

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

Ortho Rehab Designs Prosthetics and Orthotics, Inc.
Docket No. A-14-82
Decision No. 2591
September 9, 2014

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

Ortho Rehab Designs Prosthetics and Orthotics, Inc. (Ortho) requests review of a decision by an Administrative Law Judge (ALJ) upholding the revocation of Ortho's Medicare billing privileges as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), *Ortho Rehab Designs Prosthetics and Orthotics, Inc.*, DAB CR3193 (2014) (ALJ Decision). The ALJ determined that the Centers for Medicare & Medicaid Services (CMS) had a legitimate basis to revoke Ortho's billing privileges effective July 18, 2013 because the undisputed facts established that, on the dates Ortho was visited by a CMS-contracted inspector, it was not "operational" as defined in the applicable regulations and did not comply with the enrollment requirement in DMEPOS Supplier Standard 7 that a DMEPOS supplier be "accessible and staffed" during its posted hours of operation. Ortho admits that it was closed on the dates the inspector visited, but argues that it is exempt from the enrollment requirement in DMEPOS Supplier Standard 7 and that it was treated unfairly because its revocation was based on visits made over two consecutive days instead of over a period of weeks or months. Ortho also appears to argue that there are genuine disputes about several material facts, so the ALJ should not have decided the case on summary judgment.

As discussed below, we find no merit to Ortho's arguments and conclude that the ALJ, based on the undisputed material facts, properly granted summary judgment to CMS and affirmed its revocation of Ortho's billing privileges on the ground that Ortho was not "accessible and staffed" during posted hours on the dates the inspector visited, as required by 42 C.F.R. § 424.57(c)(7)(i)(C). However, we also conclude that the ALJ erred in determining that CMS had a basis to revoke under section 424.535(a)(5)(ii) on the ground that Ortho was not "operational" as defined in section 424.502. Because CMS based the effective date of the revocation on a provision that applied only to revocation on the latter basis, we modify the effective date of the revocation to September 4, 2013 in accordance with section 424.57(e), which governs the effective date of instances of noncompliance with any of the supplier standards set forth in section 424.57(c).

Legal 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) (Supplier Standard 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 privileges for noncompliance with any of the supplier standards. *Id.* § 424.57(e).¹ Section 424.57(e) provides that the effective date of revocation for noncompliance with any of the enrollment standards under section 424.57(c) is 30 days after the supplier is sent notice of the revocation. *See* 75 Fed. Reg. 52,629, 52,648-52,649 (Aug. 27, 2010).

CMS may also revoke a supplier’s billing privileges if an on-site review reveals that the supplier is “no longer operational.” 42 C.F.R. § 424.535(a)(5)(ii). A supplier is operational if, among other things, 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 [the] items or services [being rendered].” *Id.* § 424.502. The effective date of revocation on this basis is the date CMS determines the supplier was “no longer operational” as a result of an on-site review. *Id.* § 424.535(g).

Case Background²

On Wednesday, July 17, 2013, at approximately 3 p.m., an inspector from the National Supplier Clearinghouse (NSC), a CMS contractor, attempted to conduct an unannounced site inspection of Ortho’s facility in Las Vegas, Nevada. CMS Ex. 1, at 1. Although Ortho’s posted hours of operation were Monday through Friday from 9 a.m. to 5 p.m., the front door was locked, no lights were on, no one appeared to be present, and no one responded to the inspector’s knocks on the door. *Id.* at 2. The inspector also noted that attached to the door were two notices from the United Parcel Service (UPS) indicating

¹ Section 424.57(e) currently appears in the Code of Federal Regulations as section 424.57(d). However, the section was redesignated section 424.57(e), which explains our use of the latter citation here. *See* Editorial Note following section 424.57 in the Code of Federal Regulations (October 1, 2012 revision); *see also* *Neb Group of Arizona*, DAB No. 2573, at 7-8 (2014) and *Benson Ejindu, d/b/a Joy Medical Supply*, DAB No 2572, at 9-10 (2014) (explaining history of the redesignation).

² The factual information in this section, unless otherwise indicated, is drawn from undisputed findings of fact in the ALJ Decision and undisputed facts in the record and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ’s findings of fact.

that it had unsuccessfully attempted to deliver packages on July 15 and 16, 2013. *Id.* The inspector returned to Ortho the following day at approximately 2 p.m., but “found everything exactly as on the day before” – the door locked, no lights on, no response to his knocks, and the UPS notices still on the door. *Id.* at 3.

By letter dated August 5, 2013, NSC notified Ortho that its Medicare billing privileges were being revoked. CMS Ex. 2. The letter explained that, based on the inspector’s two attempted site visits, NSC had determined that Ortho was out of compliance with Supplier Standard 7 because its facility was “closed and locked” during its posted hours of operation. *Id.* at 1-2. The letter explained that NSC had also determined that Ortho was “not operational to furnish Medicare covered items and services,” so it was considered to be in violation of section 424.535(a)(5)(ii) and “all supplier standards” as defined in section 424.57(c). *Id.* at 2. The letter stated that Ortho’s billing privileges were revoked effective July 18, 2013, the date that CMS had determined Ortho’s practice location was “not operational,” and that it was barred from re-enrolling in Medicare for two years from that date. *Id.* at 1.

In a request for reconsideration, Ortho admitted that its office was closed the week of July 15 through 21, 2013 for vacation. CMS Ex. 3. Ortho explained: “We close our office one week a year, and since we see patients by appointment, no person seeking medical treatment was inconvenienced. . . . This information was announced on our voice mail regarding our office closure for this week.” *Id.* Ortho requested that the contractor “put the revocation on hold” and schedule another inspection of the facility. *Id.*

NSC issued an unfavorable reconsideration decision dated November 24, 2013 upholding the revocation on the ground that Ortho “has not shown compliance with supplier standard 7.” CMS Ex. 4, at 4. After detailing the contents of Ortho’s reconsideration request, the hearing officer noted that according to photographs taken by the inspector during his visits, “there was no sign on the front door to explain why the business was not open or when it would reopen.” *Id.* at 3. The hearing officer also stated that she had attempted to reach Ortho’s owner by telephone, but that when she called, the phone “went unanswered and rang continuously with no messaging system.” *Id.* The hearing officer concluded, “[t]he fact remains that the site inspector was unable to complete a site investigation for Ortho . . . because the facility location on record with the NSC was not open at the times of the site visit attempts, and the site inspector was unable to verify compliance with the supplier standards.” *Id.* Thus, “[r]eview of the case file . . . does not verify compliance with supplier standard 7 and the NSC is deemed appropriate in their conclusion based upon the information on record with the NSC at the time.” *Id.*

Ortho timely filed an appeal with an ALJ. CMS moved for summary judgment in its favor, arguing that Ortho's admission that it was closed on the dates the inspector visited established that it was not operational and did not meet the DMEPOS supplier standards on those dates.³ Ortho opposed CMS's motion, contending that as a DMEPOS supplier working with custom made orthotics and prosthetics, it is exempt from Supplier Standard 7, and that it was not treated the same as other providers and suppliers who were visited by inspectors over a series of weeks or months, rather than days, before having their billing privileges revoked. Ortho also argued that it was not non-operational, in the sense of out of business, but was instead closed for vacation for a single week, and that it had adequately notified potential customers of the closure by posting a sign on its front door (which apparently fell down) and by announcing its closure on its voicemail greeting.

The ALJ rejected Ortho's arguments and granted CMS's motion for summary judgment, upholding the revocation on the grounds that Ortho was not operational and failed to comply with Supplier Standard 7 on July 17 and 18, 2013 because it was not open to the public during its posted hours. ALJ Decision at 3-6. The ALJ also concluded that because Ortho was not operational on those dates, CMS had the authority to revoke Ortho's billing privileges retroactive to July 18, 2013 pursuant to section 424.535(g). *Id.* at 6. Ortho timely requested review of the ALJ Decision.

Standard of Review

We review the ALJ's grant of summary judgment *de novo*, construing the facts in the light most favorable to Ortho and giving it the benefit of all reasonable inferences. *See Livingston Care Ctr.*, DAB No. 1871, at 5 (2003), *aff'd*, *Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 388 F.3d, 168, 172-73 (6th Cir. 2004). Summary judgment is appropriate when there is no genuine dispute about a fact or facts material to the outcome of the case and the moving party is entitled to judgment as a matter of law. *Id.*; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986). The party moving for summary judgment (here, CMS) has the initial burden of demonstrating that there is no genuine issue of material fact for trial and that it is entitled to judgment as a matter of law. *Celotex*, 477 U.S. at 323. If the moving party carries that burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Industrial Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986) (quoting Rule 56(e) of the Federal Rules of Civil Procedure).

³ In addition to arguing that Ortho was out of compliance with Supplier Standard 7, CMS argued before the ALJ that Ortho was out of compliance with Supplier Standard 8, which requires a supplier to permit CMS or its agents to conduct on-site inspections to ascertain compliance with the DMEPOS supplier standards. *See* 42 C.F.R. § 424.57(c)(8). Neither the initial nor the reconsidered decision cited Supplier Standard 8 as a basis for revocation.

Analysis

On appeal, Ortho challenges the ALJ's conclusions that it was not in compliance with Supplier Standard 7 or operational on July 17 and 18, 2013. Ortho reprises its arguments that it is exempt from Supplier Standard 7 and that revocation is inappropriate because other providers and suppliers were visited over a longer span of time before having their billing privileges revoked. Ortho also appears to argue that the ALJ erred in disposing of the case on summary judgment because there are genuine disputes about several material facts. Below, we explain why we find no merit in Ortho's arguments. We also explain why we modify the effective date of the revocation to September 4, 2013.

1. The ALJ properly sustained the revocation of Ortho's Medicare billing privileges based on its noncompliance with the requirements of Supplier Standard 7.

Ortho admitted the material fact that its office was closed from July 15 through 21, 2013. This admission establishes that Ortho failed to comply with Supplier Standard 7. As noted above, Supplier Standard 7 requires in relevant part that a supplier's facility be "accessible and staffed during posted hours of operation." 42 C.F.R.

§ 424.57(c)(7)(i)(C). Ortho's posted hours were Monday to Friday from 9 a.m. to 5 p.m., but, as Ortho concedes, it was closed when the inspector visited at approximately 3 p.m. on Wednesday, July 17, 2013 and approximately 2 p.m. on Thursday, July 18, 2013. The ALJ correctly observed that Ortho "could not have been 'accessible and staffed' during its posted business hours when its doors were closed and no one was inside." ALJ Decision at 4. As the preamble to the proposed rule that added section 424.57(c)(7)(i)(C) explained:

The supplier's place of business must be staffed during the supplier's posted hours of operation. The supplier's place of business must be accessible to the public, CMS, the NSC and any of its agents during the supplier's posted hours of operation regardless of whether beneficiaries routinely visit the facility. . . . 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). Because Ortho's door was locked and no staff was present on the dates the inspector visited, Ortho was out of compliance with Supplier Standard 7 on those dates.

Contrary to what Ortho argues, it is not excepted from the requirements of Supplier Standard 7. Ortho relies on Supplier Standard 30, 42 C.F.R. § 424.57(c)(30), which requires a supplier to be open to the public for 30 hours per week, except certain specific types of suppliers, including "a DMEPOS supplier working with custom made orthotics and prosthetics." Ortho also relies on two comments touching on this exception that are

addressed in the preamble to the final rule that added Supplier Standard 30 to the regulations. According to Ortho, these comments and the exception in Supplier Standard 30 establish that a supplier of custom orthotics and prosthetics, such as Ortho, is not subject to any of the requirements of Supplier Standard 7.

Ortho's reliance on the text of and preamble to Supplier Standard 30 is misplaced. Ortho's billing privileges were revoked based on noncompliance with Supplier Standard 7, not Supplier Standard 30, so the latter standard's exception for suppliers of custom orthotics and prosthetics is not relevant. Nothing in the text of the regulations or the preamble suggests that the exception for suppliers of custom orthotics and prosthetics in Supplier Standard 30 applies to Supplier Standard 7 as well. By its own terms, the exception in Supplier Standard 30 applies only to Supplier Standard 30. The only exception in Supplier Standard 7 relevant to suppliers of custom orthotics and prosthetics is the exception to the requirement in section 424.57(c)(7)(i)(A)(1) that a supplier maintain a practice location of at least 200 square feet. *See* 42 C.F.R. § 424.57(c)(7)(i)(A)(2). The Secretary provided very specifically for the exceptions she created in the precise Supplier Standards where they were to apply. If she had wanted any of these exceptions to apply more broadly, she would have made that explicit in the regulations.

As the ALJ pointed out, although Supplier Standard 30 would have allowed Ortho to be open for less than 30 hours a week, Ortho chose to adopt Monday through Friday from 9 a.m. to 5 p.m. as its posted hours of operation (for a total of 40 hours per week). ALJ Decision at 5-6. Even though these hours exceeded the requirements of Supplier Standard 30, under Supplier Standard 7, once Ortho posted those hours, it needed to be "staffed and accessible" during those hours. Because Ortho was admittedly not staffed and accessible during its posted hours on July 17 and 18, 2013, it was not in compliance with Supplier Standard 7 on those dates. Failure to comply with even one supplier standard is a sufficient basis for revoking a supplier's billing privileges under section 424.57(e). *See A to Z DME*, DAB No. 2303, at 3 (2010); *1866ICPayday.com*, DAB No. 2289, at 13 (2009). Thus, Ortho's noncompliance with Supplier Standard 7 provided a basis for CMS to revoke Ortho's billing privileges.

2. CMS was authorized to revoke Ortho's billing privileges based on attempted site visits made on two consecutive days.

Ortho contends that it was inappropriate for CMS to revoke its billing privileges based on attempted site visits made on two consecutive days. Ortho cites to several cases in which CMS based a revocation on site visits made over a period of several weeks or months, and argues that if the inspector had made his second visit the following week instead of the following day, he would have found Ortho open for business.

The ALJ correctly rejected Ortho's argument. As the ALJ pointed out, the regulations do not require CMS to perform a second site inspection at any time before deciding to revoke a supplier's billing privileges. ALJ Decision at 5. Moreover, the Medicare Program Integrity Manual (MPIM), a publication which provides guidance to CMS contractors but is not legally binding, instructs only that inspections to determine whether a provider or supplier continues to meet the requirements for its provider or supplier type should be conducted "in a manner which limits the disruption for the provider or supplier" and that all inspections should be "done Monday through Friday (excluding holidays) during [a provider or supplier's] posted business hours." MPIM, CMS Pub. 100-08, Ch. 15, § 15.20.1.A.2, B. The MPIM provides that a second site inspection should be done if "on the first attempt the facility is closed but there are no obvious indications the facility is non-operational." *Id.* § 15.20.1.B. But, even then, the MPIM instructs only that the second visit should be attempted "on a different day during posted hours of operation." *Id.* Thus, there was nothing inappropriate or unfair about CMS basing the revocation of Ortho's billing privileges on two site inspections attempted over two consecutive days during Ortho's posted hours of operation.

3. There are no genuine disputes of material fact that precluded the ALJ from disposing of the case on summary judgment.

Ortho also appears to challenge the ALJ's decision to dispose of the case on summary judgment. It contends that the ALJ erroneously rejected as immaterial evidence Ortho submitted to show that it had posted a sign on its front door announcing its temporary closure from July 15 to 21, 2013 and that the hearing officer did not call its owner. (Ortho claimed in the proceeding before the ALJ that the sign fell on the floor. *See* ALJ Decision at 4.) Ortho argues that this evidence must be material because in the reconsidered decision the hearing officer specifically noted that photographs taken by the inspector did not show a sign on the front door explaining the facility's closure and stated that she had unsuccessfully attempted to call Ortho's owner.

The ALJ properly concluded that Ortho's evidence did not create a genuine dispute of material fact about whether Ortho complied with the enrollment requirements. Although the hearing officer noted the apparent absence of a sign regarding the closure in her decision, the presence of a sign would not have been a basis for overturning the revocation of Ortho's billing privileges. As the ALJ explained, even if Ortho's sign about its week-long closure had "stayed adhered to its front door . . . that fact would not have made it compliant with the enrollment requirements" because "[c]losure during posted business hours, even if only temporary, violates the regulations." ALJ Decision at 4-5, citing *Complete Home Care*, DAB No. 2525, at 5 (2013). Similarly, although the hearing officer mentioned in her decision that she tried and failed to reach Ortho's owner by telephone, there would still be a basis for revocation even if she did not in fact attempt to call. The ALJ correctly observed that "even accepting as true that the hearing officer did not call [Ortho's] owner during the reconsideration level of appeal, that fact does not

open [Ortho's] doors or staff its location on July 17 and July 18, 2013." *Id.* at 5. As we explained above, it is the fact – which Ortho concedes – that it was not open and staffed on the dates the inspector visited that put it out of compliance with Supplier Standard 7 and authorized CMS to revoke its billing privileges.

Thus, there is no genuine dispute of material fact, so the ALJ correctly disposed of the case on summary judgment.

4. Because the reconsideration decision did not make a finding that Ortho was not operational, the ALJ erred in determining that revocation was also appropriate on that ground.

In addition to determining that Ortho's admission that it was closed on July 17 and 18, 2013 established that it was out of compliance with Supplier Standard 7 and so CMS was authorized to revoke its billing privileges under section 424.57(e), the ALJ also determined that Ortho's admission established that it was not operational within the meaning of section 424.502 on those dates, and thus that revocation was also appropriate under section 424.535(a)(5)(ii). ALJ Decision at 4. However, although the initial determination stated that Ortho was not operational, the reconsidered decision did not. *Compare* CMS Ex. 2, at 1-2 *with* CMS Ex. 4, at 2-4. The reconsidered determination stated only that Ortho "has not shown compliance with supplier standard 7" as the legal basis for the revocation. CMS Ex. 4, at 4. Ortho's right of appeal was from the reconsidered determination, not the initial determination. 42 C.F.R. § 498.5(l)(2); *see also Neb Group of Arizona*, at 5-6; *Joy Medical Supply*, at 5. Thus, the only issue properly before the ALJ was whether there was a legal basis for revocation of Ortho's billing privileges pursuant to section 424.57(e), not whether Ortho was not operational and thereby subject to revocation under section 424.535(a)(5)(ii). Accordingly, the ALJ erred in reaching a revocation ground not before him and concluding that Ortho's Medicare billing privileges could additionally be revoked on the ground that it was not operational. This error is harmless however, since, as stated above, the ALJ's conclusion that Ortho was not in substantial compliance with Supplier Standard 7 was sufficient to uphold the revocation.

5. Under section 424.57(e), the correct effective date for the revocation of Ortho's billing privileges based on its failure to meet the requirements of Supplier Standard 7 is September 4, 2013.

In light of our decision to sustain the revocation of Ortho's billing privileges solely based on its noncompliance with Supplier Standard 7, it is necessary to modify the effective date of the revocation determined by CMS and upheld by the ALJ. In its August 5, 2013 notice of revocation, CMS, through NSC, advised Ortho that the revocation was effective July 18, 2013 based on the determination that Ortho's practice location was "not operational" on that date. CMS Ex. 2, at 1. Although the reconsideration decision

upheld the revocation on the alternative ground stated in the August 5, 2013 notice – noncompliance with Supplier Standard 7 – the reconsideration decision did not discuss or alter the July 18, 2013 effective date. CMS Ex. 4. Under section 424.535(g), the effective date of a revocation is 30 days from the date CMS mails the supplier notice of its revocation determination, except if CMS issues a revocation based on a finding that the supplier is “no longer operational” (or on several other specified bases). Where being found no longer operational is the basis, section 424.535(g) provides that the effective date is the “date that CMS or its contractor determined that the provider or supplier was no longer operational.” This provision cannot properly be applied here because, as discussed above, the reconsidered determination did not make a finding that Ortho was no longer operational, and we have concluded that the ALJ’s upholding the revocation on that ground was error.

Because the sole basis for revocation properly decided by the ALJ and affirmed by the Board in this appeal is Ortho’s noncompliance with Supplier Standard 7, the effective date of revocation should be determined in accordance with section 424.57(e)’s effective-date provision. As the Board discussed in several recent decisions, section 424.57(d) in the Code of Federal Regulations (October 1, 2012 revision) states that 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), but this provision does not accurately reflect regulatory history as to either the section’s designation or the timing of the effective date. *See Norpro Orthotics & Prosthetics, Inc.*, DAB No. 2577, at 7-8 (2014); *Neb Group of Arizona*, at 7; *Joy Medical Supply*, at 5. 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. Applying that rule here, we conclude that the proper effective date of the revocation is September 4, 2013.

Conclusion

For the reasons discussed above, we affirm the ALJ Decision to uphold the revocation of Ortho's Medicare billing privileges based on its noncompliance with the requirements of section 424.57(c)(7)(i)(C), but we modify the effective date of the revocation to September 4, 2013.

_____/s/
Leslie A. Sussan

_____/s/
Constance B. Tobias

_____/s/
Sheila Ann Hegy
Presiding Board Member