

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Mary C. Manesis, DPM, PA,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-361

Decision No. CR2865

Date: July 26, 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 billing privileges of Petitioner Mary C. Manesis, DPM, PA, a podiatrist and 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) and (8), which relate to requirements for maintaining an operational physical location that is accessible to the public, Medicare beneficiaries, the government and its inspectors. Petitioner appealed. For the reasons stated below, I affirm CMS's determination to revoke Petitioner's Medicare billing privileges.

I. Case Background and Procedural History

Petitioner was enrolled in the Medicare program as a DMEPOS supplier. *See* CMS Exhibit (Ex.) 4, at 1. In October 2011, it is undisputed that her company's physical address of record was 4201 FM 1960 W, Suite 230, Houston, Texas. P. Ex. 1, at 2. An NSC compliance inspector working on behalf of CMS attempted to conduct site inspections at Petitioner's location twice in October 2011. At the time of the two inspection attempts, Petitioner's signage on the door of her suite showed her hours of

operation were Monday through Friday, from 8:00 a.m. to 5:00 p.m. CMS Ex. 3, at 3, 16, 20. The NSC inspector attempted the first site visit on October 3, 2011, at 1:03 p.m. CMS Ex. 3, at 2. He was unable to conduct an inspection because the door was locked, the lights were off, and no one answered his repeated knocking. The inspector telephoned a number of record for Petitioner, and the inspector reported a representative informed him that the hours of operation were Monday through Friday, 8:00 a.m. to 5:00 p.m. CMS Ex. 3, at 7. The telephone representative reportedly stated that the “location is not available for appointments as each professional will come to my home or facility.” CMS Ex. 3, at 7. The inspector attempted a second visit on October 4, 2011, at 11:23 a.m. CMS Ex. 3, at 2. Again, the inspector was unable to conduct an inspection because the door was locked, the lights were off, and no one answered his repeated knocking. CMS Ex. 3, at 7. The inspector recommended in his report that Petitioner be considered non-operational. CMS Ex. 3, at 7.

On October 13, 2011, NSC sent a letter notifying Petitioner that her supplier number was revoked, retroactive to October 4, 2011, the date of the second site visit 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 this effective date. CMS Ex. 4, at 1. The notice letter explained that the basis for revocation was because the business was closed during posted hours of operation on October 3 and 4, 2011, when a NSC inspector attempted to complete site inspections to verify Petitioner’s compliance with supplier standards. CMS Ex. 4, at 1. The notice letter further informed Petitioner of her right to complete a corrective action plan (CAP) within 30 days, or to request reconsideration of the revocation determination within 60 days, of the postmark of the notice. CMS Ex. 4, at 2.

On November 10, 2011, Petitioner submitted a letter to NSC in which she stated “[t]his letter serves as both notification of our reconsideration request and our Corrective Action Plan.” Petitioner stated that, as an orthotics provider she was exempt from the requirement that a supplier be open to the public for a minimum of 30 hours per week and instead was allowed to be open “by appointment only.” Petitioner explained, however, that she had “regretfully neglected” to update her posted hours of operation to by appointment only. Petitioner noted that she only treats patients in nursing facilities and that her staff are generally located in those nursing facilities. She also noted, however, that her staff are still available for consultations by appointment at the office location. Petitioner stated further that her office would be moving to another location within 60 days, and she would submit an application to NSC to change the practice location once it was finalized. CMS Ex. 5.

Upon receipt of Petitioner’s letter, NSC scheduled a new site inspection. On December 1, 2011, at 10:38 a.m., a NSC inspector went to Petitioner’s location of record. CMS Ex. 6, at 2. A taped sign on Petitioner’s window stated “By Appointment Only Please Call 281-537-1599.” CMS Ex. 6, at 3, 7, 11. The inspector found the door locked, lights off,

and no one answered his repeated knocking. CMS Ex. 6, at 7. Later, the inspector called Petitioner's telephone number, introduced himself to the telephone representative, and stated he needed to make an appointment with someone at the company. CMS Ex. 6, at 7. The telephone representative stated he believed that the office location was closed but would forward the inspector's message to someone who could assist him. CMS Ex. 6, at 7. A company representative reportedly called the inspector on December 2, 2011 and stated that the company had moved to another location on November 30, 2011. CMS Ex. 6, at 7. She stated that she would email the new location to the inspector. CMS Ex. 6, at 7. As of December 4, 2011, the inspector had not received any emails. CMS Ex. 6, at 7. The inspector recommended that Petitioner be considered non-operational. CMS Ex. 6, at 7.

By letter dated December 13, 2011, NSC informed Petitioner that it was "acknowledg[ing] the receipt of your action plan regarding the revocation of your supplier number." NSC stated that Petitioner was in violation of 42 C.F.R. § 424.535(a)(5)(ii) because it was not operational during the attempted site inspections. NSC stated that Petitioner's compliance with the standards at 42 C.F.R. § 424.57 could not be verified. NSC also stated, "[a]s you failed to submit a request for reconsideration by December 13, 2011, you have waived your rights to further administrative [sic]." NSC reiterated that Petitioner was barred from re-enrolling in the Medicare program for two years from the effective date of this revocation. CMS Ex. 7.

Petitioner filed a request for a hearing with the Departmental Appeals Board, Civil Remedies Division, by letter dated April 16, 2012. The case was assigned to me, and I issued a prehearing order. Both parties submitted briefs and proposed exhibits. Due to jurisdictional concerns that Petitioner would not be able to properly proceed at the administrative law judge (ALJ) appeal level without a reconsideration determination, on October 15, 2012, I issued a Decision Dismissing Request for Hearing and Remanding for Reconsideration Determination. *Mary C. Manesis, DPM, PA*, CR2646 (2012); CMS Ex. 8.

On November 26, 2012, NSC issued a reconsidered determination. NSC determined that, at the time of unannounced site inspections in October and December 2011, Petitioner's facility was closed, and the inspector could not verify Petitioner's compliance with supplier standards. Accordingly, NSC concluded that Petitioner was not in compliance with supplier standard eight, which requires that a supplier must permit CMS or its agents to conduct on-site inspections to ascertain compliance with supplier standards. 42 C.F.R. § 424.57(c)(8). NSC upheld the revocation of Petitioner's supplier number.

On January 30, 2013, Petitioner filed another request for an ALJ hearing (RFH). With her hearing request, Petitioner attached several documents marked as "Ex. 1" through "Ex. 11," which I accept as part of the record. This case was again assigned to me for decision. In accordance with my February 5, 2013 Acknowledgment and Pre-hearing

Order (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 later filed her 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 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). Petitioner listed two proposed witnesses for whom she also filed affidavits of written direct testimony (P. Ex. 2 and P. Ex. 3). CMS did not request to cross-examine Petitioner's proposed witnesses. I find, therefore, that an in-person hearing in this case is unnecessary, and I issue this decision on the full merits of the written record.

II. Issue

The sole issue in this case is whether CMS was legally authorized to revoke Petitioner's enrollment as a supplier in the Medicare program, effective October 4, 2011.

III. Findings of Fact and Conclusions of Law

A. CMS had legitimate bases to revoke Petitioner's supplier number because an NSC inspector was not able to access Petitioner's location of record to perform compliance inspections in October 2011.

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 supplier enrollment 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 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, must be accessible and staffed during posted hours of operation, and must maintain a visible sign and post its hours of operation. 42 C.F.R. § 424.57(c)(7). A provider or supplier must also be "operational," which means it "has a qualified physical practice location, is open to the public for the purpose of

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

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 visit 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).

Here, on October 3, 2011, at 1:03 p.m., an NSC inspector attempted to conduct an unannounced site inspection on behalf of CMS at Petitioner’s location during its posted hours of operation, which were Monday through Friday, 8:00 a.m. to 5:00 p.m. However, the inspector found that the door was locked and no one answered his repeated knocking. CMS Ex. 3, at 7. The inspector called Petitioner’s telephone number and spoke to a representative who confirmed that the business hours were Monday through Friday, 8:00 a.m. to 5:00 p.m. The representative told the inspector that the location was not available for appointments and that someone would go to his home or facility. *Id.*; P. Br. at 10. The inspector took date-stamped photographs. CMS Ex. 3, at 18-21. The inspector made a second attempt the next day, October 4, 2011, at 11:23 a.m. Again, the door was locked, and no one answered the inspector’s repeated knocking. CMS Ex. 3, at 7. The inspector took date-stamped photographs. CMS Ex. 3, at 14-17.

After NSC received Petitioner’s CAP subsequent to the revocation of Petitioner’s supplier number, the NSC inspector made a third site visit on December 1, 2011, at 10:38 a.m. However, the door was locked, the lights were off, and no one answered the inspector’s repeated knocking. CMS Ex. 6, at 7. The inspector noted that on his previous visits, the posted hours of operation were Monday through Friday, 8:00 a.m. to 5:00 p.m., but now a sign taped to the window indicated that business hours were by appointment only. CMS Ex. 6, at 7. The inspector later called Petitioner’s telephone number and requested an appointment. The representative stated that he “believed this office location was closed, but would forward [his] message to someone who could assist [him].” CMS Ex. 6, at 7. The representative stated that he was in Massachusetts. On December 2, 2011, the NSC inspector received a call from a representative, who stated that the company had moved to another location on November 30, 2011. The representative did

not know the new address but said she would email it later to the inspector. As of December 4, 2011, the inspector reported he had not received any emails from Petitioner. CMS Ex. 6, at 7. The inspector recommended that Petitioner be considered non-operational. CMS Ex. 6, at 7.

Petitioner does not dispute that on October 3 and 4, 2011, her office was closed and locked, with no staff on site when the NSC inspector visited the premises during Petitioner's posted hours of operation. Petitioner admits that she "regretfully neglected to update our posted hours of operation to 'By Appointment Only'" and that she "immediately remedied the posted hours of operation sign upon receiving the first revocation letter." P. Ex. 3, at 1; RFH. Petitioner argues, however, that she is a closed-door supplier who provides podiatric services and custom-made orthotics to Medicare beneficiaries only in nursing facilities. Petitioner contends that as an orthotics supplier, pursuant to 42 C.F.R. § 424.57(c)(30)(ii)(C), she is exempt from the requirement that suppliers be open to the public a minimum of 30 hours per week. Further, Petitioner contends that as a closed-door business, she can have hours that are by appointment only, and she is not required to be open to the general public and staffed during specified hours.² P. Br. at 12-16. She maintains that her office was "properly staffed and accessible to the NSC inspector" because a company representative answered the telephone each time the inspector called Petitioner's number, and thus, she should not be found to have violated 42 C.F.R. § 424.57(c)(8). According to Petitioner, "[h]ad the inspector validly identified himself and requested an appointment to conduct an inspection, the inspection at that location would have occurred." P. Br. at 13.

A supplier is generally required to be "open to the public a minimum of 30 hours per week" (42 C.F.R. § 424.57(c)(30)(i)); however, a DMEPOS supplier working with custom-made orthotics, such as Petitioner, is exempt from this requirement. 42 C.F.R. § 424.57(c)(30)(ii)(C). Nonetheless, even though Petitioner was permitted to be open by appointment only and was not required to be open 30 hours each week, her place of business was still required to post accurate hours of operation and to be accessible and staffed during these posted hours in order to be considered "operational." 42 C.F.R. § 424.57(c)(7); 42 C.F.R. § 424.502.

I am not persuaded by Petitioner's claim that, because her office was open only by appointment, having a telephone representative available to answer calls was sufficient for staffing purposes, and it was not necessary to have an employee available on site. Even if Petitioner was eligible to be open to the public only by appointment given her

² A "closed door" business is defined in the relevant Federal regulations as a business such as a pharmacy or supplier that provides services "only to beneficiaries residing in a nursing home that complies with all applicable Federal, State, and local laws and regulations." 42 C.F.R. § 424.57(c)(7)(i)(F)(iii).

status as an orthotics supplier, the fact remains that she had posted specific hours of operation on her door in October 2011, and the office failed to be open to CMS or its agents during these posted hours so that they could conduct an on-site inspection. Although Petitioner claims that her off-site telephone representative had the ability to make an appointment for the inspector, I do not find that this constitutes proper staffing during posted business hours. Moreover, when the inspector called Petitioner's number during his attempted site visit on October 3, 2011, the telephone representative confirmed that the business hours were Monday through Friday, from 8:00 a.m. to 5:00 p.m. and stated that the "location [was] not available for appointments as each professional [would] come to my home or facility." CMS Ex. 3, at 7. Thus, contrary to what Petitioner claims, the inspector had no success in making an appointment, even after contacting the telephone representative. Furthermore, even if the inspector did not specifically identify himself as an inspector when attempting to make an appointment as Petitioner alleges, a supplier's facility must also be open to the public and Medicare beneficiaries. Therefore, Petitioner was still not compliant with Medicare requirements.

Based on Petitioner's failure to have her physical location be open and accessible to the public, Medicare beneficiaries, the government, and the NSC inspector on two separate occasions during its posted hours of operation, I conclude that Petitioner was not operational within the meaning of 42 C.F.R. §§ 424.57(c)(7),(8) and 424.502. Therefore, CMS had the authority to revoke Petitioner pursuant to 42 C.F.R. § 424.535(a)(5)(ii).

B. I am unauthorized to consider Petitioner's remedial actions regarding the change in her signage after CMS properly revoked her Medicare billing number.

Petitioner's assertion that she was in compliance, once she changed her signage to reflect that her hours were "By Appointment Only," does not establish that her business was operational as of the time of the attempted on-site inspections in October 2011, which is the relevant period underlying CMS's revocation determination. Petitioner admitted that, at the time of the two failed inspections in October, the posted business hours on her suite incorrectly showed that her office was open for business Monday through Friday, 8:00 a.m. to 5:00 p.m. P. Ex. 2, at 3 (Kallfelz Affid. ¶ 9).

Petitioner's argument that she updated her signage and was in compliance at some later date after receiving notice of the revocation does not allow me to reverse CMS's revocation determination. *See A to Z DME*, DAB No. 2303, at 6 (2010) ("An argument that the supplier became operational at some later point in time would not, by itself, demonstrate that CMS's revocation determination was erroneous.") As the Board similarly stated in *Pepper Hill Nursing & Rehab Ctr., LLC*, "[A] provider or supplier is required to furnish the evidence that demonstrates that the Medicare contractor made an error at the time an adverse determination was made, not that the provider or supplier is now in compliance." *Pepper Hill Nursing & Rehab Ctr., LLC*, DAB No. 2395, at 6

(2011), *citing* 73 Fed. Reg. 36,448, 36,452 (June 27, 2008). Further, a CMS contractor's refusal to reinstate a supplier's billing privileges based on a CAP is not appealable to an ALJ. *DMS Imaging, Inc.*, DAB No. 2313, at 5 (2010).

C. I am unauthorized to grant Petitioner's requests for equitable relief.

At the reconsideration level and during this appeal, Petitioner makes various arguments for equitable relief despite not meeting the legal requirements for suppliers. Petitioner concedes that her posted hours of operation were incorrect in October 2011, but she asks NSC to "pardon [her] oversight." Petitioner argues that her supplier number should be reinstated since she only treats residents in nursing facilities, where it is difficult for them to leave to be seen by a specialist. CMS Ex. 5. Petitioner claims that she also received "inconsistent" and "conflicting information" from NSC regarding Medicare requirements. RFH; P. Ex. 2, at 4 (Kallfelz Affid. ¶ 13). Petitioner contends further that NSC wrongly upheld her revocation on the grounds that she failed to inform NSC of her address change when she moved. RFH. Finally, Petitioner argues that the NSC inspector failed to follow-up with the telephone representatives with whom he spoke during his October and December 2011 site visits. P. Br. at 10-11, 16.

Petitioner's equitable arguments give me no grounds to grant her any relief. *See 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."). Moreover, I have no authority to declare statutes or regulations invalid or ultra vires. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 14 (2009) ("[a]n ALJ is bound by applicable laws and regulations and may not invalidate either a law or regulation on any ground."). I must sustain CMS's determination if a legitimate basis for revocation existed with facts establishing noncompliance with one or more of the regulatory standards. *Id.* at 13.

Further, Petitioner's contention that NSC gave her "conflicting information" may also be construed to be a claim of equitable estoppel. It is well-established by federal case law, and in Board precedent, that: (1) estoppel cannot be the basis to require payment of funds from the federal fisc; (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. *See, e.g., Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414 (1990); *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63 (1984); *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); *US Ultrasound*, DAB No. 2302, at 8 (2010). Here, Petitioner has not alleged affirmative misconduct by the government. It is also well-settled that those who deal with the government are expected to know the law. *See Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63. Accordingly, I must reject any equitable estoppel argument here.

As for Petitioner's additional assertions regarding the relocation of her practice and the December 1, 2011 attempted on-site inspection, I find that it is not necessary to address them. The events surrounding those allegations occurred after the October 2011 failed on-site visits, which are the basis of CMS's revocation that I sustain here, and Petitioner's official address of record in October 2011 is not in dispute.

IV. Conclusion

I find that Petitioner was not operational when her business location was not open and accessible on two separate occasions in October 2011, during its posted hours of operation. I therefore sustain the revocation of Petitioner's supplier billing number. Accordingly, Petitioner is barred from re-enrolling in Medicare for two years effective October 4, 2011, the date CMS properly determined Petitioner was not operational.

/s/

Joseph Grow
Administrative Law Judge