Petitioner that it was subject to a two-year bar to re-enrollment pursuant to 42 C.F.R. § 424.535(c). CMS Ex. 1 at 6.

Petitioner submitted a request for reconsideration that was received by Palmetto on August 16, 2013. CMS Ex. 1 at 1. Palmetto notified Petitioner by letter dated October 25, 2013, that the revocation of its enrollment and billing privileges was upheld based on violation of supplier standard 7, 42 C.F.R. § 424.57(c)(7). CMS Ex. 1 at 1-5.

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated December 13, 2013 (RFH). The case was assigned to me for hearing and decision on January 2, 2014, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. No issue has been raised as to the timeliness of Petitioner's request for hearing, the parties do not challenge my authority to decide this case, and I conclude that I have jurisdiction.

On February 3, 2014, CMS filed a combined prehearing brief and motion for summary judgment (CMS Br.), with CMS Exs. 1 through 3. On February 20, 2014, Petitioner filed its opposition to CMS' motion for summary judgment (P. Br.), with Petitioner's exhibit (P. Ex.) 1.[5] On April 4, 2014, CMS waived its right to file a reply brief. The parties have

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[3] The citation to 42 C.F.R. § 424.57(e) was a clerical error as that provision relates to revalidation of billing privileges every three years, which is not an issue in this case. I conclude that Palmetto intended to cite 42 C.F.R. § 424.57(c), which includes supplier standard 7.

[4] This regulatory requirement is known as durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier standard 7.

[5] Petitioner's exhibit was not correctly marked as required by the Prehearing Order. However, the exhibit was not returned to Petitioner for correction because there was no potential for confusion based on the incorrect marking. Petitioner marked and filed a 17-page document as SMP (for Superior Medical Products) Exhibit 1. Petitioner also marked and filed separately documents marked as SMP Exhibit 1, page 17a, 17b, 17c, 17d, 17e, and 17 f.

not objected to my consideration of the exhibits and CMS Exs. 1 through 3 and P. Ex. 1 are admitted as evidence. Petitioner also filed documents with its request for hearing, some of which duplicate documents included in P. Ex. 1. I treat the documents filed with the request for hearing as P. Ex. 2 pages 1 through 6, and they are also admitted as evidence.

II. Discussion

A. Applicable Law

Section 1831 of the Social Security Act (the Act) (42 U.S.C. § 1395j) establishes the supplementary medical insurance benefits program for the aged and disabled known as Medicare Part B. Administration of the Part B program is through contractors, such as Palmetto. Act § 1842(a) (42 U.S.C. § 1395u(a)). Payment under the program for services rendered to Medicare-eligible beneficiaries may only be made to eligible providers of services and suppliers.[6] Act §§ 1835(a) (42 U.S.C. § 1395n(a)); 1842(h)(1) (42 U.S.C. § 1395(u)(h)(1)). Petitioner is a durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier.

The Act requires the Secretary to issue regulations that establish a process for the enrollment of providers and suppliers, including the right to a hearing and judicial review in the event of denial or non-renewal. Act § 1866(j) (42 U.S.C. § 1395cc(j)). Pursuant to 42 C.F.R. § 424.505, a supplier must be enrolled in the Medicare program and be issued a billing number to have billing privileges and to be eligible to receive payment for services rendered to a Medicare eligible beneficiary. To receive direct-billing privileges, a DMEPOS supplier must 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 maintain a physical facility on an appropriate site. 42 C.F.R. § 424.57(c)(7). An appropriate site for the physical facility must meet certain criteria, including that the practice location is in a location accessible to the public, Medicare beneficiaries, and CMS and its agents, and that the practice location must be accessible

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[6] A "supplier" furnishes services under Medicare. The term supplier applies to physicians or other practitioners and facilities that are not included within the definition of the phrase "provider of services." Act § 1861(d) (42 U.S.C. § 1395x(d)). A "provider of services," commonly shortened to "provider," includes hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, hospice programs, and a fund as described in sections 1814(g) and 1835(e) of the Act. Act § 1861(u) (42 U.S.C. § 1395x(u)). The distinction between providers and suppliers is important because they are treated differently under the Act for some purposes.

and staffed during posted hours of operation. 42 C.F.R. § 424.57(c)(7)(i)(B), (C). A DMEPOS supplier must provide complete and accurate information in response to questions on its application for Medicare billing privileges and must report to CMS any changes in information supplied on the application within 30 days of the change. 42 C.F.R. § 424.57(c)(2). 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). Finally, a DMEPOS supplier must at all times 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.

The Secretary has delegated the authority to revoke enrollment and billing privileges to CMS. 42 C.F.R. § 424.535. CMS or its Medicare contractor may revoke an enrolled supplier's Medicare enrollment and billing privileges and supplier agreement for any of the reasons listed in 42 C.F.R. § 424.535. Specifically, CMS may revoke a supplier's enrollment and billing privileges if the supplier is determined not to be in compliance with the enrollment requirements. 42 C.F.R. § 424.535(a)(1). CMS may also revoke a currently enrolled supplier's Medicare enrollment and billing privileges if CMS determines, upon on-site review, that the supplier is no longer operational to furnish Medicare covered items or services, or the supplier fails 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. 42 C.F.R. § 424.535(a)(5)(ii). After a supplier's Medicare enrollment and billing privileges are revoked, the supplier is barred from reenrolling in the Medicare program for one to three years. 42 C.F.R. § 424.535(c).

A supplier whose enrollment and billing privileges have been revoked may request reconsideration and review as provided by 42 C.F.R. pt. 498. A supplier submits a written request for reconsideration to CMS or its contractor. 42 C.F.R. § 498.22(a). CMS or its contractor must give notice of its reconsidered determination to the supplier, giving the reasons for its determination and specifying the conditions or requirements the supplier failed to meet, and the right to an ALJ hearing. 42 C.F.R. § 498.25. If the decision on reconsideration is unfavorable to the supplier, the supplier has the right to request a hearing by an ALJ and further review by the Departmental Appeals Board (the Board). Act § 1866(j)(8) (42 U.S.C. § 1395cc(j)(8)); 42 C.F.R. §§ 424.545, 498.3(b)(17), 498.5. A hearing on the record, also known as an oral hearing, is required under the Act. *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 748-751 (6th Cir. 2004). The supplier bears the burden to demonstrate that it meets enrollment requirements with documents and records. 42 C.F.R. § 424.545(c).

B. Issues

Whether summary judgment is appropriate; and

Whether there was a basis for the revocation of Petitioner's billing privileges and Medicare enrollment.

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis.

1. Summary judgment is appropriate.

A provider or supplier denied enrollment in Medicare or whose enrollment had been revoked has a right to a hearing and judicial review pursuant to section 1866(h)(1) and (j) of the Act and 42 C.F.R. §§ 424.454(a), 498.3(b)(1), (5), (6), (8), (15), (17), 498.5. The Act requires a hearing on the record, also known as an oral hearing. Act §§ 205(b), 1866 (h)(1) and (j); *Crestview*, 373 F.3d at 748-51. A party may waive appearance at an oral hearing, but must do so affirmatively in writing. 42 C.F.R. § 498.66. In this case, Petitioner has not waived the right to oral hearing or otherwise consented to decision based only upon the documentary evidence or pleadings. Accordingly, disposition on the written record alone is not permissible, unless CMS' motion for summary judgment has merit.

Summary judgment is not automatic upon request. Rather, it is limited to certain specific conditions. The procedures established by 42 C.F.R. pt. 498 related to ALJ hearings applicable in this case do not include a summary judgment procedure. However, appellate panels of the Board have long recognized the availability of summary judgment in cases subject to 42 C.F.R. pt. 498, and the federal courts have recognized the Board's interpretative rule. *See, e.g.*, *Crestview*, 373 F.3d at 749-750. Furthermore, I adopted a summary judgment procedure as a matter of judicial economy within my authority to regulate the course of proceedings and made it available to the parties in the litigation of this case by my Prehearing Order. Prehearing Order §§ II.D and II.G.

Summary judgment is appropriate when there is no genuine dispute as to any issue of material fact for adjudication or the moving party is entitled to judgment as a matter of law. In determining whether there are genuine issues of material fact for trial, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. The party requesting summary judgment bears the burden of showing that there are no genuine issues of material fact for trial or that it is entitled to judgment as a matter of law. Generally, the non-movant may not defeat an adequately supported summary judgment motion by relying on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material

fact, i.e., a fact that would affect the outcome of the case if proven. *Mission Hosp. Reg'l Med. Ctr.*, DAB No. 2459, at 4 (2012) (and cases cited therein); *Experts Are Us, Inc.*, DAB No. 2452, at 4 (2012) (and cases cited therein); *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300, at 3 (2010) (and cases cited therein); *see also, Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The standard for deciding a case on summary judgment and an ALJ's decision-making in deciding a summary judgment motion differ from resolving a case after a hearing. On summary judgment, the ALJ does 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, on summary judgment the ALJ construes the evidence in a light most favorable to the non-movant and avoids deciding which version of the facts is more likely true. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291, at 5 (2009). The Board has also recognized that on summary judgment it is appropriate for the ALJ to consider whether a rational trier of fact could find that the parties' evidence would be sufficient to meet that party's evidentiary burden. *Dumas Nursing & Rehab., L.P.*, DAB No. 2347, at 5 (2010). The Secretary has not provided for the allocation of the burden of persuasion or the quantum of evidence in 42 C.F.R. pt. 498. The Board, however, has provided some persuasive analysis regarding the allocation of the burden of persuasion in cases subject to 42 C.F.R. pt. 498. *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 Fed. App'x 181 (6th Cir. 2005).

In deciding that summary judgment is appropriate, I note that Petitioner does not dispute the material facts. Petitioner was a DMEPOS supplier at the time of the inspections. Petitioner admits that his posted hours of operation were Monday through Friday, 8:00 a.m. to 9:00 a.m. CMS Ex. 2 at 1. Petitioner does not dispute that Palmetto's inspector attempted to inspect his location on Thursday, July 18, 2013, at 8:28 a.m. and Friday, July 19, 2013 at 8:16 a.m.[7] Petitioner does not deny that the inspector's attempted visits were on dates and at times when his posted hours indicated that the facility should have been open. Petitioner admits that his facility was not open when the inspector visited. RFH, P. Br., CMS Ex. 1 at 15-28.

I conclude, after viewing the evidence before me in the light most favorable to Petitioner and drawing all inferences in Petitioner's favor, that there is no dispute as to any material fact in this case that requires a trial. The issues in this case that require resolution are

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[7] There was an initial visit on July 17, 2013 at 3:59 p.m., but that visit was outside Petitioner's posted hours and the fact he was not open at the time of that visit is not a basis for finding a violation of supplier standard 7.

issues of law related to the interpretation and application of the regulations that govern enrollment and billing privileges in the Medicare program and application of the law to the undisputed facts of this case. The issues in this case must be resolved against Petitioner as a matter of law. The undisputed evidence shows that there is a basis for revocation of Petitioner's Medicare enrollment and billing privileges effective August 24, 2013. Accordingly, I conclude summary judgment is appropriate.[8]

2. There was a basis to revoke Petitioner's Medicare enrollment and billing privileges pursuant to 42 C.F.R. §§ 424.57(d) and 424.535(a)(1) for violation of 42 C.F.R. § 424.57(c)(7)(i)(C) (supplier standard 7).

3. The effective date of revocation is August 24, 2013, pursuant to 42 C.F.R. § 424.57(d).

a. Facts

The facts are not disputed. On Thursday, July 18, 2013 at about 8:28 a.m., a SACU investigator attempted to inspect Petitioner's facility at Petitioner's address on file with CMS, 2400 Augusta Drive, Suite 365, Houston, Texas 77057. The investigator found the door locked and the office appeared not to be accessible. The investigator returned to Petitioner's facility on Friday, July 19, 2013 at about 8:16 a.m., and again found the door locked and the office appeared not open and accessible. CMS Ex. 1 at 15-28. The inspector knocked several times and received no response; the inspector also could see through a transom window that no lights were on inside the office suite. CMS Ex. 1 at 20. Petitioner does not dispute that the inspections were attempted as reported by the SACU investigator, or that the doors to his office were locked and he was not open for business when the investigator tried to gain access. Petitioner does not dispute that the facility should have been open on the dates and at the times that the investigator attempted to inspect. RFH; P. Br.

b. Analysis

Palmetto informed Petitioner in the notice of the initial determination dated August 9, 2013, that revocation was based on noncompliance with supplier standard 7 because his business was not open when an inspector attempted to conduct two site visits during Petitioner's reported hours of operation. Palmetto also advised Petitioner that revocation was pursuant to 42 C.F.R. § 424.535(a)(5)(ii) based on a conclusion that Petitioner was

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[8] If the issue of whether or not Petitioner was operational was properly before me, P. Exs. 1 and 2 would cause the conclusion, giving the benefit of all favorable inferences to Petitioner, that there are material issues of fact in dispute that would require a trial.

not operational. Palmetto advised Petitioner that the effective date of revocation was July 19, 2013, the date on which CMS determined that Petitioner was not operational. CMS Ex. 1 at 6-7. Palmetto notified Petitioner of the reconsideration determination by letter dated October 25, 2013. Palmetto advised Petitioner that the revocation of his enrollment and billing privileges was upheld on reconsideration based on the fact that Petitioner's facility was not open when the SACU investigator attempted inspections. Therefore, the reconsideration hearing officer concluded that the evidence did not show that Petitioner was in compliance with supplier standard 7. CMS Ex. 1 at 1-4. Although the reconsideration hearing officer sets forth the definition of operational and states that a supplier must be operational, she did not specifically find or conclude that the Petitioner was not operational and therefore subject to revocation of enrollment and billing privileges pursuant to 42 C.F.R. § 424.535(a)(5). Rather, she concluded that revocation was appropriate because Petitioner failed to show compliance with supplier standard 7. Accordingly, I conclude that the specific issue before me is whether or not Petitioner was in compliance with 42 C.F.R. § 424.57(c)(7) (supplier standard 7). Whether or not there was a basis for revocation pursuant to 42 C.F.R. § 424.535(a)(5) because Petitioner was not operational is not at issue before me because it was not a basis for revocation upheld on reconsideration. It is well established that even a single violation of a single supplier standard is an adequate basis for revocation of billing privileges and enrollment. *1866ICPayday.com*, DAB No. 2289, at 13 (2009).

CMS argues before me that Petitioner was not "operational" and the facility was not accessible to the public, Medicare beneficiaries, CMS, or its agents, as required by supplier standard 7, 42 C.F.R. § 424.57(c)(7), on the dates the SACU investigator could not gain access to Petitioner's facility. CMS Br. at 1, 5. CMS argues that a violation of this standard constitutes a sufficient basis to revoke Petitioner's billing privileges and participation in Medicare pursuant to 42 C.F.R. § 424.535(a)(5)(ii). CMS Br. at 1. CMS conflates revocation based on violation of supplier standard 7 (42 C.F.R. § 424.57(c)(7)(i)(C)), which requires that Petitioner's facility be accessible and staffed during posted hours of operation; and violation of 42 C.F.R. § 424.535(a)(5), which authorizes CMS to revoke because it has determined that a supplier is no longer operational. The Board recognized a distinction between these regulatory requirements in *Complete Home Care*, DAB No. 2525, at 6 (2013), concluding that it did not need to decide whether or not a supplier was operational where it found a single violation of 42 C.F.R. § 424.57(c)(7)(i)(C). The evidence that Petitioner was closed to the public on the dates of two inspections, during hours when the facility should otherwise be open, is some evidence that Petitioner was no longer operational. However, whether a facility is open to the public during posted hours of operation is only one of the criteria established by 42 C.F.R. § 424.502 for deciding whether a supplier is operational. An analysis of whether a facility is "operational" within the meaning of 42 C.F.R. § 424.502 also requires consideration of evidence related to the other factors listed in the regulation such as whether or not Petitioner was prepared to submit valid Medicare claims, whether the facility was properly staffed, equipped, and stocked to furnish items

or services the supplier was authorized to furnish by its Medicare enrollment. The evidence before me that would be considered on the issue of whether or not Petitioner was operational at the time of the visits is not conceded by Petitioner and a trial would be required to resolve disputed issues of material fact. Furthermore, and more significantly, whether or not Petitioner was operational within the meaning of 42 C.F.R. § 424.502 is not at issue in this case because violation of 42 C.F.R. § 424.535(a)(5) was not the basis on which the reconsideration hearing officer upheld revocation.

Supplier standard 7 requires that Petitioner maintain an appropriate site that meets specified criteria, including that it be accessible and staffed during posted hours of operation. CMS or its agents must also be able to inspect the site during normal hours of operation to ensure compliance with participation requirements. Petitioner does not deny his facility was not accessible and staffed during his normal hours of operation when the SACU investigator attempted to conduct inspections. Accordingly, Petitioner violated supplier standard 7 (42 C.F.R. § 424.57(c)(7)(i)(C)) and there is a basis for the revocation of Petitioner's enrollment and billing privileges pursuant to 42 C.F.R. §§ 424.57(d) and 424.535(a)(1).

In this case, Petitioner was not in compliance with the special enrollment requirement for DMEPOS suppliers established by 42 C.F.R. § 424.57(c)(7)(i)(C) because Petitioner's facility was admittedly unstaffed and inaccessible to the public during his hours of operation. Although 42 C.F.R. § 424.535(a)(1) contemplates that Petitioner would be allowed to file a corrective action plan, in this case that would be a needless act because Petitioner cannot correct his admitted violation of supplier standard 7.

Pursuant to 42 C.F.R. § 424.57(d) the effective date of the revocation of Petitioner's billing privileges and Medicare enrollment is August 24, 2013, which is 15 days after the August 9, 2013 notice of the initial determination was issued. The July 19, 2013 effective date listed in the notice of initial determination is incorrect as a retroactive effective date would be authorized in this case only if revocation was based on a determination that Petitioner was no longer operational. 42 C.F.R. § 424.535(g).

Petitioner states that it has been a provider since 1996 and has always been very attentive to the supplier standards. Petitioner's owner asserts that he has passed all of his previous site inspections and his accreditation is up to date. He further informed me that he is the only employee and he usually travels to nursing facilities to work with the beneficiaries there to provide for their needs because they cannot travel. He states that generally no one comes to his office during posted hours but his sign states that he is available by appointment after 9 a.m. Monday through Friday. He also states that he is usually in his office during the stated hours of operation from 8 a.m. to 9 a.m. and he does not know how he missed the site inspector on those two days. Petitioner states that he has been a diligent, committed professional and is dedicated to his field. He asks that I give him favorable consideration and re-instate him. Even if I accept all Petitioner's assertions as

true for purposes of summary judgment, those facts have no impact on the outcome in this case as those facts are not material to the determination that Petitioner violated supplier standard 7. Furthermore, to the extent that Petitioner's arguments may be construed as a request for equitable relief, I have no authority to grant equitable relief. *US Ultrasound*, DAB No. 2302, at 8 (2010) ("[n]either the ALJ nor the Board is authorized to provide equitable relief by reimbursing or enrolling a supplier who does not meet statutory or regulatory requirements."). I am also required to follow the Act and regulations and have no authority to declare statutes or regulations invalid. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 14 ("[a]n ALJ is bound by applicable laws and regulations and may not invalidate either a law or regulation on any ground.").

III. Conclusion

For the foregoing reasons, I conclude that Petitioner's Medicare enrollment and billing privileges are revoked effective August 24, 2013.

/s/
Keith W. Sickendick
Administrative Law Judge