

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Mane Medical Equipment & Supplies, Inc.,

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-13-120

Decision No. CR2787

Date: May 15, 2013

DECISION

I sustain the revocation of the Medicare enrollment and billing privileges for Mane Medical Equipment & Supplies, Inc. (Petitioner) based on its noncompliance with 42 C.F.R. § 424.57(c)(22) (supplier standard 22), which requires suppliers to be continually accredited by a Centers for Medicare and Medicaid Services (CMS) approved accreditation organization.

I. Background and Procedural History

Petitioner, a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), had been enrolled in Medicare since August 12, 2005. Palmetto GBA National Supplier Clearinghouse (NSC), a Medicare contractor responsible for enrolling and issuing billing numbers to Medicare suppliers, revoked Petitioner's Medicare number and billing privileges on August 3, 2012, and the revocation became effective 30 days from the postmark date of the letter, on September 2, 2012. CMS Exhibit (CMS Ex.) 23, at 2.

Although Petitioner may disagree with its reasons for doing so, it is undisputed that the relevant accreditation organization did not approve Petitioner's accreditation at the time

of the Medicare enrollment revocation. The numerous and involved attempts that Petitioner, CMS, and CMS's contractors made to rectify Petitioner's accreditation issues, before and after the revocation, are summarized below:

- The Compliance Team (TCT), a CMS approved accreditation organization, accredited Petitioner as of July 23, 2009. CMS Ex. 1; CMS Ex. 13, at 3.
- Petitioner signed a two-year accreditation contract with TCT, including contracting for annual evaluation visits allowing TCT to survey the facility. CMS Ex. 13, at 3; CMS Ex. 5, at 6.
- TCT issued a certificate of accreditation to Petitioner, with an expiration date of August 27, 2011. CMS Ex. 2.
- In February 2011, TCT began notifying Petitioner that it needed to renew its accreditation. CMS Ex. 13, at 3.
- Petitioner did not respond to TCT, and Petitioner's accreditation with TCT expired as of August 27, 2011. CMS Ex. 13, at 3; CMS Ex. 5, at 5-15.
- In March 2012, NSC contacted TCT for verification of Petitioner's accreditation, which could not be confirmed. CMS Ex. 3, at 1; CMS Ex. 13, at 3.
- On March 15, 2012, NSC notified Petitioner that it was revoking its Medicare supplier number, effective 30 days from March 15, 2012. NSC explained that it had received information from TCT that Petitioner was no longer accredited as of August 27, 2011, a violation of supplier standard 22, which requires that all DMEPOS suppliers be accredited by a CMS-approved accreditation organization to receive and retain a billing number. CMS Ex. 3, at 1.
- The March 15, 2012 letter informed Petitioner that it had the right to request reconsideration within 60 days and to submit a corrective action plan (CAP) within 30 days of the postmark date of the letter. CMS Ex. 3, at 1.
- On April 9 and 12, 2012, Petitioner requested reconsideration. CMS Ex. 4, at 1-2; CMS Ex. 5, at 1-3.
- On April 27, 2012, upon review of Petitioner's corrective action, NSC approved reinstatement of Petitioner's supplier number, effective April 14, 2012. CMS Ex. 6.
- After e-mail and phone exchanges, TCT determined Petitioner could apply to TCT as a "transition . . . not a renewal" supplier. On April 27, 2012, Petitioner submitted a "Full DMEPOS Transition Application" to TCT. CMS Ex. 7; CMS Ex. 13, at 3; Petitioner Appendix (P. Appendix) 3.
- The Transition Application, signed by Petitioner's President, specifically notes that "[TCT] reserves the right to [survey] the provider applicant locations at any time during the course of this contract. Accreditation is contingent upon an on-site evaluation score of 90% or better." CMS Ex. 7, at 3; P. Appendix 3.

- Due to the “expediency in nature expressed by” Petitioner, and the fact Petitioner was not accredited, TCT fast-tracked the scheduling of an on-site visit to the facility. CMS Ex. 13, at 3.
- On May 9, 2012, TCT made an on-site “renewal” visit to survey Petitioner. Petitioner scored 79%. CMS Ex. 8.
- On May 10, 2012, TCT informed Petitioner that it had failed to maintain a minimum score of 90% during the May 9, 2012 on-site visit and that its score was not high enough to maintain accreditation. CMS Ex. 9.
- In the May 10, 2012 letter, TCT stated that Petitioner’s business would be reported to CMS as “accredited.” Conversely, in the same letter, TCT informed Petitioner that TCT allows for three options after initial failure notification: CAP and Evaluation; Calls (with an advisor to review negative scoring), CAP, and Evaluation; and Appeal. Petitioner was informed that if the initial CAP was not approved, it would be given 14 days to submit a revised CAP. If a second CAP was not approved, the revocation would be reported to CMS. CMS Ex. 9.
- On May 22, 2012, NSC conducted a site visit of Petitioner. The record does not contain any documents reflecting the results of that visit. P. Appendix 6.
- On August 3, 2012, NSC notified Petitioner that it was revoking its Medicare supplier number effective 30 days from the letter’s postmark date, September 2, 2012, and that Petitioner was barred from re-enrolling in Medicare for one year from September 2, 2012. CMS Ex. 10. NSC informed Petitioner that it was taking this action specifically based on 42 C.F.R. § 424.57(c)(22), which requires that DMEPOS suppliers be accredited by a CMS-approved accreditation organization to receive and retain a supplier billing number. NSC stated that it had been confirmed that Petitioner was no longer accredited as of May 9, 2012. NSC notified Petitioner that it could submit a CAP within 30 days or request reconsideration of the decision within 60 days of the postmark date. CMS Ex. 10.
- On August 10, 2012, TCT approved Petitioner’s accreditation CAP (a separate process from NSC’s CAP) subject to a passing score on an upcoming on-site visit survey. P. Appendix 14.
- On August 14, 2012, Petitioner notified TCT that it was ready for an on-site remedial visit, pursuant to its CAP with TCT, as of August 20, 2012. CMS Ex. 11.
- On August 27, 2012, Petitioner submitted a CAP to NSC pursuant to the August 3, 2012 NSC revocation letter. Petitioner stated that it disagreed with NSC’s conclusion that it was no longer accredited as of May 9, 2012. Petitioner asserted that it was accredited through August 31, 2012, based on a three-year accreditation cycle. CMS Ex. 12.

- TCT conducted the August 30, 2012 on-site visit survey “for allowance of an NSC Corrective Action Plan if capable” and to “verify and validate the TCT Quality Standards.” CMS Ex. 13, at 3.
- On September 5, 2012, TCT informed Petitioner that it again failed to achieve the minimum score of 90% during the August 30, 2012 on-site visit survey. CMS Ex. 13, at 1.
- TCT found that although some areas of concern from the May 9, 2012 on-site visit survey had improved, there were still some areas of concern such as: Petitioner’s policy and procedures were templates not reflecting its current practices and did not incorporate all requirements needed within quality standards; equipment management; unsubstantiated financial management; undocumented shared space with Mane Medical Billing Services; and lack of personal protection equipment. One of the most “concerning points” for the TCT investigator while on-site was that Petitioner’s main phone was not answered by its owner/president (its only staff) when it rang six or eight times, the owner/president let it go to voicemail every time, but the owner/president answered his cell phone. CMS Ex. 13, at 3-4.
- On September 17, 2012, Petitioner requested reconsideration, arguing that it was accredited by TCT as of August 31, 2012, as verified by an accreditation certificate e-mailed from TCT to Petitioner on April 14, 2012. Furthermore, Petitioner claimed TCT’s May 10, 2012 letter notified CMS that Petitioner was accredited. CMS Ex. 14; P. Appendix 1c.
- On September 19, 2012, the CMS Center for Program Integrity sent a letter responding to allegations Petitioner made against TCT. The individual responding to Petitioner was a senior technical advisor for the Program Integrity Group in the Center and a registered nurse.¹ She informed Petitioner, that while TCT’s communications with Petitioner were “very confusing and in part incorrect” and that CMS “expect[ed] better customer service from [its] deemed accreditation organizations,” the fact remained that Petitioner was aware that its on-site visit on May 9, 2012 scored a failing 79%. The August 30, 2012 visit also did not meet minimum requirements, particularly because Petitioner needed to be available “24 hours/day, seven days/week due to its furnishing oxygen.” She noted that the points Petitioner argued did not have a significant bearing on the fact that Petitioner was not providing quality services to Medicare beneficiaries. She noted that TCT had given Petitioner more than one opportunity to improve the quality of its service provision. Finally, she did not disturb NSC’s revocation decision. CMS Ex. 15; CMS Ex. 23.
- On September 20, 2012, NSC acknowledged receipt of Petitioner’s CAP. NSC stated that Petitioner still did not comply with supplier standard 22 because it was not accredited by TCT. CMS Ex. 16.

¹ CMS submitted the nurse’s declaration as CMS Ex. 23.

- On September 24, 2012, Petitioner again requested NSC reconsider the revocation of its supplier number. Petitioner stated that it was in fact accredited through August 31, 2012, and noted the accreditation certificate e-mailed to it on April 14, 2012. It also again referenced TCT's statement of May 10, 2012 that it was accredited. Petitioner also stated that the May 9, 2012 on-site visit survey was to validate its compliance for renewal purposes and had no bearing on its current accreditation status. CMS Ex. 17.
- On October 4, 2012, the President of TCT wrote Petitioner to state that its accreditation expired on August 27, 2011. TCT stated that it had no contact with Petitioner until April 12, 2012, when a TCT employee advised Petitioner that its accreditation had expired. The President stated that subsequent back-to-back validation surveys did not show Petitioner achieved compliance following the August 27, 2011 expiration date of accreditation, and NSC chose to use the May 9, 2012 date as Petitioner's accreditation expiration date. TCT's president further explained that TCT would conduct a review process and that Petitioner could expect a formal response to its appeal. CMS Ex. 18.
- On October 22, 2012, the NSC Medicare Hearing Officer upheld the revocation of Petitioner's Medicare billing privileges, based on noncompliance with supplier standard 22 requiring maintenance of accreditation. She noted that the information provided did not demonstrate that Petitioner was in compliance with supplier standard 22 and instead showed that Petitioner did not achieve or maintain a passing score of 90% or over at the May 9, 2012 on-site visit. CMS Ex. 20.
- In an undated letter, the President of TCT upheld the denial of its accreditation decision on "final review." The President noted that although Petitioner disputes the expiration date of its accreditation certificate, the original certificate issued in 2009 expressly provided for expiration in 2011, as did its July 2010 certificate of accreditation and August 2010 correspondence reflecting results of a July 27, 2010 on-site inspection. She noted that TCT made numerous efforts to contact Petitioner in advance of the August 2011 expiration date, and there was no excuse for Petitioner to ignore these efforts. The statement in the May 10, 2012 letter that Petitioner "be reported to CMS as accredited" was a clerical oversight and should have been removed. However, the "totality of our communications . . . indicates unequivocally that [Petitioner] failed to meet the minimum accreditation standards." She notes that none of the confusion surrounding the May 9, 2012 on-site visit would be relevant had Petitioner remedied its deficiencies prior to TCT's August 30, 2012 on-site visit survey, which Petitioner failed with a lower score than on the May 9, 2012 on-site visit survey. She notes that while Petitioner made some improvements, its score was lowered by shortcomings in other areas not identified by the first inspection. CMS Ex. 22.
- Petitioner was able to bill and be reimbursed by Medicare under its supplier number through September 2, 2012. CMS Ex. 23, at 2 ¶ 5.

On November 14, 2012, the Civil Remedies Division of the Departmental Appeals Board received Petitioner's hearing request, dated November 6, 2012, accompanied by Appendices 1a-c and 2-14. I was assigned to hear and decide the case. In response to my November 20, 2012 Acknowledgment and Pre-hearing Order (Order), on December 26, 2012, CMS filed a motion for summary disposition and brief and 23 proposed exhibits. On January 16, 2013, Petitioner filed a motion for reversal of revocation and brief, accompanied by one proposed exhibit. In the absence of objection, I admit CMS Exs. 1 through 23.² CMS did not object either to Petitioner's Appendices or to the exhibit Petitioner filed with its brief. I admit as exhibits Petitioner's Appendices 1a-c and 2-14, and P. Ex. 1. CMS offered the written direct testimony of one witness, but Petitioner has not requested cross-examination in accordance with my Order. Petitioner did not list any witnesses. Therefore, I do not find it necessary to convene an in-person hearing. Accordingly, the record is closed, and having considered all of the documentary evidence. I issue this decision based on the complete written record. *See* Order ¶ 10.

II. Discussion

A. Applicable Authority

Section 1834(a)(20)(F)(i) of the Social Security Act (Act) states that the Secretary "shall require suppliers . . . on or after October 1, 2009 . . . to have submitted to the Secretary evidence of accreditation by an accreditation organization designated . . . as meeting applicable quality standards"

CMS's regulations implement this requirement among the "supplier standards" at 42 C.F.R. § 424.57(c), that DMEPOS suppliers must meet to maintain Medicare billing privileges. As relevant here, section 424.57(c) provides:

(c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards. . . .

* * * *

(22) All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment for those specific products and services.

² Many of CMS's exhibits are duplicates of Petitioner's Appendices. Where there is duplication, I refer to the CMS exhibits.

Suppliers of DMEPOS are subject to on-site surveys, both announced and unannounced, for accreditation purposes. *See* 42 C.F.R. § 424.58(a), (b). The regulations provide generally that CMS will revoke a supplier's billing privileges if the supplier is found not to meet the supplier standards or other requirements in section 424.57(c). 42 C.F.R. § 424.57(e).³ CMS may also revoke a currently enrolled supplier's Medicare billing privileges and any corresponding supplier agreement for noncompliance when the supplier is determined not to be in compliance with enrollment requirements. 42 C.F.R. § 424.535(a)(1). A supplier is granted an opportunity to correct the deficient compliance before a final determination to revoke billing privileges. *Id.* Revocation generally becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the supplier. 42 C.F.R. § 424.535(g).

A supplier that has had its billing privileges revoked is "barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar 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).

B. Issue

The issue in this case is whether the revocation of Petitioner's Medicare billing privileges was legally authorized.

C. Findings of Fact and Conclusion of Law

CMS was authorized to revoke Petitioner's supplier enrollment and billing privileges, effective September 2, 2012, based on evidence that Petitioner was not continually accredited as required by 42 C.F.R. § 424.57(c)(22).

While the background of this case may appear complex, the material facts are not. TCT, the Medicare approved accrediting organization, maintains that Petitioner failed a May 9, 2012 on-site accreditation survey. TCT maintains that Petitioner later failed an August 30, 2012 on-site accreditation survey. Thus, over the course of two separate on-site surveys of its operations, and despite several opportunities to correct its noncompliance, Petitioner was unable to show, on the date that NSC revoked its Medicare enrollment, that it was continuing to meet supplier standards of continual accreditation that were required to maintain its Medicare billing privileges.

³ Paragraph (e) of section 427.57 was previously designated paragraph (d) and was re-designated by the rulemaking that imposed the surety bond requirements at paragraph (d); however, the re-designations have not yet been incorporated in the Code of Federal Regulations. 42 C.F.R. § 424.57, Editorial Note (2012).

Petitioner's primary response to its failure to meet standards on May 9, 2012, and its failure to meet those standards again at the second on-site visit survey on August 30, 2012, is to argue that its certificate of accreditation did not expire until August 31, 2012. CMS Exs. 4, at 2; 12; 14; 17; and 21, at 1. As CMS notes, however, Petitioner's argument demonstrates a "fundamental misunderstanding" of the regulatory requirements for DMEPOS supplier accreditation. While an individual accreditation organization may issue a certificate of accreditation that spans a given timeframe, even assuming Petitioner was originally accredited for three years through August 31, 2012, the expiration date on a certificate of accreditation is not a substitute for a DMEPOS supplier's continuing obligation to maintain compliance with certification standards under 42 C.F.R. § 424.57(c). An accreditation organization such as TCT has an obligation to determine whether a DMEPOS supplier is meeting supplier standards, and it does so through various means, including both announced and unannounced on-site visit surveys.

In the contract Petitioner's President signed on April 27, 2012, TCT specifically informed Petitioner that TCT reserves the right to survey it at any time during the course of the contract. Regulations require that if an accreditation organization finds out that a supplier is not meeting accreditation requirements during a survey, the accreditation organization must notify CMS of the noncompliance on an on-going basis. 42 C.F.R. § 424.58(c). Supplier standards are in place to ensure that DMEPOS suppliers provide quality products and services to Medicare beneficiaries including, as is the case here, being sufficiently available to individuals for whom the DMEPOS supplier is supplying oxygen. To allow an unexpired certificate of accreditation to, as CMS notes, "trump" a DMEPOS supplier's intervening failure to meet minimum accreditation standards would be contrary "to statute, regulation, and common sense."

Petitioner also argues that the timing of the revocation notice was unfair because in its May 10, 2012 letter, TCT stated that if Petitioner's initial accreditation CAP was not approved, it would have 14 days to submit a revised CAP. If TCT did not approve Petitioner's revised CAP, only then did TCT state it would report Petitioner's revocation to CMS. Petitioner argues, however, that TCT did not follow these steps. Instead, TCT reported Petitioner's revocation to NSC prior to Petitioner submitting its revised accreditation CAP. Petitioner's argument is unavailing, though, because the regulations actually required TCT to notify CMS when Petitioner failed to meet accreditation requirements. Specifically, an accreditation organization such as TCT is required to notify CMS monthly about, among other things, survey-related information (such as a summary of findings or a CAP), accreditation decisions, and adverse actions including revocation of supplier accreditation. 42 C.F.R. § 424.48(c). Further, regardless of whether TCT's statement conflicted with the obligations of regulatory requirements, Petitioner still did not ultimately receive a passing score for accreditation on the August 30, 2012 on-site visit survey.

NSC's letter revoking Petitioner's supplier number and billing privileges specifically offered Petitioner 30 days in which to submit a CAP to NSC. CMS Ex. 10, at 2. Petitioner did so on August 27, 2012. CMS Ex. 12. NSC ultimately determined, however, that Petitioner did not include any evidence in its CAP that it met supplier standards. CMS Ex. 16. Neither the Act nor regulations provide for appeal of CMS's (or the CMS contractor's) denial of a CAP. See *DMS Imaging, Inc.*, DAB No. 2313, at 5-8 (2010). Further, during the reconsideration and appeal process, the issue is whether a basis for revocation, legally sufficient to support CMS's action, existed at the time of the revocation notice, not whether that basis was later eliminated pursuant to a CAP. See *Eastern Plumas District Hospital*, DAB CR2168, at 3 n.3 (2010) (explaining a key difference between a CAP and a reconsideration).

Although Petitioner also argues that TCT did not honor contractual obligations to prepare it for site visits, Petitioner never disputes that CMS recognized TCT as having the authority to accredit DMEPOS suppliers. TCT's unequivocal and considered position is that Petitioner was not accredited on the date of Petitioner's August 3, 2012 revocation. I do not, therefore, have the authority to interfere with that determination because it is from a properly-recognized accrediting authority.

III. Conclusion

CMS, through its contractor NCS, had a legitimate basis to revoke Petitioner's supplier number and billing privileges, effective September 2, 2012, based on Petitioner's failure to comply with continual accreditation requirements for suppliers.

/s/

Joseph Grow
Administrative Law Judge