

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Norpro Orthotics & Prosthetics, Inc.
Docket No. A-14-54
Decision No. 2577
June 11, 2014

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Norpro Orthotics & Prosthetics, Inc. (Norpro), a Florida-based company that was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), requests review of the January 14, 2014 decision of an Administrative Law Judge (ALJ). *NORPRO Orthotics & Prosthetics, Inc.*, DAB CR3081 (2014) (ALJ Decision).¹ In that decision, the ALJ sustained the revocation of Norpro's Medicare billing privileges by the Centers for Medicare & Medicaid Services (CMS) on the ground that Norpro was out of compliance with the DMEPOS supplier standard at 42 C.F.R. § 424.57(c)(7). For the reasons stated below, we affirm the ALJ's conclusion that CMS lawfully revoked Norpro's Medicare billing privileges. We hold, however, that Norpro's revocation became effective on May 2, 2013, rather than on April 17, 2013, the effective date imposed by the ALJ.

Background

In order to maintain Medicare enrollment and associated "billing privileges," a DMEPOS supplier must be in compliance with the 30 "supplier standards" set forth in 42 C.F.R. § 424.57(c). Under section 424.57(c)(7), a DMEPOS supplier is required to maintain "a physical facility on an appropriate site." An "appropriate site" must, among other things, be "accessible and staffed during posted hours of operation." 42 C.F.R. § 424.57(c)(7)(i)(C). CMS (through its contractors) performs on-site inspections to verify compliance with the supplier standards and other Medicare requirements. *See id.* §§ 424.57(c)(8), 424.517. CMS is authorized to revoke a DMEPOS supplier's billing

¹ In his decision, the ALJ referred to the petitioner in this case as "NORPRO," consistent with the petitioner's letterhead, which reads "NORPRO ORTHOTICS & PROSTHETICS, INC." This decision uses "Norpro" because that is how petitioner refers to itself in the text of its request for review and on its public website. *See* Req. for Rev. (R.R.) at 1; <http://www.norproinc.com/>.

privileges for noncompliance with any of the supplier standards. *Id.* § 424.57(d).² CMS is also authorized to revoke a supplier's billing privileges for any of the "reasons" listed in section 424.535(a). (Section 424.535 applies to all types of Medicare "suppliers," not just DMEPOS suppliers.)

The following facts are undisputed. Norpro operates several facilities in Florida, including a facility in Lake Worth. At 12:29 p.m. on Thursday, February 21, 2013, an inspector from Palmetto GBA National Supplier Clearinghouse (NSC), a CMS contractor, attempted to conduct an "ad hoc" site visit at Norpro's Lake Worth facility. The facility's posted hours of operation were 8:30 a.m. to 5:00 p.m., Monday through Thursday, and Friday by appointment, but when the inspector arrived, the facility's front door was locked and no one responded to the inspector's knocks on the door. The inspector attempted to visit the facility again on Tuesday, March 5, 2013, at 10:06 a.m. At that time, the front door to the facility was unlocked, the lights were on inside, and the sound of a radio playing in the rear of the facility was faintly audible, but no one was present in the lobby area or behind a reception desk. The inspector called out several times but received no response. She also attempted to open an interior door leading from the lobby further into the facility, but the door was locked and no one responded to her knocks on the door. The inspector returned to the facility later that day at 11:23 a.m., but once again she "found no one responding to [her] being present in the facility." CMS Ex. 2, at 6.

By letter dated April 2, 2013, CMS, through NSC, notified Norpro that its supplier billing privileges had been revoked. The letter stated that Norpro's Florida Orthotist and Prosthetist licenses on file had expired, in violation of section 424.57(c)(1); that its liability insurance policy on file had expired, in violation of section 424.57(c)(10); and that its Lake Worth facility was closed during the NSC inspector's attempted on-site visits on February 21 and March 5, 2013, so it had failed to maintain a facility on an "appropriate site," in violation of section 424.57(c)(7). CMS Ex. 1. The letter also stated that, based on the closure, CMS had determined the facility was "not operational to furnish Medicare covered items and services," in violation of section 424.535(a)(5)(ii). *Id.* at 2. The letter explained that the revocation was effective March 5, 2013, the date CMS had determined that the facility was not operational (and the date of the NSC inspector's second attempted on-site visit), and that Norpro was barred from re-enrolling in Medicare for two years from this effective date. *Id.* at 1.

² The editorial note following section 424.57 in the Code of Federal Regulations (CFR) states that a January 2, 2009 final rule (74 Fed. Reg. 198) re-designated paragraph (d) of section 424.57 as paragraph (e) but that this and other changes to section 424.57 were not incorporated into the codified text of the regulations because of an "inaccurate amendatory instruction." Our references to section 424.57(d) in this decision are to the current codification of that section rather than the re-designated section, but, as explained later, we apply the re-designated section when changing the effective date. As the Board explained in *Benson Ejindu, d/b/a Joy Medical Supply*, the re-designated section took effect with publication of the final rule in the Federal Register, even though the CFR has not been amended to reflect that change. *See* DAB No. 2572, at 10 n.8 (2014).

Norpro's owner requested reconsideration of CMS's initial revocation decision. He alleged that the Lake Worth facility "is open Monday through Friday from 8:30 AM to 5:00 PM, closing only for lunch from noon to 1:00 PM" and is staffed by "a full time employee that is supposed to be there those hours." CMS Ex. 3, at 1. The owner stated that he did not "want to believe" that the employee hired to staff the facility at the time of the inspections "took advantage of my trust in her and took off without letting someone know," but that "she was nervous sometimes on the days when some of the other [surrounding] offices were closed, so maybe she had the door locked" when the inspector visited. *Id.* The owner further stated that the errant employee "is no longer with the company" and emphasized that "if the door was not open it was without my knowledge." *Id.* With his letter, the owner enclosed up-to-date copies of Norpro's liability insurance policy and the Florida licenses for two orthotists and one prosthetist, as well as excerpts of daily schedules for the Lake Worth facility in February and March 2013. *Id.* at 2-7.

In a reconsideration decision dated June 24, 2013, CMS, through NSC, again concluded that Norpro's Medicare billing privileges should be revoked because Norpro was out of compliance with section 424.57(c)(7), but determined that Norpro had shown compliance with section 424.57(c)(1) and (10). CMS Ex. 4. Norpro subsequently filed a request for hearing before an ALJ, seeking reinstatement of its supplier number "[i]n light of the changes we have made," namely replacing the employee who was supposed to staff the Lake Worth facility at the time of the attempted inspections and regularly checking the facility to make sure that it is open during its posted hours. Req. for Hearing.

CMS moved for summary judgment in its favor, arguing that the revocation of Norpro's billing privileges was appropriate because its Lake Worth facility was not accessible and staffed on the three occasions the NSC inspector attempted to visit, in violation of section 424.57(c)(7). Norpro did not initially respond to CMS's motion, but after the ALJ issued an order to show cause why the appeal should not be dismissed as abandoned, Norpro submitted a letter explaining that it did not realize a response was necessary "since we had already explained our past situation and the changes that we were making to rectify the problem." Show Cause Resp. Norpro requested that the ALJ decide the appeal "based on the information and documents that we have already sent," explaining, "We cannot dispute what the site inspector says she found because we were not there. As stated in our appeal we trusted that our employee was there doing her job." *Id.*

The ALJ interpreted Norpro's letter as a request for a decision on the written record, which he granted. ALJ Decision at 3. The ALJ determined that the record established that Norpro's Lake Worth facility "was not open to the public and properly staffed" during its posted hours of operation on the three occasions the NSC inspector attempted to visit. *Id.* at 1, 3-4. Accordingly, the ALJ concluded, Norpro was out of compliance with the DMEPOS supplier standard at 42 C.F.R. § 424.57(c)(7), so CMS was authorized to revoke Norpro's Medicare billing privileges. *Id.* at 5-6.

Although the ALJ sustained CMS's revocation determination, he altered the effective date of the revocation from March 5, 2013 – the date CMS had decided Norpro's facility was not operational, according to CMS's initial revocation determination – to April 17, 2013 – 15 days after the date CMS issued the initial determination. In setting March 5 as the effective date, CMS had presumably relied on the provision in section 424.535(g) that the effective date of a revocation based on a finding that a supplier's practice location is not operational is the date CMS or its contractor determined the location was no longer operational. The ALJ noted that while the initial determination had determined that Norpro was not operational and had identified section 424.535(a)(5)(ii) as one of the bases for revocation, the reconsidered determination on which his review was predicated relied only on section 424.57(c)(7) as the basis for the revocation. ALJ Decision at 6-7. Thus, the ALJ reasoned, the provision in section 424.535(g) regarding the effective date of a revocation based on a non-operational practice location did not apply. *Id.* at 6. Instead, the ALJ concluded, “[w]hen a revocation is based on a failure to meet the Supplier Standards, ‘revocation is effective 15 days after the entity is sent notice of the revocation.’” *Id.* at 6-7, citing 42 C.F.R. § 424.57(d).

Norpro timely requested review of the ALJ Decision by the Board.

Standard of Review

The standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence in the record as a whole. The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *Guidelines -- Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program* (Guidelines), <http://www.hhs.gov/dab/divisions/appellate/guidelines/prosupenrolmen.html>.

Analysis

- 1. The ALJ correctly concluded that CMS was authorized to revoke Norpro's Medicare billing privileges because Norpro was out of compliance with section 424.57(c)(7).**

The ALJ correctly concluded that the record established that Norpro's Lake Worth facility was not “accessible and staffed during posted hours of operation” on the three occasions the NSC inspector attempted to visit, and therefore that CMS was authorized to revoke Norpro's billing privileges based on its noncompliance with section 424.57(c)(7).

As the ALJ noted in upholding the revocation, the inspector's report submitted by CMS detailed the inspector's three unsuccessful attempts to visit the Lake Worth facility and documented those attempted visits with photographs. ALJ Decision at 3-4, citing CMS Ex. 2. Before the ALJ, Norpro emphasized that it hired an employee to staff the facility during its hours of operation, but acknowledged that it appeared the employee was not doing her job and that it could not dispute the inspector's report. We agree with the ALJ that the report established that Norpro's facility was not accessible and staffed during its posted hours of operation on February 21 and March 5, 2013. As detailed in the report, the inspector attempted to visit the facility during its posted hours of operation once on February 21 and twice on March 5. During these visits, the inspector never encountered any staff and was either unable to enter the facility at all or able to gain access to only the front lobby, despite repeatedly knocking on doors and calling out. CMS Ex. 2, at 6. The absence of staff and limited-to-nonexistent access to the facility are inconsistent with the requirements of section 424.57(c)(7).

In both its request for reconsideration by CMS and its request for review before the Board, Norpro suggested that the employee who was supposed to be staffing the facility at the time of the attempted on-site visits was present but had the door locked for her safety and peace of mind. CMS Ex. 3, at 1; R.R. at 1. Norpro did not explain, however, why the employee would not have responded to the inspector's knocks if this was the case. Norpro also asserted for the first time before the Board that the employee might have been around the back of the facility on a break at the times the inspector visited. R.R. at 2. The Board generally does not consider issues or arguments that could have been presented to the ALJ but were not. Guidelines.³ In any event, if the employee was present behind a locked door or behind the facility on a break when the inspector visited, the facility was not "staffed" then as section 424.57(c)(7) requires. In order to meet section 424.57(c)(7)'s requirements, a facility must be continually staffed during its posted hours of operation. *See Complete Home Care, Inc.*, DAB No. 2525, at 6 (2013). The preamble to the proposed rule that added section 424.57(c)(7)(i)(C) explained that a "supplier is not in compliance with this standard if no one is *available* during the posted hours of operation." 73 Fed. Reg. 4503, 4506 (Jan. 25, 2008) (emphasis added). Similarly, the preamble to the final rule explained that exceptions to the staffing requirement have always been made for emergencies, disasters, and federal and state holidays, but emphasized that DMEPOS suppliers "should be available during posted

³ We also note Norpro submitted no evidence to support this new argument. Even if it had submitted such evidence, the Board would not have been able to consider it since it is not authorized to consider evidence not submitted to the ALJ in provider or supplier enrollment appeals. 42 C.F.R. § 498.86(a).

business hours” and should “do [their] best to plan and staff for temporary absences.” 75 Fed. Reg. 52,629, 52,636 (Aug. 27, 2010). During the inspector’s visits to the Lake Worth facility, no employees were available to assist her, nor did she see any employees on the premises. In addition, there was no signage or other mechanism letting a customer know how a staff member could be reached and be readily available. Under these circumstances, the facility was not “staffed” in accordance with section 424.57(c)(7).

Under the scenarios alleged by Norpro, the facility also was not “accessible” during its posted hours of operation as section 424.57(c)(7) requires. As the Board recently explained, the word “accessible” in section 424.57(c)(7)(i)(C) is appropriately defined as “‘providing access,’ ‘capable of being reached,’ or ‘capable of being used or seen.’” *Benson Ejindu, d/b/a Joy Medical Supply*, DAB No. 2572, at 6, quoting *Webster’s New Int’l Dictionary, Unabridged*. However, a DMEPOS supplier’s facility “does not ‘provid[e] access’ to a Medicare beneficiary,” nor can it “be ‘used’ or physically ‘reached’ by the beneficiary” if the facility’s “entry door is locked during posted hours, no one responds to a knock on the door, and there is no alternative means of gaining entry for a customer seeking to purchase or at least consider purchasing Medicare-covered supplies.” *Id.* When she visited the Lake Worth facility, the inspector encountered locked doors and did not get a response to her knocks. Norpro did not allege, nor do the photos taken by the inspector show, that there were any instructions posted on the facility’s front door, interior door, or reception desk area for how to access the facility and obtain assistance in the event that the doors were locked or the reception area was unstaffed. Thus, the facility was not “accessible” within the meaning of section 424.57(c)(7).

Norpro also reprised on appeal its argument that revocation is inappropriate because it simply trusted the employee to do her job and if she was failing to staff the facility as required, she was doing so without anyone’s knowledge. R.R. at 1-2. As the ALJ correctly explained in rejecting this argument, a supplier is “responsible for ensuring compliance with the Supplier Standards and for the conduct of its employees,” so Norpro’s lack of knowledge about its employee’s failure does not provide a basis for reversing the revocation. ALJ Decision at 5, citing *Louis J. Gaefke*, DAB No. 2554, at 5-6 (2013) (holding that CMS was authorized to revoke podiatrist’s billing privileges for improper billing even if podiatrist’s billing agent was responsible for submission of the improper claims). We also note that Norpro’s contention that it was unaware of any failure by the employee to appropriately perform her job is undermined by Norpro’s assertion on appeal that at some date prior to the attempted on-site inspections, Norpro’s owner “experienced a similar situation as did [the] inspector.” R.R. at 2. Specifically, the owner purportedly arrived unexpectedly at the facility, found the front door unlocked

but the reception desk unstaffed and the interior door locked, called out for the employee but received no response, and then discovered the employee behind the building smoking and talking on her cell phone. *Id.* Although the owner allegedly reprimanded the employee and “trusted that her irresponsibility was resolved,” this incident put him on notice that the employee might not be appropriately carrying out her responsibilities. *Id.*

Norpro also emphasized that it has been in business for 30 years and has never been sanctioned before and that if the revocation is upheld it will need to downsize and release many loyal employees. R.R. at 1-2. Norpro did not make these arguments before the ALJ, and it was inappropriate for Norpro to raise them for the first time on appeal. *See* Guidelines. In any event, Norpro’s arguments are essentially a plea for equitable relief. While the Board is authorized to review whether CMS has a legal basis to revoke a provider’s or supplier’s billing privileges, it cannot restore those privileges on equitable grounds. *See, e.g., Neb Group of Arizona LLC*, DAB No. 2573, at 6 (2014) (citing cases). Thus, neither Norpro’s alleged long-standing history of compliance with the Medicare requirement nor the alleged effect of a revocation provide a basis for reversing the revocation.

Accordingly, we affirm the ALJ’s conclusion that CMS lawfully revoked Norpro’s Medicare billing privileges.

2. The correct effective date for the revocation is May 2, 2013, 30 days after the date that CMS issued the initial revocation determination.

As the ALJ noted, CMS’s reconsidered determination based the revocation of Norpro’s billing privileges only on a finding of noncompliance with section 424.57(c)(7). *See* CMS Ex. 4. The ALJ sustained the revocation, as do we, based solely on a finding that Norpro’s Lake Worth facility was not “accessible and staffed during posted hours of operation” in violation of that section. Thus, as the ALJ concluded, the effective date of revocation should be determined in accordance with section 424.57’s effective date provision.

As it currently appears in the CFR, paragraph (d) of section 424.57 states that the effective date of a revocation based on a violation of section 424.57(c) “is effective *15 days* after the [supplier] is sent notice of the revocation” (italics added). The ALJ erroneously relied on this text in determining that the effective date of Norpro’s revocation should be April 17, 2013. ALJ Decision at 7. As we noted above, the regulation’s editorial note states that a January 2, 2009 final rule (74 Fed. Reg. 198) re-designated paragraph (d) of section 424.57 as paragraph (e) but that this and other changes to section 424.57 were not incorporated into the codified text of the regulation because of an “inaccurate amendatory instruction.” On August 27, 2010, CMS published a final rule in the Federal Register which revised paragraph (e) – that is, the re-designated

paragraph (d) – to extend the effective date of a revocation based on section 424.57(c) *from 15 to 30 days* after the supplier is notified of the revocation. 75 Fed. Reg. at 52,648-52,649. CMS indicated that it was making this change “[i]n order to be consistent with [its] regulations at [42 C.F.R.] § 424.535(g),” which states a general rule that the effective date of a revocation is 30 days from the date CMS mails the supplier notice of its revocation determination. *Id.* at 52,645. As re-designated and amended by the January 2, 2009 and August 27, 2010 final rules, the effective date provision in section 424.57 now provides in relevant part:

(e) Failure to meet standards — (1) Revocation. CMS revokes a supplier's billing privileges if it is found not to meet the standards in paragraphs (b) and (c) of this section. Except as otherwise provided in this section, the revocation is effective 30 days after the entity is sent notice of the revocation, as specified in § 405.874 of this subchapter. . . .

Id. at 52,648.⁴

In two recent decisions issued after the parties completed their briefing in this case, *Benson Ejindu, d/b/a Joy Medical Supply*, DAB No. 2572, and *Neb Group of Arizona LLC*, DAB No. 2573, the Board described this history of section 424.57's effective date provision and applied the 30-day rule. We notified the parties here of these decisions and gave them an opportunity to submit statements presenting any reasons why the 30-day effective date provision would not apply if we were to sustain the ALJ's decision to uphold the revocation for failure to comply with section 424.57(c)(7). In response, both Norpro and CMS indicated that they agreed the 30-day provision should apply. *See* CMS's Suppl. Resp. (June 4, 2014); E-Mail from Norpro (May 28, 2014). We conclude that the 30-day provision applies and thus find that the effective date of Norpro's revocation is May 2, 2013.

⁴ The reference to section 405.874 in section 424.57(e) is outdated. The relevant portions of that regulation have been moved to 42 C.F.R. § 405.800(b). *See* 77 Fed. Reg. 29,002, 29,016-29,017 (May 12, 2012). Section 405.800(b)(2) presently states that “[t]he revocation of a provider's or supplier's billing privileges is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational.”

Conclusion

For the reasons stated above, we affirm the ALJ's determination that CMS was authorized to revoke Norpro's Medicare billing privileges, but we reverse the ALJ's determination that the effective date of the revocation was April 17, 2013 and hold that the effective date of the revocation is May 2, 2013.

_____/s/
Leslie A. Sussan

_____/s/
Constance B. Tobias

_____/s/
Sheila Ann Hegy
Presiding Board Member