Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Orthopaedic Surgery Associates
Docket No. A-14-90
Decision No. 2594
September 29, 2014

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Orthopaedic Surgery Associates (OSA), 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 an Administrative Law Judge (ALJ) decision dated May 6, 2014. *Orthopaedic Surgery Associates*, DAB CR3221 (2014) (ALJ Decision). The ALJ affirmed the determination by the Centers for Medicare & Medicaid Services (CMS) to revoke OSA's Medicare billing privileges and related supplier number, effective July 26, 2013. The ALJ concluded that CMS had a legitimate basis to revoke OSA's Medicare enrollment because the evidence of record established that on the dates OSA's Boca Raton facility was visited by a CMS-contracted inspector, the facility was not "operational" under 42 C.F.R. § 424.535(a)(5)(ii) and was not in compliance with the DMEPOS supplier standard found at 42 C.F.R. § 424.57(c)(7)(i)(C).

As discussed below, we conclude that the ALJ properly affirmed CMS's revocation of OSA's Medicare billing privileges because OSA admitted that its facility was closed during its posted hours of operation on the dates the inspector visited and, therefore, it was not in compliance with section 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) based upon a finding that the facility was not operational.

Because the effective date for the revocation here was based on a provision that applied only to revocation on the latter basis, we modify the effective date of the revocation to October 20, 2013 in accordance with 424 C.F.R. § 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 42.57(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 supplier 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 is also authorized to revoke a provider's or supplier's billing privileges for any of the "reasons" listed in section 424.535(a). (Section 424.535 applies to all types of Medicare providers and suppliers, not just DMEPOS suppliers.) However, section 424.535(a)(1) states that "[a]ll providers and suppliers are granted an opportunity to correct the deficient compliance requirement before a final determination to revoke billing privileges, except for those imposed under paragraphs (a)(2), (a)(3), or (a)(5) of this section." Under section 424.535(a)(5)(ii), CMS may revoke a supplier's billing privileges if an on-site review reveals that the supplier is "no longer operational." 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 Background[2]

OSA operates two facilities in Florida, one in Boca Raton and one in Boynton Beach. On Friday, July 12, 2013 at approximately 11 a.m., and again on Friday, July 26, 2013 at approximately 10 a.m., an inspector from the National Supplier Clearinghouse (NSC), a CMS contractor, attempted to conduct unannounced site visits at OSA's Boca Raton

[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 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.

facility. The facility's posted hours of operation were Monday, Thursday, and Friday from 8 a.m. to 6 p.m., but, according to the inspector's report, at the time of the attempted visits the facility was not open for business, no employees or staff appeared to be present, and there were no signs of customer activity. CMS Ex. 1, at 2.

In a letter dated September 20, 2013, NSC informed OSA that, based on the two attempted site visits, it was revoking OSA's Medicare supplier number and billing privileges and imposing a two-year re-enrollment bar. CMS Ex. 2, at 1. NSC explained that it had determined OSA was in violation of Supplier Standard 7 because OSA's facility was not open during its posted hours of operation on the two dates the inspector visited. *Id.* at 2. NSC explained that it had also determined that the facility was not operational to furnish Medicare covered items and services and concluded that OSA was "considered to be in violation of 42 C.F.R. § 424.535(a)(5)(ii) and all supplier standards as defined in 42 C.F.R. § 424.57(c)." *Id.* NSC revoked OSA's supplier number effective July 26, 2013, the date of the second attempted site visit and the date CMS "determined [OSA's] facility [was] not operational." *Id.* at 1. The letter provided that if OSA believed the revocation determination was incorrect, OSA could request reconsideration by a contractor hearing officer. *Id.* at 2-3.

OSA timely filed a request for reconsideration in which it stated in relevant part that:

> We apologize for not being available to complete an inspection of our facility. We had physicians out of the office at that time which resulted in a change in office hours. In an effort to maintain compliance with DMEPOS supplier standards, we have updated our office hours of operation as a corrective action plan.

CMS Ex. 3, at 1. With its request, OSA enclosed a Medicare enrollment application that updated its hours of operation and added a new physician to the practice.

By letter dated October 24, 2013, a Medicare hearing officer issued an unfavorable reconsideration decision concluding that OSA "has not shown compliance with supplier standard 7." CMS Ex. 5, at 4. The hearing officer stated that at the time of the unannounced site visits, "the facility was not open." *Id.* at 2. The hearing officer noted that OSA had changed its hours of operation after being informed of the revocation, but explained that the "submission of the change of the hours of operation after the revocation . . . does not verify compliance at the times of the attempted site inspections." *Id.* at 3. The hearing officer also noted that, although OSA had attempted to submit a CAP, it had not been "afforded the rights to [a] corrective action plan (CAP) but rather a reconsideration request." *Id.* The hearing officer concluded: "The fact remains that the site inspector was unable to complete a site investigation for [OSA] because the facility location on record with the NSC was not open during posted hours of operation. . . ." *Id.* at 3-4. Thus, the hearing officer determined, the case file and additional information submitted by OSA "does not verify compliance with supplier standard 7, and the NSC is

deemed appropriate in their revocation. . . ." *Id.* at 4. Finally, the hearing officer concluded that her "decision has been made in accordance with Medicare guidelines, as outlined in 42 CFR 424.57." *Id.*

OSA subsequently requested a hearing before an ALJ. In that proceeding, OSA again admitted that its staff "were not available to complete an inspection of our facility" and that the absence of physicians from the facility "resulted in a change in office hours" on the dates of the attempted inspections. P. Pre-Hr. Br. at 1. Nonetheless, OSA argued that CMS should have contacted it by phone to verify its compliance with the DMEPOS supplier standards or given it an opportunity to file a CAP before revoking its supplier number. OSA also asserted that it had updated its hours of operation and was now in full compliance with the standards. CMS moved for summary judgment, arguing OSA's admission that its facility was closed at the times of the attempted inspections established that it was not operational and did not meet Supplier Standard 7 on those dates. CMS also argued that OSA's subsequent change to its hours of operation was irrelevant and that ALJs lack jurisdiction to review CMS's determination to accept or reject a supplier's CAP. CMS Mot. for Summ. J. at 5-6.

In a decision based on the written record, the ALJ affirmed CMS's revocation of OSA's Medicare billing privileges.[3] The ALJ noted that OSA "admits that both of the attempted site inspections could not be completed because [OSA's] personnel were not in the office during its posted hours of operation." ALJ Decision at 4. Thus, the ALJ concluded that because the facts established OSA's facility was not open and available for a site inspection on July 12 and 26, 2013, during its posted hours, CMS had a legitimate basis to conclude that the facility was not operational under section 424.535(a)(5)(ii) and that it was not in compliance with the requirements of Supplier Standard 7. *Id.* at 5. The ALJ also concluded that OSA did not have a right to file a CAP and that, in any event, he had no jurisdiction to review CMS's denial of a CAP. *Id.* at 6.

OSA timely requested review of the ALJ Decision before the Board.[4]

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[3] The ALJ advised the parties in a pre-hearing order that they needed to 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. CMS did not submit any written direct testimony for witnesses or request to cross-examine OSA's proposed witnesses. Thus, the ALJ determined that an in-person hearing was unnecessary, and that it was appropriate to issue a decision based on the written record. ALJ Decision at 2-3. OSA does not challenge the ALJ's determination.

[4] OSA stated that it was submitting a "request for review, in the form of an oral discussion by phone" (RR at 1st p. (unnumbered)), which the Board construed as a request for oral argument. Accordingly, the Board's acknowledgment letter explained that the parties' briefs are generally the only record additions on appeal, but that if OSA wanted to have oral argument, OSA should file a submission explaining the basis for its request within 15 days after receipt of CMS's reply brief. OSA never filed such a submission, so we construe from its inaction that it decided not to pursue its request for oral argument. In any event, we have determined that oral argument would not aid the resolution of the appeal, so we issue this decision based on the current record.

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. *See Guidelines — Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program* (Guidelines), *available at* http://www.hhs.gov/dab/divisions/appellate/guidelines/prosupenrolmen.html.

Analysis

On appeal, OSA continues to concede that it deviated from its posted hours of operation on the dates the inspector visited, but argues that the temporary closures do not justify the revocation of its supplier number. OSA also reprises its contention that it should have been allowed to submit a CAP and asserts that the revocation has been "difficult" on its patients, and, therefore, the Board should "find good cause" to reinstate its billing privileges. RR at 1st-2nd pp. Below, we explain why OSA's arguments lack merit. We also explain why we modify the effective date of the revocation to October 20, 2013.

1. The ALJ properly sustained the revocation of OSA's Medicare billing privileges, which was authorized by section 424.57(e), based on OSA's noncompliance with the requirements of Supplier Standard 7.

OSA admits that its physicians were "out of the office" at the time of the attempted on-site visits, "which resulted in a change of office hours" on those dates. RR at 1st p. This admission establishes that OSA 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). At the time of the attempted inspections, OSA's posted hours were Monday, Thursday, and Friday from 8 a.m. to 6 p.m. Yet, as OSA concedes, its facility was closed when the inspector visited at approximately 11 a.m. on Friday, July 12, 2013 and approximately 10 a.m. on Friday, July 26, 2013. Thus, the ALJ correctly observed that a DMEPOS supplier is neither "open to the public" nor "accessible" as required by Supplier Standard 7 if its location is closed because staff is out of the office for any reason. ALJ Decision at 5.

OSA argues that the closure was temporary and that because it "only dispense[s] DME to our own patients while a physician is in the office," it was not "appropriate to send staff to an empty office on the two Fridays the inspector attempted to visit." RR at 1st p. This argument lacks any merit. 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). In addition, in response to comments suggesting that CMS should allow facilities to temporarily close during posted hours to account for circumstances including short-term closures and patient deliveries, the drafters explained in the preamble to the final rule that CMS believed a supplier "should be available during posted business hours" and "should do its best to plan and staff for temporary absences." 75 Fed. Reg. 52,629, 52,636 (2010). Thus, OSA's assertions that the facility was closed only temporarily during its posted hours and that there was no reason to staff the facility while no physician was available are immaterial for purposes of determining its compliance with Supplier Standard 7.

Because OSA was not open for business and no staff was present on the dates the inspector visited, the ALJ correctly concluded that OSA 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, LLC*, DAB No. 2303, at 3 (2010); *1866ICPayday.com*, DAB No. 2289, at 13 (2009). Thus, the ALJ correctly concluded that OSA's noncompliance with Supplier Standard 7 provided a legitimate basis for CMS to revoke OSA's billing privileges.

2. OSA was not entitled to submit a CAP before having its billing privileges revoked and cannot obtain equitable relief in this forum.

OSA's other arguments for overturning the revocation lack merit. OSA contends that it should have been given the opportunity to submit a CAP before CMS revoked its supplier number and billing privileges. There is no merit to this argument because section 424.57(e) does not contain any requirement to provide a supplier an opportunity to submit a CAP or correct any deficiencies before the revocation decision is made. *Neb Group of Arizona*, at 6 n.4. OSA also emphasizes that it corrected the deficiency by altering its posted hours of operation and submitting a new enrollment application containing the revised hours. RR at 1st-2nd pp. Even if that assertion is true, corrections made after revocation are immaterial to whether the revocation was authorized in the first place. *See Neb Group of Arizona*, at 6; *A to Z DME*, at 6-7 citing 73 Fed. Reg. 36,448, 36,452 (June 27, 2008). In addition, CMS's decision to reject a proposed CAP is not an initial determination subject to appeal under 42 C.F.R. Part 498, so neither the ALJ nor

the Board have jurisdiction to review such a decision. ALJ Decision at 6, citing 42 C.F.R. § 405.809; *see also DMS Imaging, Inc.*, DAB No. 2313, at 7-10 (2010) (in appeal of section 424.535(a)(1) revocation, Board agrees ALJ was not authorized to hear CMS contractor's rejection of supplier's CAP and consequent refusal to reinstate billing privileges).

In essence, OSA asks the Board to restore its billing privileges on equitable grounds, arguing that the revocation has "inconvenienced" its patients and prevented it from "provid[ing] the quality care that our patients deserve and are used to receiving." RR at 2nd p. The Board cannot provide the relief OSA seeks because the Board lacks the authority to restore OSA's billing privileges on equitable grounds. *See Letantia Bussell, M.D.*, DAB No. 2196, at 12-13 (2008) (explaining that ALJs and the Board are authorized to review only whether CMS has a legal basis to revoke a provider's or supplier's billing privileges).

3. Because the reconsideration decision did not make a finding that OSA was not operational, the ALJ erred in determining that there also was a basis to revoke on the alternative ground that OSA was not operational as defined in section 424.502.

The ALJ determined that OSA's admission that its staff was out of the office at the times of the attempted inspections established both that it was out of compliance with Supplier Standard 7 and that it was not operational. ALJ Decision at 4-6. Although the initial determination stated that OSA was not operational, however, the reconsidered decision did not. *Compare* CMS Ex. 2, at 2 *with* CMS Ex. 5, at 3-4. In the reconsidered determination the hearing officer quoted the definition of "operational" in the course of explaining why OSA's change to its hours of operation did not verify compliance with the supplier standards at the time of the attempted inspections, but stated only that OSA "has not shown compliance with supplier standard 7" as the legal basis for the revocation. CMS Ex. 5, at 3-4.

OSA's right of appeal was from the reconsidered determination, not the initial determination. 42 C.F.R. § 498.5(l)(2); *see also Keller Orthotics, Inc.*, DAB No. 2588, at 7 (2014), citing *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 OSA's billing privileges pursuant to section 424.57(e) based on noncompliance with Supplier Standard 7, not whether OSA 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 OSA's Medicare billing privileges could additionally be revoked on the ground that OSA was not operational. This error is harmless, however, since, as stated above, the ALJ's conclusion that OSA failed to comply with Supplier Standard 7 was sufficient to uphold the revocation.

4. Under section 424.57(e), the correct effective date for the revocation of OSA's billing privileges based on its failure to meet the requirements of Supplier Standard 7 is October 20, 2013.

In light of our decision to sustain the revocation of OSA's billing privileges based solely 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 September 20, 2013 notice of revocation, CMS, through NSC, advised OSA that the revocation was effective July 26, 2013 based on the determination that OSA'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 September 20, 2013 notice – noncompliance with Supplier Standard 7 – the reconsideration decision did not discuss or alter the July 26, 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 where 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 for revocation, 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 OSA 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 OSA'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 Keller Orthotics*, at 9; *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 October 20, 2013, 30 days from the date of NSC's letter notifying OSA of the revocation.

Conclusion

For the reasons discussed above, we affirm the ALJ's decision to uphold the revocation of OSA's Medicare billing privileges based on OSA's noncompliance with the requirements of section 424.57(c)(7)(i)(C), but we modify the effective date of the revocation to October 20, 2013.

/s/
Sheila Ann Hegy

/s/
Leslie A. Sussan

/s/
Stephen M. Godek
Presiding Board Member