Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Medcore Home Medical Equipment,

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-13-181

Decision No. CR2796

Date: May 23, 2013

DECISION

Palmetto GBA National Supplier Clearinghouse (NSC), an administrative contractor acting on behalf of the Centers for Medicare and Medicaid Services (CMS), revoked Petitioner Medcore Home Medical Equipment's Medicare billing privileges. NSC determined that Petitioner violated the supplier standards set out at 42 C.F.R. § 424.57(c)(1) and (c)(21) because it failed to produce a required state license during a site inspection. Petitioner appealed. For the reasons stated below, I affirm the determination to revoke Petitioner's billing privileges.

I. Case Background and Procedural History

Petitioner is a Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier located in Livonia, Michigan. Petitioner is engaged in furnishing oxygen cylinders, concentrators, and related respiratory supplies and services. CMS Exhibit (Ex.) 6, at 1-2; Petitioner Brief (P. Br.) at 1. During a site inspection conducted on May 8, 2012, the surveyor asked Petitioner to furnish a copy of its Manufacturer and Wholesaler License, issued by the Michigan Board of Pharmacy, authorizing Petitioner to conduct its business as a distributor of medical devices. P. Br. at 2; *see also* P. Exs. 4, 5. Petitioner failed to produce the required license.

In a letter dated July 31, 2012, NSC notified Petitioner that it was revoking Petitioner's Medicare supplier number and billing privileges effective August 30, 2012, and that Petitioner was barred from re-enrollment for one-year. NSC informed Petitioner that it determined that Petitioner was not in compliance with 42 C.F.R. § 424.57(c)(1) and (c)(21) based on its failure to submit the Manufacturer and Wholesaler License issued by the Michigan Board of Pharmacy. The letter advised Petitioner that it could file a corrective action plan (CAP) and request reconsideration. CMS Ex. 1.

Petitioner submitted a CAP dated August 3, 2012, to NSC. Petitioner's CAP stated that Petitioner applied for a license with the Michigan Board of Pharmacy. Petitioner also indicated that it would provide NSC with a copy of the license once the Board of Pharmacy issued it. CMS Ex. 2.

On August 31, 2012, NSC acknowledged receipt of Petitioner's CAP. NSC noted that Petitioner had not furnished proof of the required state license and that "[t]he Michigan Board of Pharmacy website stated that your licenses were pending." CMS Ex. 3, at 1. NSC concluded that Petitioner was still out of compliance with 42 C.F.R. § 424.57(c)(1) and (c)(21). NSC stated that Petitioner was entitled to request reconsideration if it was dissatisfied with the decision. CMS Ex. 3.

On September 19, 2012, Petitioner filed a request for reconsideration with NSC. Petitioner enclosed a print-out from the Department of Licensing and Regulatory Affairs' website to show its license was now active. Petitioner stated that once it received the license, it would forward a copy to NSC. The print-out from the state agency's website shows a license issue date of "09/17/2012" and notes that the issue date is the date the license was first issued. CMS Ex. 4.

On October 23, 2012, NSC issued a reconsidered determination. NSC noted that Petitioner obtained the required state license, with an expiration date of June 30, 2013, and that the license became active on September 17, 2012. NSC found, however, that Petitioner failed to establish that it was in compliance with all of the standards at the time the revocation became effective. Accordingly, NSC concluded that Petitioner was not in compliance with 42 C.F.R. § 424.57(c)(1) and (c)(21), and that revocation of Petitioner's billing privileges was appropriate. CMS Ex. 5; *see also* CMS Ex. 7.

On November 29, 2012, Petitioner timely filed a request for a hearing with the Departmental Appeals Board, Civil Remedies Division. In response to my December 10, 2012 Acknowledgment and Pre-hearing Order (Order), CMS timely filed a motion for summary judgment and brief (CMS Br.), along with seven proposed exhibits (CMS Exs. 1-7). Petitioner requested an extension of time to submit its pre-hearing exchange, which I granted. On March 12, 2013, Petitioner filed its pre-hearing exchange, with a brief (P. Br.) and six proposed exhibits (P. Exs. 1-6). Because neither party has objected to any of the proposed exhibits, I admit CMS Exs. 1-7 and P. Exs. 1-6 into the record. Further,

because both parties have affirmatively stated that there is no need for an in-person hearing in this case (CMS Br. at 6; P. Br. at 1), I issue this decision on the basis of the written record. Order ¶¶ 10, 11.

II. Discussion

In order to participate in the Medicare program as a supplier,[1] individuals and entities must meet certain criteria to enroll and receive billing privileges. 42 C.F.R. §§ 424.505, 424.510. Further, DMEPOS suppliers must meet specific requirements, referred to as "supplier standards," which are set forth at 42 C.F.R. § 424.57(c). *Id*. § 424.57(a). CMS will revoke a supplier's billing privileges if the supplier fails to comply with regulatory requirements. *Id*. § 424.57(d).

A. Issues

The issues in this case are whether Petitioner was in compliance with 42 C.F.R. § 424.57(c)(1) and (c)(21), and, if not, whether CMS was required to revoke Petitioner's billing privileges.

B. Findings of Fact, Conclusions of Law, and Analysis[2]

1. Petitioner did not possess a license from the Michigan Board of Pharmacy when NSC performed the May 8, 2012 site inspection, and did not obtain such a license until September 17, 2012.

NSC conducted a site inspection of Petitioner's location on May 8, 2012, and requested that Petitioner produce a Manufacturer and Wholesaler License issued by the Michigan Board of Pharmacy. P. Br. at 2; P. Exs. 4, 5. Petitioner acknowledges that it did not have the license when asked and only applied for it in August 2012. CMS Ex. 2; P. Br. at 2; P. Ex. 6. The Michigan Board of Pharmacy issued the license on September 17, 2012. CMS Exs. 4, 6, 7. Therefore, I find that Petitioner did not possess a license from the Michigan Board of Pharmacy on May 8, 2012, and, consequently, did not produce it when requested during the site inspection on that date.

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[1] Petitioner, as a supplier of DMEPOS, is considered a "supplier" for Medicare purposes. *See* 42 C.F.R. § 498.2.

[2] My findings of fact and conclusions of law are set forth in italics and bold font.

2. Michigan law requires Petitioner to have a license from the Michigan Board of Pharmacy.

CMS argues that Petitioner, as a supplier engaged in furnishing oxygen cylinders, concentrators, and related respiratory supplies and services (P. Br. at 1), was required to obtain a license from the Michigan Board of Pharmacy. CMS Br. at 1-2, 7; P. Exs. 4, 5. CMS notes that the Michigan Board of Pharmacy, among its functions, regulates and controls the distribution of medical devices. Mich. Comp. Laws Ann. § 333.17722(a). The Michigan statute defines "device" as follows:

> "Device" means an instrument, apparatus, or contrivance, including its components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or to affect the structure or function of the body of human beings or other animals.

Id. § 333.17703(1). CMS asserts that the Michigan Board of Pharmacy must "[g]rant a pharmacy license for each separate place of practice in which the compounding or dispensing of prescription drugs or devices, or both, . . . is to be conducted." *Id*. § 333.17722(c). In this proceeding, Petitioner has not disputed that it needed to have a license from the Michigan Board of Pharmacy; Petitioner has only argued that it was not informed it needed to have such a license. CMS Ex. 6; P. Br. at 1-2. Therefore, I conclude Petitioner was required under state law to have a license from the Michigan Board of Pharmacy.

3. Petitioner was not in compliance with 42 C.F.R. § 424.57(c)(1) and (c)(21).

CMS determined that Petitioner violated the supplier standards in 42 C.F.R. § 424.57(c)(1) and (c)(21). Section 424.57(c)(1) requires that a supplier:

> [o]perates its business and furnishes Medicare-covered items in compliance with the following applicable laws: . . . (ii) *State licensure and regulatory requirements*. If a State requires licensure to furnish certain items or services, a DMEPOS supplier – (A) Must be licensed to provide the item or service . . . .

Section 424.57(c)(21) requires that a supplier "[p]rovides to CMS, upon request, any information required by the Medicare statute and implementing regulations."

It is not disputed that at the time of the site inspection, the surveyor asked Petitioner's representative for a copy of its Manufacturer and Wholesaler License and that the representative admitted that Petitioner did not have this license. Therefore, I find that

Petitioner's failure to have the required license and its inability to respond to NSC's request for documentation concerning that license, during the site inspection, is a violation of 42 C.F.R. § 424.57(c)(1) and (c)(21).

4. Equitable estoppel cannot be applied against CMS.

Petitioner argues that CMS never previously indicated that a Michigan Manufacturer and Wholesaler License was a necessary prerequisite to its enrollment in Medicare as a supplier. Petitioner states that during the accreditation process, neither its private consultant nor any of CMS's contractors required Petitioner to have a Michigan Manufacturer and Wholesaler License. P. Br. at 1. According to Petitioner, it passed previous site inspections in 2009, 2010, and 2011, and, during each of those inspections, the surveyors "never once requested" the license. CMS Ex. 6, at 1. Petitioner states that it was only during the last site inspection in 2012 that the surveyor requested the Manufacturer and Wholesaler License, and indicated that this license must be produced during the site inspection. P. Br. at 2; *see* P. Exs. 4, 5. Because Petitioner did not have the license, Petitioner applied for it and submitted it to Medicare after it was received. P. Br. at 2. Petitioner suggests that CMS is partly to blame for the fact that it was unaware of this state license requirement, claiming that "[t]he surveyor is responsible for ensuring that suppliers are in compliance with the Centers for Medicare Services." P. Br. at 2. Petitioner states that it has a good reputation and "believe[s] revoking our enrollment is unfair to our business, our employees and the community we serve." P. Br. at 2.

That Petitioner was unaware of the state licensure requirement because CMS had not brought it to Petitioner's attention is not a defense to the revocation of billing privileges. It is a supplier's responsibility to comply with Medicare requirements, including obtaining all relevant federal and state licenses. *See* 42 C.F.R. § 424.516(a)(2) (requiring suppliers to certify that they meet all federal and state licensing requirements). It is not CMS's responsibility to inform a supplier that it needs to obtain state licensure.

As CMS points out, Petitioner's argument appears to be a claim for equitable estoppel. However, I am unable to grant any relief. It is well-established that: (1) estoppel cannot be the basis to require payment of funds from the federal government; (2) estoppel cannot lie against the government, if at all, absent a showing of affirmative misconduct, such as fraud; and (3) I am not authorized to order payment contrary to law based on equitable grounds. It is well-settled that those who deal with the government are expected to know the law and may not rely on the conduct of government agents contrary to law. *See e.g.*, *Oklahoma Heart Hosp.*, DAB No. 2183, at 16 (2008); *Wade Pediatrics*, DAB No. 2153, at 22 n.9 (2008), *aff'd*, 567 F.3d 1202 (10th Cir. 2009); *Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414 (1990); *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51 (1984). Petitioner alleges no affirmative misconduct against the

government; rather, this is a case in which Petitioner did not know about all the applicable state licensure requirements. Accordingly, Petitioner's equitable estoppel arguments must be rejected.

5. The regulations require CMS to revoke Petitioner's billing privileges and impose at least a one-year reenrollment bar.

If a supplier does not continue to meet the DMEPOS supplier standards, CMS must revoke that supplier's billing privileges. 42 C.F.R. § 424.57(d). I do not have the authority to overturn an action that CMS was required to take. *See 1866ICPayday.com, L.L.C.*, 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.").

III. Conclusion

Because the record establishes that Petitioner violated 42 C.F.R. § 424.57(c)(1) and (c)(21), I affirm CMS's determination to revoke Petitioner's Medicare billing privileges.

/s/
Scott Anderson
Administrative law Judge